Advanced Obesity Treatment Options
Maine AAP Spring Conference 2017
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23 Million children in US with Overweight or Obesity

1 in 3 ME Kindergarteners have overweight or obesity
27.6% of ME high school students have overweight or obesity
4.5 million children in US with Severe Obesity

Need: Preventing and/or Reversing the many related co-morbid health diseases associated with BMI’s >85th %

Prevalence

- overweight & obesity affected 32% of the U. S. youth aged 2 to 19 years in 2012 (NHANES). 1
  - Preschool children (2-5 Years Old)
    - 14.6% overweight
    - 5.6% obese
  - 6 to 11 year olds
    - 16.8% overweight
    - 17.4% obese
  - Adolescents 12 to 19 years of age
    - 13.9% overweight
    - 20.6% obese

- Prevalence by Obesity Class (2014 NHANES) 2
  - 17.4% of children met criteria for class I obesity (12.7 million children)
  - 6.3% for class II (Severe obesity)
  - 2.4% for class III (Severe obesity)

- A clear, statistically significant increase in all classes of obesity continued from 1999 through 2014. 2
- Severe obesity (Class II & III) is the fastest-growing subcategory of obesity in youth 2

Ogden, Carroll, Kit, et al. (2014) 1; Skinner, Perrin, Steton (2016) 2; Kelly et al. (2013) 3; Ogden, Carroll, Fryer, et al. (2015) 4
Current AAP & USPSTF Recommendations

AAP 2010 Guidelines

• Stages
  • Stage 1: PCP
  • Stage 2: PCP w/monthly f/u
  • Stage 3: Multidisciplinary
  • Stage 4: Multidisciplinary; consider adding surgical procedure
  • New flip charts 2015

USPSTF 2010 Recommendations

• Mod-High intensity for BMI > 85%
• Minimum of 25 hours in 6 months
• Must include behavioral component
• Grade B
  - Covered by ACA as Preventive Service
  - Grandfathered policy
  - No cost sharing

Endocrine Society Guidelines: April 2017

• Summary:

Multi-factorial Contributing Factors

Etc., etc.
Case Study

A parent of a 3 year old boy with a BMI >99th% shares that her son will "have a tantrum if I say no to more crackers" even if he just had large serving.

Obesity 1.0
Treatment Focus

- Express empathy
- Review positive parenting skills
- Redirection
- Tough love with limiting additional servings
- Behavior Modification in order to impact Physiology
- Likely to fail

Obesity 2.0

A calorie is not a calorie
Sugar is not sugar
Fat is not fat
Activity - not exercise
Energy management system
"Set point"
A gene is not a gene
The ERS is an exquisitely complex, redundant, & essential foundation for human existence.

Which is more complicated?!!

The ERS is under hormonal and neural control, modulated by environmental factors.

ERS Physiology Drives Behavior
Homeostatic vs. Non-Homeostatic Regulation of Body Weight

Phenotypes: exist with individual, unique responses
Normal ERS physiology + phenotypic triggers = ERS pathophysiology

**Modulate & Manage**
- Diet
- Activity
- Responses to cues
- Stress
- Sleep
- Circadian rhythms
- Depression
- Anxiety
- Medications

**Understand and accept**
- Age
- Ethnicity
- Gender
- Genetics

Implications of a complex biology
"Gluttony and Sloth" or...

Satiety center
Hedonistic center
Stress
Epigenetics
HFCS
Obesogens
Microbiome

Obesity 2.0 Pathophysiology First:
Treatment Focus

- Positive Parenting Skills
- Share the science and physiology that explains that physiology is driving the behavior.
- This reframes the discussion: replaces blame and "bad behavior" with a new starting place.

So....
Obesity is a disease that:

- Shortens ones lifespan
- Clinical comorbidities – which present during childhood
- Psycho-social comorbidities
- Economic consequences
Obesity 2.0 Treatment

Self-Directed Interventions

Primary Care Interventions

Diet and activity not enough for most people with obesity

Comprehensive Multi-disciplinary Treatment
by Obesity Specialists

Surgery unacceptable for most people with obesity

Case #2: 17 yr old Female

PT initially referred to WOW age 9 yrs: BMI 32.5

PMHx: devel delay/?autism spectrum, hyperlipidemia, constipation

FHx: Obesity, Hyperlipidemia, CVD, T2DM, CA, OSA

SocHx: parents divorced, shared custody

Food Hx: food as replacement for finger sucking and for coping, juice and soda

PA: involved in 4-H, PE at school, had PT eval through school

Initial Labs: Tot Chol: 375 LDL 293 Trig 125 HDL 57

PE: at initial visit: Wt. 120lbs BMI 32.5 BP 110/50 P 84, exam wnl

Plan: Stage 3 intensive lifestyle change in comprehensive team model

Physician, RN, RD and PhD visits: Phase 1, 2, 3 over 12-15 months: also referred to lipid clinic.

Statin started. Sleep Study: Mild Apnea – no CPAP

Results: periods of BMI stability, however, by age 16 BMI=48.89

Phenotype: ?? But needs MORE

Case: 17 yr old Female
Confronting Weight Bias

• Through positive Pt-Team relationship: Mother open to discussion
• Challenges:
  • Small volume of literature/trials on use of medications in children
  • Mother's personal medication experience and fears
  • Other providers involved in patients care unsure about medications
  • What to do? Mother not open to Bariatric surgical consideration now or in near future
    • Reviewed GAP - medications presently used in pediatrics for other diseases
    • Reviewed the safety issues with these medications
    • Shared the information and offered pt and mom time to reflect and follow up in 2-4 wks

Confronting Weight Bias - care givers

• Family members
• Teachers/PE Teachers/coaches
• Daycare providers

Confronting Weight Bias - health care team

• Providers – RNs – psychologists
• Waiting Rooms – seating that is appropriate for all patients
• Scales – where are they
Additive Treatment Strategies

Self-directed life style change

Professional directed life style change

Add

Medications

Weight Loss Devices

Weight Loss Surgery

Post-surgical Combination Therapy
Pediatric Obesity Pharmacotherapy

- Orlistat
- Metformin
- Exenatide


Orlistat

- Approved for obesity treatment ages 12+
- Administered orally three times daily with meals
- Mechanism of action = lipase inhibition
- 2.5% BMI reduction at one year
- No cardiometabolic risk factor improvements
- Oily spotting, flatus with discharge, fecal urgency, fatty/oily stool

Orlistat

- Largest randomized, controlled trial (N = 539) reported BMI reduction of 2.4% at 1 year (mean baseline BMI = 36 kg/m²)
Metformin
- Used for glycemic control in type 2 diabetes
- Administered orally
- Weight-loss mechanism of action is largely unknown
- Not approved for weight loss by FDA
- 3% BMI reduction at one year
- Modest improvements in glucose, insulin, and HOMA-IR
- Nausea, vomiting, headache

Metformin
- Randomized, controlled trial in adolescents 13-18 years old reported 3% BMI reduction at 1 year with 2000 mg per day (XR)

Exenatide
- Used for glycemic control in type 2 diabetes
- Administered by subcutaneous injection
- Probable weight-loss mechanisms
  - Central effect on hypothalamus (appetite)
  - Slowing of gastric motility and CNS effect (satiety)
- Not approved by FDA for weight loss
- 3-4% BMI reduction at six months
- Improvement in glucose tolerance
- Nausea, abdominal pain, diarrhea, headache, vomiting
Exenatide

- Randomized, controlled trial in adolescents 12-19 years old reported 3% BMI reduction at 3 months with 10 mcg dose twice per day

Pediatric Pipeline
Medications Recently Approved for Adults

Lorcaserin

- Administered orally twice daily
- Mechanism of action: selective serotonin 5-HT2C receptor agonist
- 1 year weight loss of 3-4% among adults
- Headache, dizziness, fatigue, nausea, dry mouth, constipation
- Juvenile animal toxicology and adolescent PK studies completed; timeline for initiation of adolescent safety/efficacy trial unknown
- Pregnancy Category X
Phentermine + Topiramate

- Administered orally once daily
- Mechanisms of action: phentermine - norepinephrine release in hypothalamus; topiramate - unknown
- 1 year weight loss of 7-9% among adults
- Paraesthesia, dizziness, dysgeusia, insomnia, constipation, dry mouth
- Juvenile animal toxicology and adolescent PK studies completed; timeline for initiation of adolescent safety/efficacy trial unknown
- Pregnancy Category X (topiramate)

Naltrexone + Bupropion

- Administered orally twice daily
- Mechanisms of action: naltrexone – opioid antagonist; bupropion – dopamine and norepinephrine reuptake inhibitor
- 1 year weight loss of 3-4% among adults
- Nausea, constipation, headache, vomiting, dizziness, insomnia, dry mouth, diarrhea
- Juvenile animal toxicology, adolescent PK, timeline for initiation of adolescent safety/efficacy trial unknown

Liraglutide

- Administered once daily by subcutaneous injection
- Mechanisms of action: central effect on hypothalamus (appetite); slowing of gastric motility and CNS effect (satiety)
- 1 year weight loss of 5-6% among adults
- Nausea, headache, diarrhea
- Juvenile animal toxicology and adolescent PK studies completed; initiation of adolescent safety/efficacy trial in 2016
Vyvanse

- In February 2015, Vyvanse (lisdexamfetamine dimesylate) became the first and only medication approved to treat moderate to severe Binge Eating Disorder in adults. Vyvanse is not for weight loss. It is not known if Vyvanse is safe and effective for the treatment of obesity.
- Approved for ADHD for age 6 years old and up.
- Starting dose 30mg/day. Treatment range 50-75mg/day

Topiramate

- Anti-epileptic: enhances GABA receptor activity inhibits carbonic anhydrase
  - Dosage: 25 – 150 mg/day
  - Interactions: AE: paresthesias, taste aversion, memory impairment
    • Kidney Stones, glaucoma
      Pregnancy Category X
      Increased levels in combination with metformin
      • Useful in antipsychotic-induced wt gain
      • Useful in binge-eating
      • Useful in PCOS

12 year old girl with BMI 40

- Lives 3 hours away
- HPI:
  - weight was normal until age 5-6 years old
  - met with “nutritionist” last year who recommended supplements
- Diet:
  - Breakfast – 2 cups cereal
  - Lunch – 3 hotdogs, no bun
  - Dinner – 2 grilled cheese sandwiches
  - Fast food 2-3 times/wk, frequent SSB
  - No food insecurity
12 year old girl with BMI 40

• Eating:
  • Hungry all the time
  • Feels out of control of eating daily
  • Eats until uncomfortable
  • Feels guilty after overeating
  • No food sneaking, stress eating, night eating

• Physical Activity:
  • Volleyball, gym 2x/week

12 year old girl with BMI 40

• Family History:
  • Dad – HTN, T2DM, obesity
  • Mom – obesity
  • Maternal aunt – bariatric surgery

• Social history:
  • Lives with both parents and sister
  • 6th grade, recently changed school due to bullying

12 year old girl with BMI 40

• Physical Exam:
  • 185 lbs; 4’9”, BMI 40.2
  • BP: 123/70; HR: 88
  • Normal, T2

• Labs:
  • TC 148; HDL 38; LDL 64; TG 230
  • A1c 5.5, glucose 88
  • ALT/AST 29/23
12 year old girl with BMI 40

- Plan
  - 1400 kcal flex meal plan
  - Physical therapy

Start 1400 kcal flex meal plan + food logging

1 month: down 6 lbs

2 months: down 1 more lb
3.5 months: up 2 lbs; frustrated; getting 2 lunches from school so instructed to remove $ from school account
12 year old girl with BMI 40

4.5 months: wt stable; patient is hungry
start phentermine 15 mg

12 year old girl with BMI 40

"She has been taking phentermine 15 mg daily for the past 2 months and lost only 5 pounds total. This weight loss occurred during her first month, with a slight increase during the second month. I expressed to mom my hesitancy to continue this medication if [patient] does not lose weight as the benefits will not outweigh the risks. Fortunately, [patient's] BP has been okay, though she is slightly tachycardic compared to before starting the phentermine. Mom and [patient] really wanted to continue the phentermine for another month. I told them that I will not refill it if she cannot lose about 1 lb per week."

12 year old girl with BMI 40

20 months:
Change in BMI – 29.6%
Change in weight – 40 lbs
Case: 17 yr old...
Deeper History: ADD and BED Scored
Plan: Add Vyvanse at 20mg daily, close follow up: 2 weeks, then monthly

Back to 17 yr old case...
2 month follow up: Vyvanse incr to 30mg

- Body Mass Index (BMI) change from 48.89 to 45.09
- 6 months on Vyvanse: BMI 43.49
- 10 months on Vyvanse (30mg/day): BMI 41.6 (wt 240)
- Total change BMI: from 170th % to 140th %
- Total Weight Change: 275 lbs to 240 lbs (down 35 lbs)
- Repeat Sleep Study (after 30lbs wt loss): WNL
- Most recent labs: 4/2017
  - Tot Chol: 208
  - Trig: 73
  - HDL: 72
  - LDL: 122 (initial 293)
  - AST: 13
  - ALT: 10

Additive Treatment Strategies

Self-directed life style change

Professional directed life style change

Add

Medications

Weight Loss Devices

Weight Loss Surgery

Post-surgical Combination Therapy
Weight loss surgery

• Spectacularly successful
  • RYGB
  • Sleeve Gastrectomy
  • AGB
• Safe
• ? long term effects
• “unacceptable”

Endoscopic mimics

• AGB
• Sleeve

Weight Loss Devices

• most are temporary
• most are adjustable
• removable
• Less weight loss than with surgeries
• ? combinations with weight loss medications
Intragastric

• Balloons
  • single
  • double
  • multiple
  • saline filled
  • air filled
  • adjustable
  • swallowed
  • Pass spontaneously

Intragastric - II

• trans pyloric shuttle
• Gellesis capsules

Extra gastric

• gastric vest
• Extragastic balloon
Gastric drainage
• Aspire Device

Endosleeves
• Gastrojejunal
• Duodenal jejunal - Endo barrier

Duodenal
• satisphere
• duodenal resurfacing
Neuromodulation
• Vagal stimulator - Maestro
  • vagus at GEJ
• ? trans cutaneous vagal stimulation
• Gastric stimulator
• Transcranial stimulation

Kids and devices and meds
• Goals
  • ? weight loss
  • ? weight stabilization
  • ? care necessary after induction
  • ? clinical comorbidities
  • ? clinical risk factors
  • ? psycho-social comorbidities

Kids and devices and meds
• Plasticity
• Set Point flexibility
• Response to Healthy Living after healthy body composition attained
The Future is now: What is coming fast

- Defining of phenotypes
- Advanced treatments
- Focused treatments
- Combination treatments
- Intervention timelines

Advocacy and Policy Change

- Physiologically based prevention
- Physiologically based intervention
- Chronic disease model
- Multidisciplinary team
- Bundled payments

Advocacy and Policy Change - II

- Outcomes
  - weight based
  - BMI based
  - health based
    - clinical comorbidities
    - psychosocial comorbidities
    - Economically based
      - cost
      - productivity
Advanced Obesity Treatment

- Based on Healthy Living as defined by Physiology
- Utilize weight loss medications in adults (FDA approved) and pediatrics (need for trials)
- Utilize weight loss device therapies (multiple approved in adults - EMMC new offering wt. loss balloon & need trials for pediatrics)
- Develop algorithms for combinations of weight loss medications and device therapies

Understanding this is a chronic disease

Staying with patients and families through successes and setbacks

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Thank You

- Acknowledgements:
  - Dee Kerry, Dr. Jan Pelletier, MAAP
  - WOW Team

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Additional Resources
Obesity Conferences and Societies

- The Obesity Society
- Obesity Medical Association
- Sub-committee on Obesity, AAP
- The Obesity Action Coalition
- Rudd Center
- Obesity Week (TOS and ASMBS)
- Blackburn Course in Obesity Medicine – June Boston
- Advanced Therapies for Pediatric Obesity- Univ. Minn, Oct

Pediatric Obesity Algorithm
ERS Hormones

<table>
<thead>
<tr>
<th>Hormone</th>
<th>Source</th>
<th>Function</th>
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</thead>
<tbody>
<tr>
<td>Leptin</td>
<td>Adipose tissue</td>
<td>Reduce hunger</td>
</tr>
<tr>
<td>Adiponectin</td>
<td>Adipose tissue</td>
<td>Stimulates catabolism</td>
</tr>
<tr>
<td>Insulin</td>
<td>Pancreas (beta cells)</td>
<td>Stimulates glucose uptake; synthesis glycogen &amp; fat</td>
</tr>
<tr>
<td>Glucagon</td>
<td>Pancreas (alpha cells)</td>
<td>Stimulates gluconeogenesis &amp; glucose release to body</td>
</tr>
<tr>
<td>Ghrelin</td>
<td>Stomach, Intestine</td>
<td>Signals hunger</td>
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<tr>
<td>GLP-1, GLP</td>
<td>Intestine</td>
<td>Stimulate insulin release</td>
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<tr>
<td>PYYs</td>
<td>Intestine</td>
<td>Signals satiety</td>
</tr>
<tr>
<td>Cortisol</td>
<td>Adrenals</td>
<td>Stimulate gluconeogenesis &amp; glucose release to body</td>
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</table>

Nelson & Cox, 2017 p. 918
# The Comorbidities of Obesity

<table>
<thead>
<tr>
<th>Endocrine/Immune Response</th>
<th>Physical Response</th>
<th>Psychological Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adiposopathy</td>
<td>Fat Mass Disease</td>
<td>Quality of Life</td>
</tr>
<tr>
<td>• Impaired fasting glucose</td>
<td>• Arthrosis</td>
<td>• Isolation from peers</td>
</tr>
<tr>
<td>• Hyperinsulinemia</td>
<td>• Immobility</td>
<td>• Decrease in ability to participate in normal childhood activities</td>
</tr>
<tr>
<td>• Metabolic Syndrome</td>
<td>• Tissue Compression</td>
<td>• Subject to bullying</td>
</tr>
<tr>
<td>• Hypertension</td>
<td>• Sleep apnea</td>
<td>• Lack of social/age appropriate relationship</td>
</tr>
<tr>
<td>• Menstrual Dysfunction</td>
<td>• Type 2 DM</td>
<td>• Anxiety/depression</td>
</tr>
<tr>
<td>(female)</td>
<td>• Metabolism &amp; Lipid Metabolism</td>
<td>• Bulimia</td>
</tr>
<tr>
<td>• Delayed Puberty (Male)</td>
<td>• NAFLD</td>
<td>• Binge eating disorder</td>
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<tr>
<td>• Dyslipidemia</td>
<td>• Dyslipidemia</td>
<td>• Night eating disorder</td>
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<tr>
<td>• Increased uric acid,</td>
<td>• Gynecomastia</td>
<td>• Isolation from peers</td>
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<tr>
<td>• Malignant tumors</td>
<td>• Cholecystitis</td>
<td>• Decrease in ability to participate in normal childhood activities</td>
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<tr>
<td>• Obstructive sleep</td>
<td>• Stress on weight-bearing joints</td>
<td>• Subject to bullying</td>
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<tr>
<td>(disorder)</td>
<td>• Slip-heel deformities</td>
<td>• Lack of social/age appropriate relationship</td>
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<tr>
<td>• Osteoarthritis</td>
<td></td>
<td>• Anxiety/depression</td>
</tr>
<tr>
<td>• Respiratory infection</td>
<td></td>
<td>• Bulimia</td>
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## Psychiatric Medications That Affect Weight

<table>
<thead>
<tr>
<th>Category</th>
<th>Weight Gain</th>
<th>Small-Neutral Weight Gain</th>
<th>Weight Loss</th>
</tr>
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<tbody>
<tr>
<td>Antipsychotics</td>
<td>Clozapine</td>
<td>Aripiprazole</td>
<td>Haloperidol</td>
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<tr>
<td></td>
<td>Olanzapine</td>
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<td>Ziprasidone</td>
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<td></td>
<td>Chlorpromazine</td>
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<td></td>
<td>Quetiapine</td>
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<td></td>
<td>Risperidone</td>
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<td>Aripiprazole</td>
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<td></td>
<td>Haloperidol</td>
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<td></td>
<td>Ziprasidone</td>
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<tr>
<td>Anti-depressants</td>
<td>Fluoxetine</td>
<td>Venlafaxine</td>
<td>Fluoxetine</td>
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<td></td>
<td>Doxepin</td>
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<td></td>
<td>Amitriptyline</td>
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<tr>
<td>Mood stabilizers</td>
<td>Lithium</td>
<td>Topiramate</td>
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<tr>
<td>Anxiolytics</td>
<td>Lorazepam</td>
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## Additional Medications That Affect Weight

<table>
<thead>
<tr>
<th>Category</th>
<th>Weight Gain</th>
<th>Small-Neutral Weight Gain</th>
<th>Weight Loss</th>
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<tbody>
<tr>
<td>ADHD</td>
<td>Valproate</td>
<td>Carbamazepine</td>
<td>Lamotrigine</td>
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<td></td>
<td>Levetiracetam</td>
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<tr>
<td>Anti-Seizure</td>
<td>Gabapentin</td>
<td>Levetiracetam</td>
<td>Topiramate</td>
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<tr>
<td>Migraine</td>
<td>Topiramate</td>
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<tr>
<td>Diabetic medications</td>
<td>Insulin &amp; analogs</td>
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<tr>
<td>Other medications</td>
<td>Glucocorticoids</td>
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<td></td>
<td>Glomerular</td>
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<td></td>
<td>Injury Provers</td>
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<tr>
<td>Cuda et al. 2016. OMA Pediatric Obesity Algorithm</td>
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</table>
Weight Gain Promoting Medications

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples</th>
<th>Other Medications</th>
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<tbody>
<tr>
<td>Atypical Antipsychotics</td>
<td>Clozapine, Zyprexa, Seroquel, risperidone, abilify</td>
<td>Ziprasidone (Geodon)</td>
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<tr>
<td>Anti-depressants</td>
<td>Trazadone, nortriptyline, amitriptyline</td>
<td>Sertraline, Fluoxetine</td>
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<tr>
<td>Anti-Epileptics</td>
<td>Gabapentin, valproic acid, carbamazepine, topiramate, lamotrigine</td>
<td>Bupropion (Wellbutrin)</td>
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<tr>
<td>Diabetes Medications: Insulin</td>
<td>T2DM: Insulin, MGCs, HbA1c, LDL, HDL, Cholesterol, Triglycerides, Vitamin D</td>
<td>Topiramate, zonisamide, lamotrigine</td>
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<tr>
<td>Metformin, sulfonylureas</td>
<td>Glipizide, pioglitazone</td>
<td>Pramlintide (Symlin)</td>
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<tr>
<td>GLP-1 analogs</td>
<td>Liraglutide (Victoza), sitagliptin (Januvia)</td>
<td>Glucagon, methyl pred</td>
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<tr>
<td>Immunosuppressive agents</td>
<td>Prednisone, methotrexate</td>
<td>Non-hormonal contraceptive</td>
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<tr>
<td>Betablockers</td>
<td>Propranolol, metoprolol, carvedil</td>
<td>Other anti-HTNs, carvedil</td>
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<tr>
<td>Anti-Histamines</td>
<td>Benadryl, hydroxyzine, cetirizine, loratadine</td>
<td>Lornoxicaine</td>
</tr>
</tbody>
</table>

Prevalence of obesity cardio-metabolic comorbidities in children (2-19 years old) enrolled in WOW from 2009 to 2016

- Insulin, Glucose, HbA1c, LDL, HDL, Cholesterol, Triglycerides, Vitamin D (all fasting)
- Obesity Class, Gender, Age groups
- Children with BMI > 95th percentile in each age category, gender, and weight class present with significant disease burden.
  - Particularly hyperinsulinemia, hyperglycemia, and Vitamin D deficiency.
- Disease burden also present in the Overweight category
- 92% of children screened (337 of 382) had one or more abnormal cardio-metabolic risk factor (excluding Vitamin D)
- Data highlight the existing (not "at risk for") abnormal laboratory disease burden in pediatric patients (including 2-5 year olds) with obesity presenting to WOW.

Cardio-metabolic risk factors by age group
Cardio-metabolic risk factors by obesity class

- **Insulin (n=119)**
- **Hemoglobin A1C (n=41)**
- **Glucose (n=26)**
- **Total Cholesterol (n=136)**
- **LDL (n=93)**
- **Triglycerides (n=222)**
- **HDL (n=175)**
- **Vitamin D (n=212)**

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**Overweight**

**Obesity Class I**