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Medications and Obesity: Exploring the Landscape and Advancing Comprehensive Care: A Workshop



March 19 – 20, 2024 Day One Recap



Every cancer. Every life.

Kristen Sullivan, MS, MPH Director, Prevention and Survivorship

Session 1 – Current State of Pharmacokinetics and Pharmacology for Obesity

Medications that affect weight status

- Strong push to consider impact on weight when prescribing meds for diabetes not as much of a consideration with other conditions
- Antipsychotics can cause weight gain
- Antidepressants some associated with wt gain, some with weight loss
- HIV medications can cause redistribution in fat
- Weight-neutral alternatives should be considered when available

Response to medications may differ based on body size/presence of obesity

- Studies showed delayed washout, delayed attainment of steady state in patients with obesity (loading regimen might be needed at the start)
- Patients with obesity should be studied as a customary component of drug development

Lack of guidance for clinicians, especially on dosing in patients with obesity. Opportunity for professional associations/other stakeholders to form working group to develop guidance.

Session 1 – Current State of Pharmacokinetics and Pharmacology for Obesity

<u>Inclusion of subjects with obesity in drug development</u>

- US population increasingly diverse, RCT use homogeneous populations leads to gaps in understanding
- Efforts from FDA regulatory guidance on inclusion (inclusion of subjects with obesity important given prevalence in population)
- Sponsors should address impact of obesity early in process modeling tools can help (model informed drug development (MIDD), decision tree modeling)

What's in the AOM pipeline

- Semaglutide and tirzepatide represented a leap forward in anti-obesity medication there are others in developments
- CagriSema semaglutide paired with amylin analogue in phase 3
- Retatrutide triple agonist 100% lost 5%; ¼ participants lost 30%
- Oral GLP1 semaglutide approved for T2D; being tested at higher doses
- Mari-Tide monthly injection in phase 2 trials
- Activin receptor inhibitors to improve body comp as weight is lost being tested

Session 2 –Advancing Optimal Obesity Treatment: Intersections Between Treatment Options

Lived experiences of patients and physician

Karen (patient) – lifelong struggle with weight; very physically active, completed numerous Ironman triathlons, but still struggled with weight; source of embarrassment and shame; high coronary calcium score convinced her it was time to think about medication; delay in starting because of supply issues

Michele (patient) – lived with obesity her entire life; tried every diet out there with minimal results; eventually developed comorbidities (HBP, sleep apnea, T2D, joint pain); her PCP helped her understand that she wasn't at fault – helped overcome her internalized bias and was then willing to consider bariatric surgery. Now she has comprehensive treatment – surgery, meds, behavioral therapy, fitness trainer. Kissed a lot of "health care frogs" before finding the right provider.

Dr. Holly Lofton (obesity med. physician) – not enough capacity of specialized obesity medicine to meet demand – primary care clinicians will need to fill the gaps; jumping through hoops with insurance is a barrier to access, wastes valuable time, and can endanger health of patient; 80% of AOM Rx aren't filled because of high cost/lack of authorization; Need weight bias training, insurance coverage, EMR tools to support clinicians, medical education

In a perfect world, everyone would have access to lifestyle, medications, and surgery options, ongoing care, and no stigma or shame.

Session 2 –Advancing Optimal Obesity Treatment: Intersections Between Treatment Options

Mental and Behavioral Health Considerations

- Variety of stressors that contribute to adherence to meds and/or QOL issues
- Eating disorders prevalent among people with high body weight (adults and peds), but often overlooked
- Self-directed dieting in youth gateway to ED and low self-esteem, while evidence-based intensive behavioral therapy associated with improved weight, psychosocial factors, and reduced risk of eating disorders.
- "Food noise" food cue reactivity or food-related intrusive thoughts. Silencing food noise may be a compelling reason why people will stay on AOM or want to start AOM
- Mood/suicidal ideation FDA found no link with GLP-1s, but suicidality has increased overall since 2020; in kids, suicide behaviors (and other mental health issues) associated with obesity
- It's critical that patients are assessed and monitored for mental health outcomes
- Need for long-term partnerships between patients and providers to help problem solve and work together on treatment

Session 2 –Advancing Optimal Obesity Treatment: Intersections Between Treatment Options

PANEL: Shifting the Paradigm to a Focus on Health Behaviors

Nutrition and AOMs

- Medical Nutrition Therapy (MNT) can optimize success with AOMs; move beyond calorie deficits focus on health goals; management of side effects identify foods that may cause symptoms/not be tolerated
- Lack of reimbursements esp by Medicare- MNT for only diabetes, kidney disease, bariatric surgery; Medicaid varies state by state

Physical activity, exercise and obesity

- We don't have a lot of body comp data, but studies suggest 25-40% of weight lost with AOMs is lean mass
- Fitness improves when you add exercise to AOM treatment (even with lean mass loss)
- We don't know the optimal dose, volume, intensity, and mode of exercise that needs to be combined with AOMs; but exercise should still be done

Best Practices – Ideal vs Current State

- Ideal People living with obesity have access to a care provider that can discuss lifestyle, medicines, and surgery;
 engage in a patient-centered decision about treatment; goal of optimized health
- Current far from ideal. Providers constrained by lack of knowledge, time, reimbursement; cost issues treatment goes to those who can pay, not those who need it most; focus on BMI not health
- Future state effective AOMs will be widely prescribed, but how will we get there? Knowledge gaps, challenges

Session 3 –Navigating Clinical Practice, Economic, and Policy Challenges of New Obesity Treatments