



ADVANCING INTEGRATED HEALTHCARE

Breakfast of Champions: Innovations in Weight Management

Breakfast of Champions | March 8, 2023

Care Transformation Collaborative of RI

CTC-RI Conflict of Interest Statement

If CME credits are offered, all relevant financial relationships of those on the session planning committee have been disclosed and, if necessary, mitigated.

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The AAFP has reviewed 'Advancing Comprehensive Primary Care Through Improving Care Delivery Design and Community Health,' and deemed it acceptable for AAFP credit. Term of approval is from 03/18/2022 to 03/18/2023. Physicians should claim only the credit commensurate with the extent of their participation in the activity. NPs and RNs can also receive credit through AAFP's partnership with the American Nurses Credentialing Center (ANCC) and the American Academy of Nurse Practitioners Certification Board (AANPCB).

Objectives

- Learn about and discuss updated guidelines, medications, and treatment approaches to overweight in adult and pediatric populations
- Review and discuss special considerations with pediatric patients and families
- Hear and discuss employer and health plan viewpoints

Agenda

Presenter/Topic	Time
Welcome <i>Linda Cabral, MM, Senior Program Manager</i>	5 minutes
Presentation <i>Angela Fitch, MD, FACP, Dipl. ABOM, Chief Medical Officer, KnownWell Health</i>	20 minutes
Presentation <i>Stephen J. Kogut, PhD, MBA, RPh, University of Rhode Island</i>	20 minutes
Reactants <i>Sarah Hagin, PhD, Director, Feeding Program, Hasbro Children's Hospital</i> <i>Susan Andrews, MD, Medical Director, General Dynamics Electric Boat</i> <i>LouAnne Giangreco, MD FACEP, Senior Medical Director-Medical Affairs, BCBSRI</i>	15 minutes
Q&A / Discussion	30 minutes

CHRONIC DISEASE MANAGEMENT FOR OPTIMAL OBESITY CARE



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PROUD
MEMBER

CLINICAL LEADERS IN OBESITY MEDICINE®



Disclosures

- Vivus advisory board
- SideKick Health advisory board
- Jenny Craig Science Advisory Chair
- NovoNordisk advisory board
- Eli Lilly advisory board
- Suvie advisor



Objectives

Understand

Understand the most effective treatments for the disease of obesity using the pillars of obesity treatment

Review

Review pharmacotherapy for obesity and develop an obesity treatment plan

Gain

Gain knowledge of how to personalize the treatment plan for optimal outcomes with shared-decision making tools

OBESITY IS A CHRONIC TREATABLE DISEASE

- Obesity
 - a disease in which excess body fat has accumulated in a dysfunctional manner to a level that may have an adverse effect on health.
- It's about biology not BMI ultimately.
- BMI is a **tool** used in diagnosis
 - Pre-obesity BMI 25-29.9
 - Class I obesity BMI 30-34.9
 - Class II obesity BMI 35-39.9
 - Class III obesity BMI ≥ 40



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OBESITY STIGMA AND BIAS



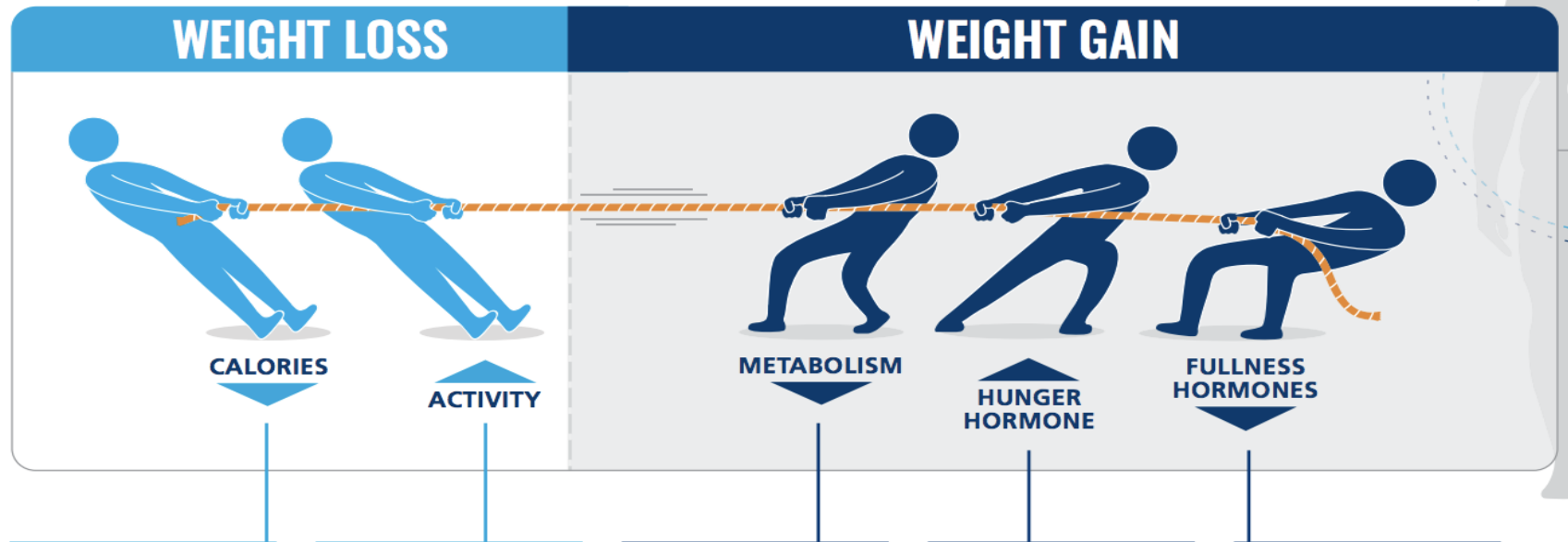
- People and society places blame and shame on the disease
- Ask permission to discuss the disease and how it affects the individual
 - Metabolic
 - Physical/functional
 - Psychological
- Consider delivering care in a trauma informed fashion
- Use people first language
 - Remove “obese” from vocabulary

www.stopweightbias.com

www.obesityaction.org



The “Tug-of-War” of Weight Management



Decreased Calories

People may see results when they limit calories, by reducing the size of meals, for example.

Increased Activity

And find ways to increase physical activity, like taking regular walks around the block. But the body reacts to weight loss by trying to regain weight.

Slower Metabolism

Metabolism (burning calories) slows down and gets more efficient, requiring fewer calories to do its job.

Increased Hunger Hormone

Hormonal signals can also change. The body increases a hunger hormone, called the ghrelin hormone, which tries to get you to eat more calories.

Decreased Fullness Hormones

And the hormones that tell the brain it's time to stop eating, the “feeling full” signals, decrease.

These are just some of the factors that make weight regain so common.



Obesity Treatment, Beyond the Guidelines

Practical Suggestions for Clinical Practice

Scott Kahan, MD, MPH^{1,2}; JoAnn E. Manson, MD, DrPH^{3,4}

» Author Affiliations

JAMA. 2019;321(14):1349-1350. doi:10.1001/jama.2019.2352

Table. An “ABCDEF” Approach to Guide Weight Counseling in Primary Care

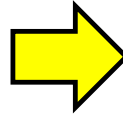
Steps	What to Do
Ask “permission”	<ul style="list-style-type: none">Assess patient readiness to discuss weight issues. Consider beginning the conversation with questions such as, “Your weight has been increasing over the years, which could lead to diabetes and other health problems. Would it be okay if we started working together on this?”
Be systematic in the clinical workup	<ul style="list-style-type: none">Elicit weight history, motivations, barriers, and social determinants.Medications that may cause weight gain include some antidepressants, antipsychotics, insulin, sulfonylureas, steroids, and pain medications.
Counseling and support	<ul style="list-style-type: none">A wide range of dietary patterns can help weight management.Physical activity, even just walking, is essential for health.Use free online tools and resources, such as Dietary Guidelines for Americans, obesity treatment guidelines, and the Diabetes Prevention Program curriculum and handouts.
Determine health status	<ul style="list-style-type: none">Evaluate for weight-related health conditions (eg, diabetes, sleep apnea), physical limitations, and decreased quality of life.
Escalate treatment when appropriate	<ul style="list-style-type: none">Consider medication (BMI ≥ 27) or bariatric surgery (BMI ≥ 35) when weight-related health conditions are present.Medication options for long-term use include orlistat, lorcaserin, phentermine/topiramate-extended release, naltrexone/bupropion-sustained release, and liraglutide.
Follow up regularly and leverage available resources	<ul style="list-style-type: none">Create a care team by identifying local obesity specialists (eg, obesity medicine physicians, registered dietitians), community programs (eg, YMCA-based diabetes prevention program), and other resources (eg, commercial weight-loss programs, health coaches, digital or telehealth platforms).A few minutes at the end of an unrelated appointment can be used to check in on patients’ progress and offer support.Utilize medical assistants and other office staff to save time by assisting with patient education, monitoring, and coordinating care.

Increasing health risks
Increasing adiposity

Obesity Treatment Pyramid

Treatment Intensity

BMI > 40
BMI > 35 with
comorbidity



Surgery



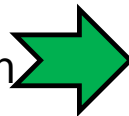
20-40% weight loss

Endoscopic Procedures



10-20% weight loss

BMI > 30
BMI > 27 with
comorbidity



Pharmacotherapy



10-25% weight loss

Prescriptive Nutritional Intervention



5-10% weight loss

Lifestyle Modification



2-5% weight loss

1. O'Neil PM, Birkenfield AL, McGowan B, et al. A randomized, phase II, placebo-and active-controlled dose-ranging study of semaglutide for treatment of obesity in subjects without diabetes. Presented at the 100th Annual Meeting of The Endocrine Society, Chicago, Illinois; March 18, 2018. Abstract OR12-5.
2. *Lancet*. 2011 Oct 22; 378(9801): 1485-1492.
3. *JAMA Surg*. 2016 Nov 1;151(11):1046-1055.
4. *Obesity (Silver Spring)*. 2011 Jan; 19(1): 110-120.

REALITY OF TREATMENT



Lifestyle



Prescriptive
Nutritional
Interventions



Pharmacotherapy



Endoscopic
Procedures/Devices

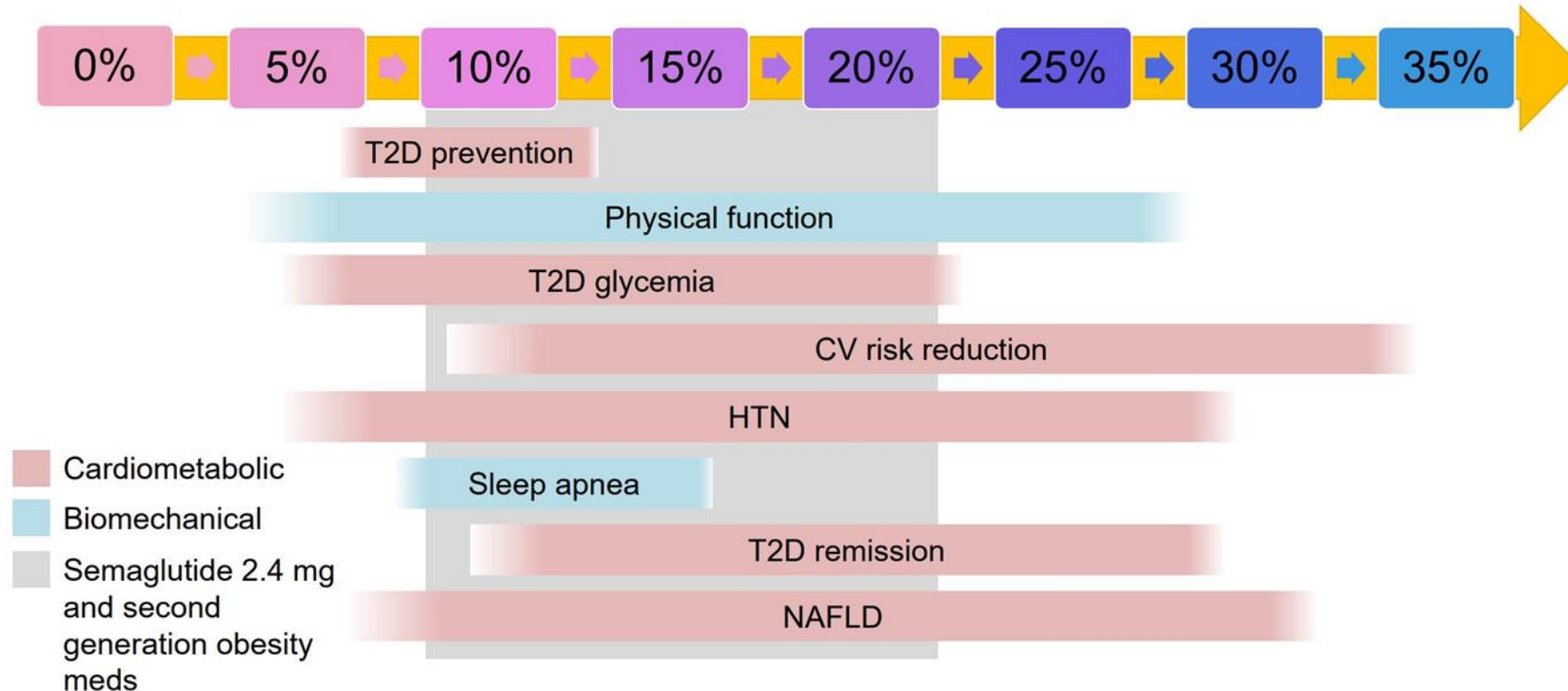


Surgery



GOAL OF OBESITY TREATMENT

New medications: treating Obesity to target



ASSESS FOR TREATMENT GOALS

- > 5% weight loss for diabetes prevention³
- > 10% weight loss for NAFLD resolution^{1,2}
- > 15-20% weight loss for diabetes remission⁴

¹Wong VW et al. J Hepatol 2013; 59:536-42

²Vilar-Gomez et al. Gastroenterology 2015; 149:367-78

³ N Engl J Med 2002; 346:393-403

⁴*The Lancet* Volume 391 Issue 10120 Pages 541-551 (February 2018)

Pt GOALS	Favors Lifestyle	Favors Medication	Favors Surgery
Needs > 20% weight loss		++	+++
Needs/wants diabetes resolution/remission	+/-	+	+++
Needs/wants fatty liver disease resolution (>10%)	+	++	+++
Needs/wants to prevent diabetes	++	+++	+++
No complications of obesity, wants weight loss	+++	++	+
Wants to be free of medication	++		+++

SHARED DECISION-MAKING EXAMPLE

PATIENT EXAMPLE



Lifestyle Modification



Prescriptive Nutritional Intervention



Surgery



Pharmacotherapy



Gold shading = injection

Devices

Weight loss %	% of patients in behavior programs (WW®, IBT)	% of patients in Virta® program	% of patients with surgery at 10 years	% of patients on tirzepatide 15mg once a week	% patients on semaglutide 2.4 mg weekly	% patients on liraglutide 3 mg daily (Plus IBT)	% patients on phentermine topiramate 15/92 mg	% patients on bupropion/naltrexone (Plus IBT)	Gelesis -100
>5%	48%	74%	96.6%	96%	90%	63% (74%)	67%	42% (66%)	58.6%
>10%	25%	49%	>80%	90%	75%	33% (52%)	47%	21% (41%)	27.2%
>15%	12%			78%	56%	(36%)	32%	10% (29%)	
>20%	10%		72%	63%	36%		15%		
>30%	4%		40%	23%					

IBT = intensive behavioral therapy.

Wilding JPH, et al. *N Engl J Med*. 2021;384(11):989-1002. Jebb SA, et al. *Lancet*. 2011;378(9801):1485-1492. Maciejewski ML, et al. *JAMA Surg*. 2016;151(11):1046-1055. Wadden TA, et al. *Obesity* (Silver Spring). 2011;19(1):110-120. Wadden TA, et al. *Obesity* (Silver Spring). 2019;27(1):75-86. Athinarayanan et al. *Front. Endocrinol.*, 05 June 2019

| <https://doi.org/10.3389/fendo.2019.00348>; AM Jastreboff et al. *N Engl J Med* 2022. DOI: 10.1056/NEJMoa2206038

WHAT WORKS FOR OBESITY TREATMENT?

■ Structure

- Programs, meal replacements

■ Accountability

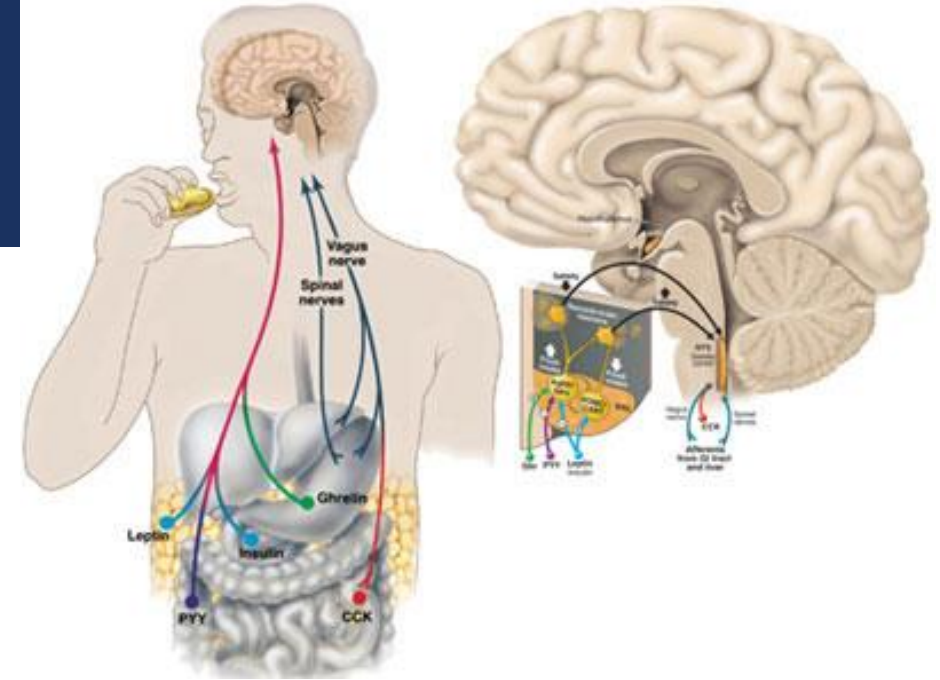
- Programming, follow up visits, virtual care, technology

■ Metabolic alterations to promote fat loss

- Surgery, medications, dietary patterns, exercise intensity, sleep

■ Environmental stimulus control

- Meal replacements, CBT, Acceptance based therapy





OBESITY TREATMENT PILLARS

ANTI-OBESITY MEDICATIONS

Objectives:

- Treat disease
 - Adiposopathy or sick fat disease (SFD)
 - Fat mass disease (FMD)
- Facilitate management of eating behavior
- Slow progression of weight gain/regain
- Improve the health, quality of life, and body weight of the patient with overweight or obesity

Adjunct to nutritional, physical activity, and behavioral therapies for patients with BMI ≥ 30 or BMI ≥ 27 with co-morbidities

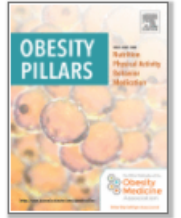
5-10 percent weight loss may improve both metabolic and fat mass disease



CLINICAL PRACTICE STATEMENTS



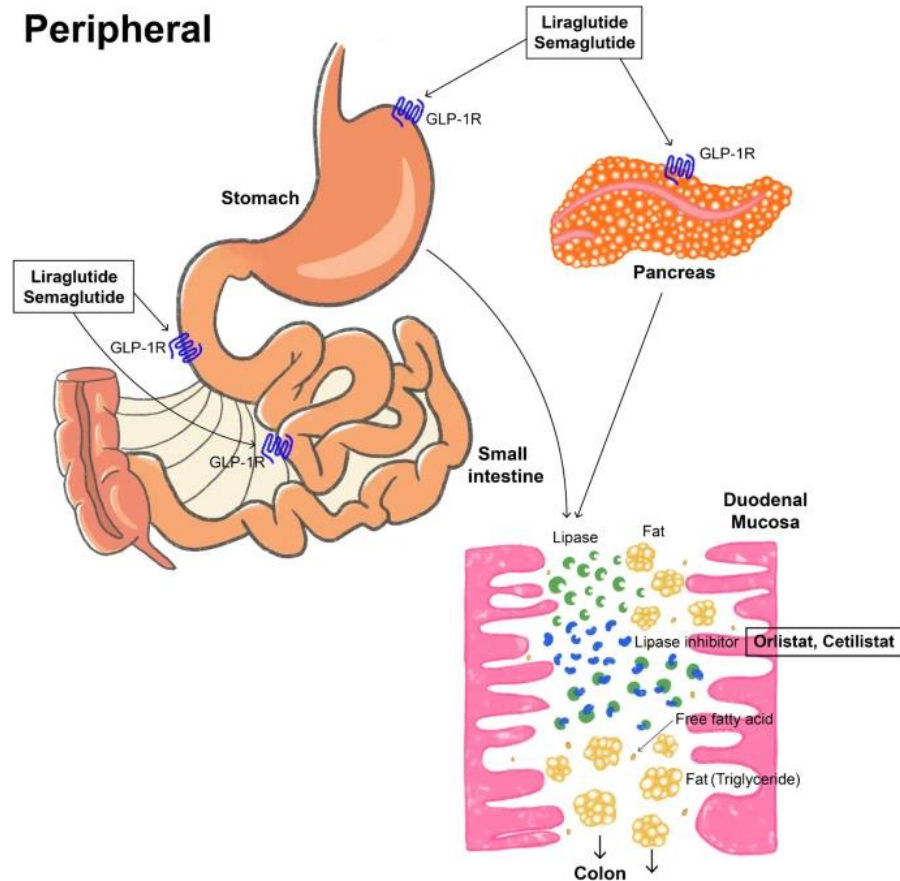
Obesity Pillars
Volume 2, June 2022, 100018



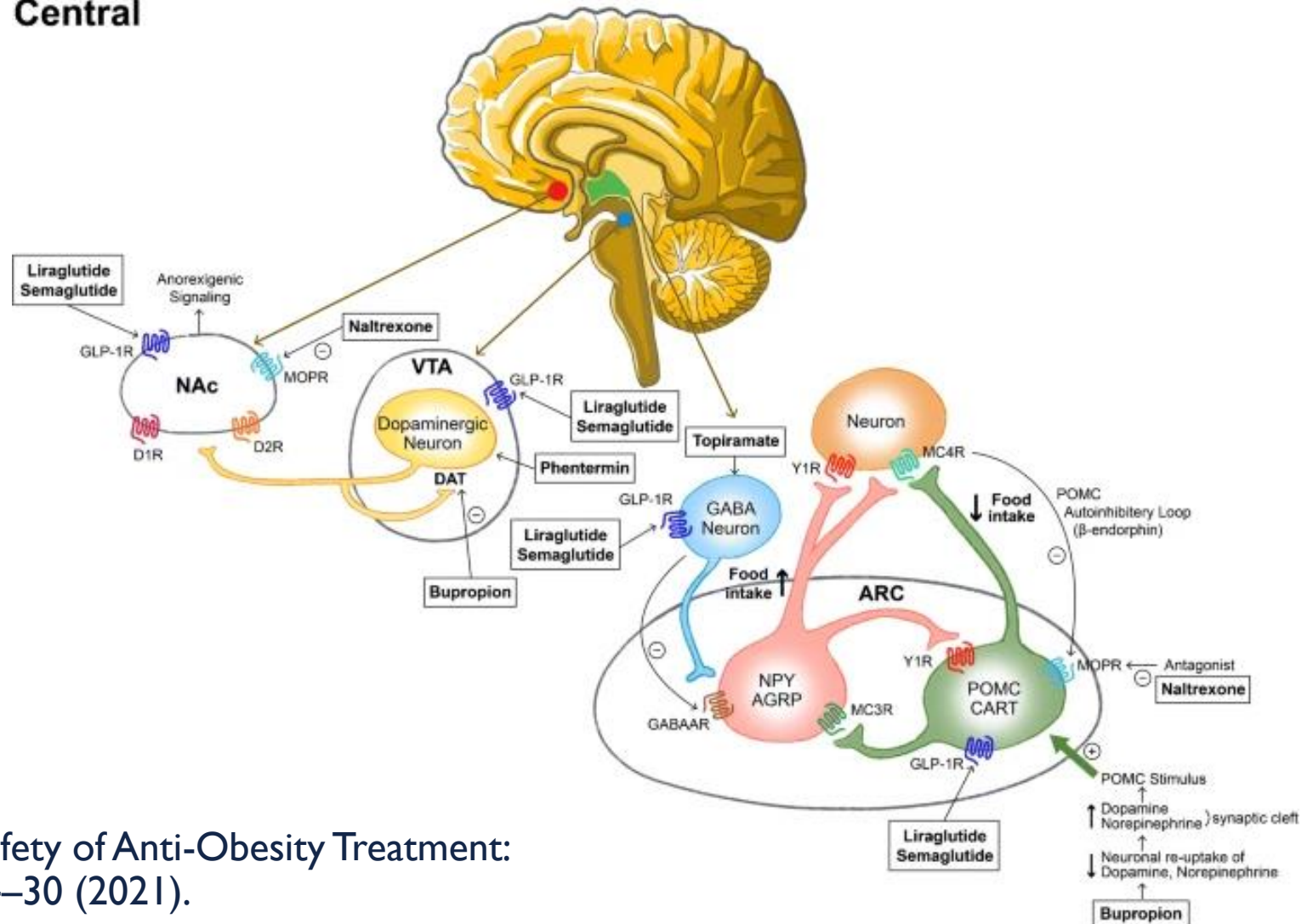
Anti-Obesity Medications and Investigational Agents: An Obesity Medicine Association (OMA) Clinical Practice Statement (CPS) 2022

Harold E. Bays^a  , Angela Fitch^b , Sandra Christensen^c , Karli Burridge^{d, e} , Justin Tondt^f 

Peripheral



Central



■ Tak, Y.J., Lee, S.Y. Long-Term Efficacy and Safety of Anti-Obesity Treatment: Where Do We Stand?. *Curr Obes Rep* **10**, 14–30 (2021).
<https://doi.org/10.1007/s13679-020-00422-w>

Metabolism

Clinical and Experimental

REVIEWS | VOLUME 113, 154388, DECEMBER 01, 2020



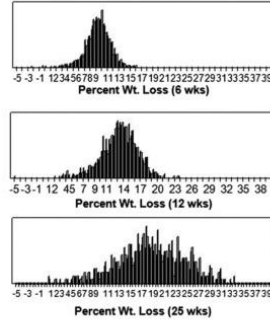
Purchase

Factors affecting weight loss variability in obesity

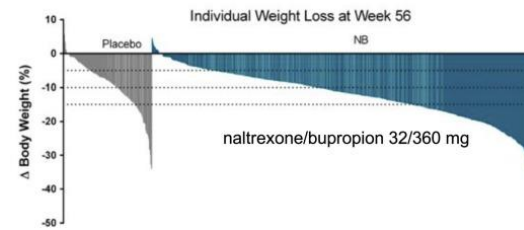
Robert Dent • Ruth McPherson • Mary-Ellen Harper



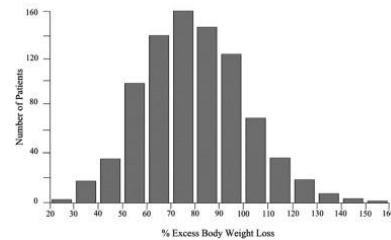
A. Diet



B. Medication



C. Surgery



VARIABLE RESPONSE TO INTERVENTION

CHOOSING MEDICATION

Is it covered by insurance?

- Medicare does not cover AOMs
- Medicaid is state dependent but covered in WI!!!!!!
- Phentermine, topiramate, bupropion, naltrexone, GLP-I

Assess for contraindications/risks

- GLP-I - pancreatitis
- Topiramate - kidney stones, severe depression
- Phentermine – cardiovascular risk, anxiety, bipolar d/o
- Bupropion – seizure disorder
- Naltrexone – opioid use

Assess for double benefits

- Topiramate for migraine or BED
- Bupropion for depression/ADHD

Does patient have diabetes, prediabetes or insulin resistance

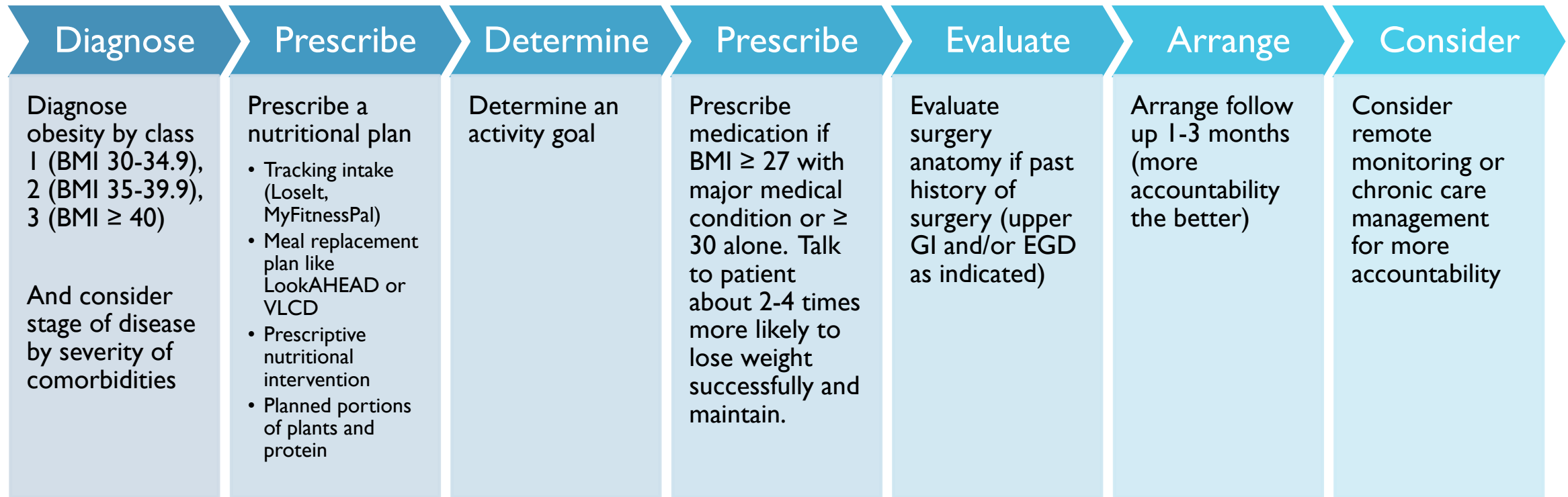
- Consider metformin, SGLT-2 and GLP-I first
- Off label use of GLP-I with semaglutide, liraglutide or covered GLP-I

ADOLESCENTS/PEDIATRICS

- Liraglutide 3mg and Semaglutide 2.4mg approved to age 12
- Benzphetamine approved to age 12
- Phentermine approved to age 16
- Topiramate
- Lisdexamphetamine for BED
- Orlistat approved to age 12
- Setmelanotide for POMC def. down to age 6



CREATE AN OBESITY TREATMENT CARE PLAN



WHAT CAN WE DO NEXT?

Measures

- **Operational Tracking**

Measure 1a: Prevalence of overweight and obesity in primary care across the organization

Measure 1b: Prevalence of overweight and obesity in clinics targeted for the collaborative

Measure 2: Obesity-related complications per patient

- **Quality Performance**

Measure 3: Documentation of obesity diagnoses

Measure 4: Assessment for obesity-related complications

Measure 6: Percent weight change in a 15-month period

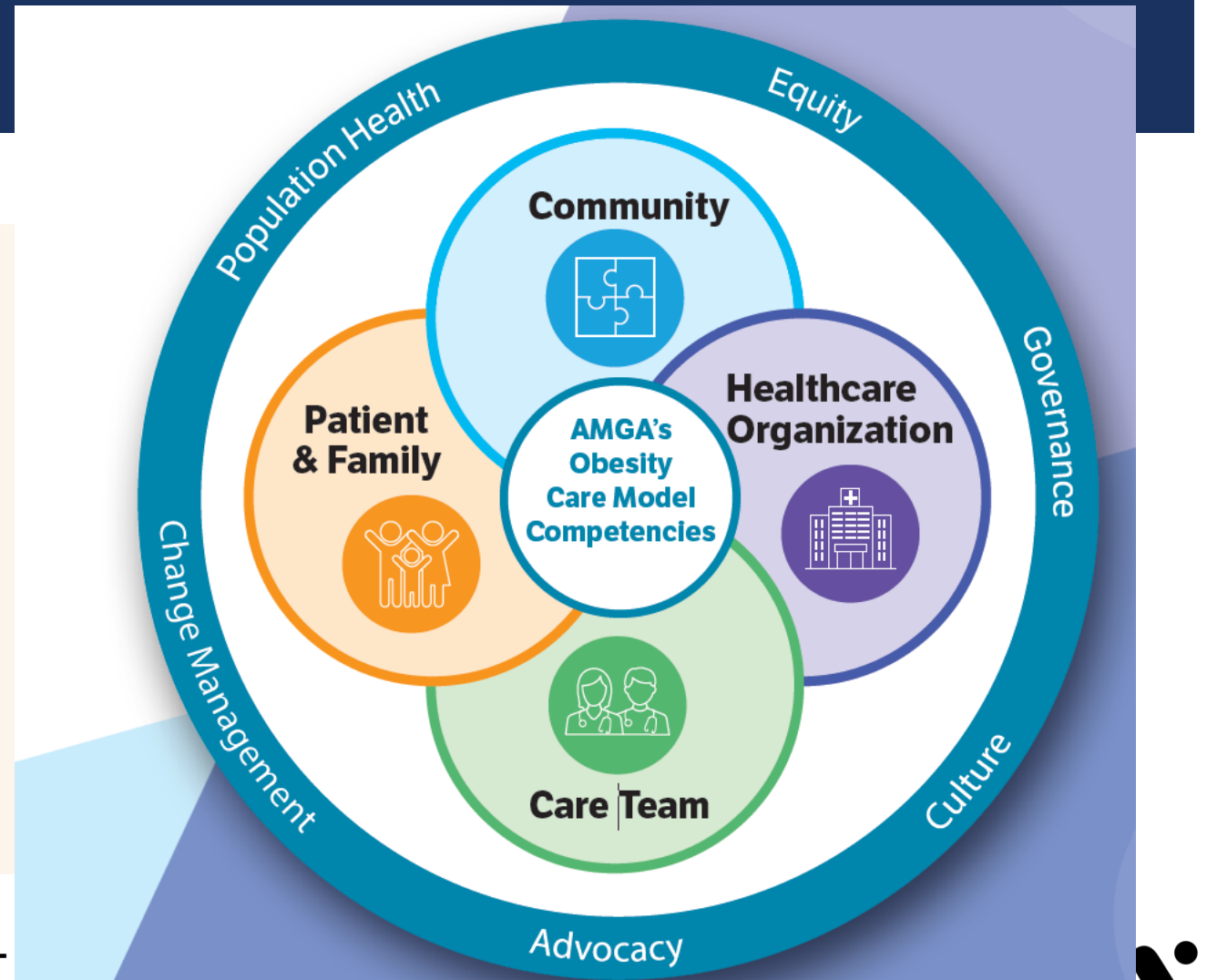
Measure 7: Prescribing of anti-obesity medications

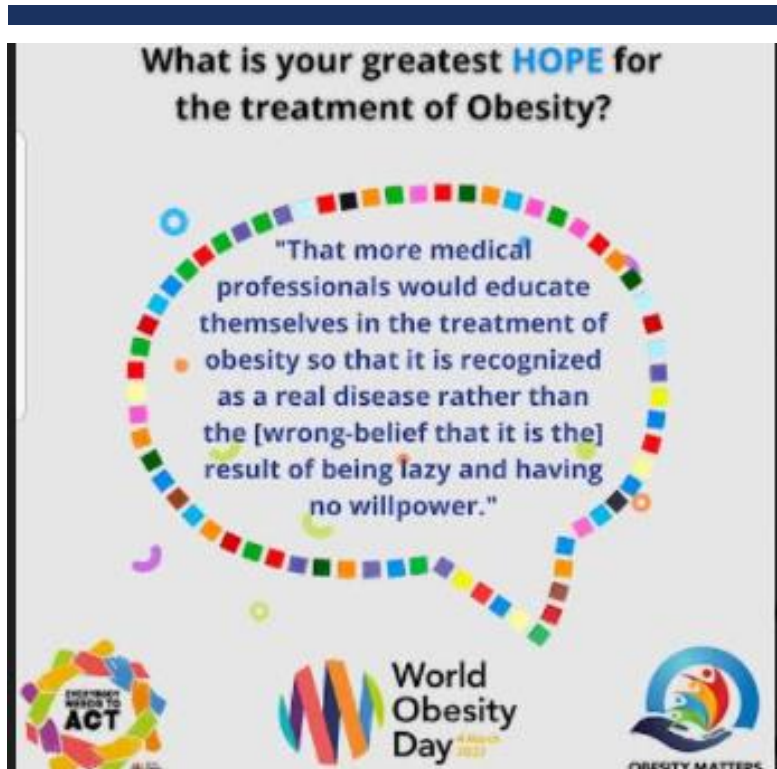
- **Patient-Centered Care (Patient-Reported Outcomes)**

Measure 5a: Number of patient-reported outcome measure surveys completed

Measure 5b: Change in patient-reported outcome measure

<https://www.amga.org/performance-improvement/best-practices/collaboratives/obesity-care-model/>





WORLD OBESITY DAY
MARCH 4TH

THANK YOU!

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www.knownwell.co



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@drangelafitch



@AngelaFitchMD

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Anti-Obesity Medication (AOM)

Stephen J. Kogut PhD MBA RPh

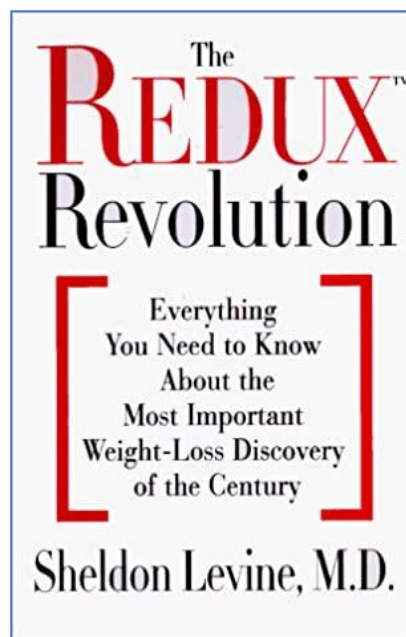
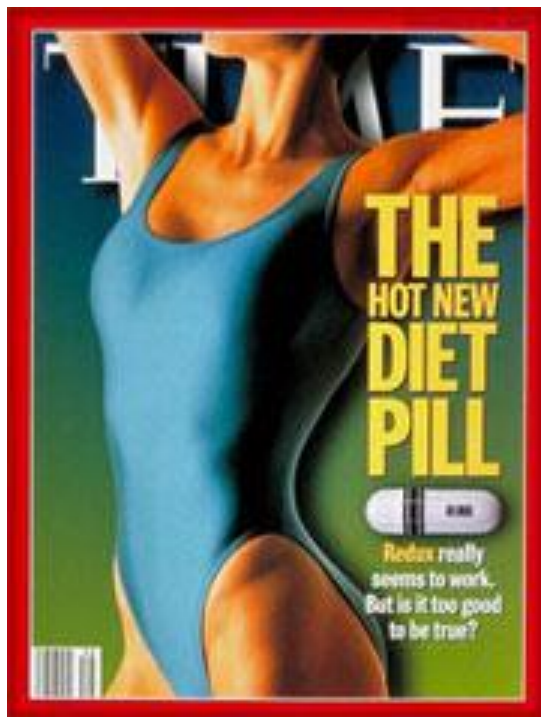
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VALVULAR HEART DISEASE ASSOCIATED WITH FENFLURAMINE-
PHENTERMINE

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BROOKS S. EDWARDS, M.D., WILLIAM D. EDWARDS, M.D., AND HARTZELL V. SCHAFF, M.D.

ABSTRACT

Background Fenfluramine and phentermine have been individually approved as anorectic agents by the Food and Drug Administration (FDA). When used in combination the drugs may be just as effective as either drug alone, with the added advantages of the need for lower doses of each agent and perhaps fewer side effects. Although the combination has not been approved by the FDA, in 1996 the total number of prescriptions in the United States for fenfluramine and phentermine exceeded 18 million.

Methods We identified valvular heart disease in 24 women treated with fenfluramine-phentermine who had no history of cardiac disease. The women presented with cardiovascular symptoms or a heart murmur. As increasing numbers of these patients with similar clinical features were identified, there appeared to be an association between these features and fenfluramine-phentermine therapy.

Results Twenty-four women (mean \pm SD age, 44 ± 8 years) were evaluated 12.3 ± 7.1 months after the initiation of fenfluramine-phentermine therapy. Echocardiography demonstrated unusual valvular morphology and regurgitation in all patients. Both right-sided and left-sided heart valves were involved. Eight women also had newly documented pulmonary hypertension. To date, cardiac surgical intervention has been required in five patients. The heart valves had a glistening white appearance. Histopathological findings included plaque-like encasement of the leaflets and chordal structures with intact valve architecture. The histopathological features were identical to those seen in carcinoid or ergotamine-induced valve disease.

Conclusions These cases arouse concern that fenfluramine-phentermine therapy may be associated with valvular heart disease. Candidates for fenfluramine-phentermine therapy should be informed about serious potential adverse effects, including pulmonary hypertension and valvular heart disease. (N Engl J Med 1997;337:581-8.)

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FENFLURAMINE and phentermine are prescription medications that have been individually approved by the Food and Drug Administration (FDA) as appetite suppressants for the treatment of obesity. When used in combination they may be just as effective as either drug alone, with the added advantages of the need for lower doses of each agent, fewer side effects, and improved patient tolerance.¹ Even though the FDA has not approved the use of the combination, in 1996 the total number of prescriptions for fenfluramine and phentermine in the United States exceeded 18 million.²

Pulmonary hypertension has been reported in association with treatment with fenfluramine^{3,4} or phentermine⁵ alone. The *d*-isomer of fenfluramine, dexfenfluramine, also increases the risk of pulmonary hypertension,⁶ particularly when patients receive high doses for more than three months. These drugs may cause pulmonary hypertension through the vasoconstrictor action of serotonin or by altering the depolarization of pulmonary vascular smooth-muscle membrane.⁷

Valvular disease has been reported after exposure to serotonin-like drugs such as ergotamine and methysergide⁸ and with increased serotonin levels associated with carcinoid disease.^{9,10} Valvular heart disease has not been reported in patients taking anorectic agents. We report 24 cases of unusual valvular disease in patients taking fenfluramine-phentermine.

METHODS

All the patients (Table 1) were identified during the course of routine evaluation for various clinical problems. No attempt was

From the Divisions of Cardiovascular Diseases and Internal Medicine (H.M.C., M.D.M., B.S.E.), Preventive and Occupational Medicine, Endocrinology, and Internal Medicine (D.D.H.), Anatomic Pathology (W.D.E.), and Thoracic and Cardiovascular Surgery (H.V.S.), Mayo Clinic and Mayo Foundation, Rochester, Minn.; and the MeritCare Medical Center, Heart Services, Fargo, N.D. (J.L.C.). Address reprint requests to Dr. Connolly at the Mayo Clinic, 200 First St. SW, Rochester, MN 55905.

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THE PREVALENCE OF CARDIAC VALVULAR INSUFFICIENCY ASSESSED
BY TRANSTHORACIC ECHOCARDIOGRAPHY IN OBESE PATIENTS
TREATED WITH APPETITE-SUPPRESSANT DRUGS

MEHMOOD A. KHAN, M.D., CHARLES A. HERZOG, M.D., JOHN V. ST. PETER, PHARM.D., GUILFORD G. HARTLEY, M.D.,
RICHARD MADLON-KAY, M.D., CANDACE D. DICK, M.D., RICHARD W. ASINGER, M.D., AND JOHN T. VESSEY, PH.D.

TABLE 5. CASES OF CARDIAC-VALVE ABNORMALITIES
MEETING THE CASE DEFINITION.

GROUP	No. OF SUBJECTS	CARDIAC-VALVE ABNORMALITIES
		no. of cases (%)
Unexposed control subjects	233	3 (1.3)
Patients	233	53 (22.7)
Patients given dexfenfluramine	39	5 (12.8)
Patients given dexfenfluramine and phentermine	31	7 (22.6)
Patients given fenfluramine and phentermine	163	41 (25.2)

Medications for Weight Loss

FDA Approval	Name	Mechanism
1959	Phentermine (Fastin™, Adipex™, Ionamin™)	sympathomimetic
1999	Orlistat (Xenical™ & Alli™)	lipase inactivation
2012	Phentermine/topiramate ER (Qsymia™)	sympathomimetic/GABA
2014	Naltrexone/bupropion (Contrave™)	opioid recept. antagonist/inhibit dopamine & NE reuptake
2014	Liraglutide (Saxenda™)	GLP-1 receptor agonist
2020	Setmelanotide (Imcivree™)*	melanocortin-4 receptor agonist
2021	Semaglutide (Wegovy™)	GLP-1 receptor agonist
Fast-tracked in 2022	Tirzepatide (potential 2023 launch)	dual GIP/GLP-1 receptor agonist

** Setmelanotide is approved for ultra-rare genetic conditions only*

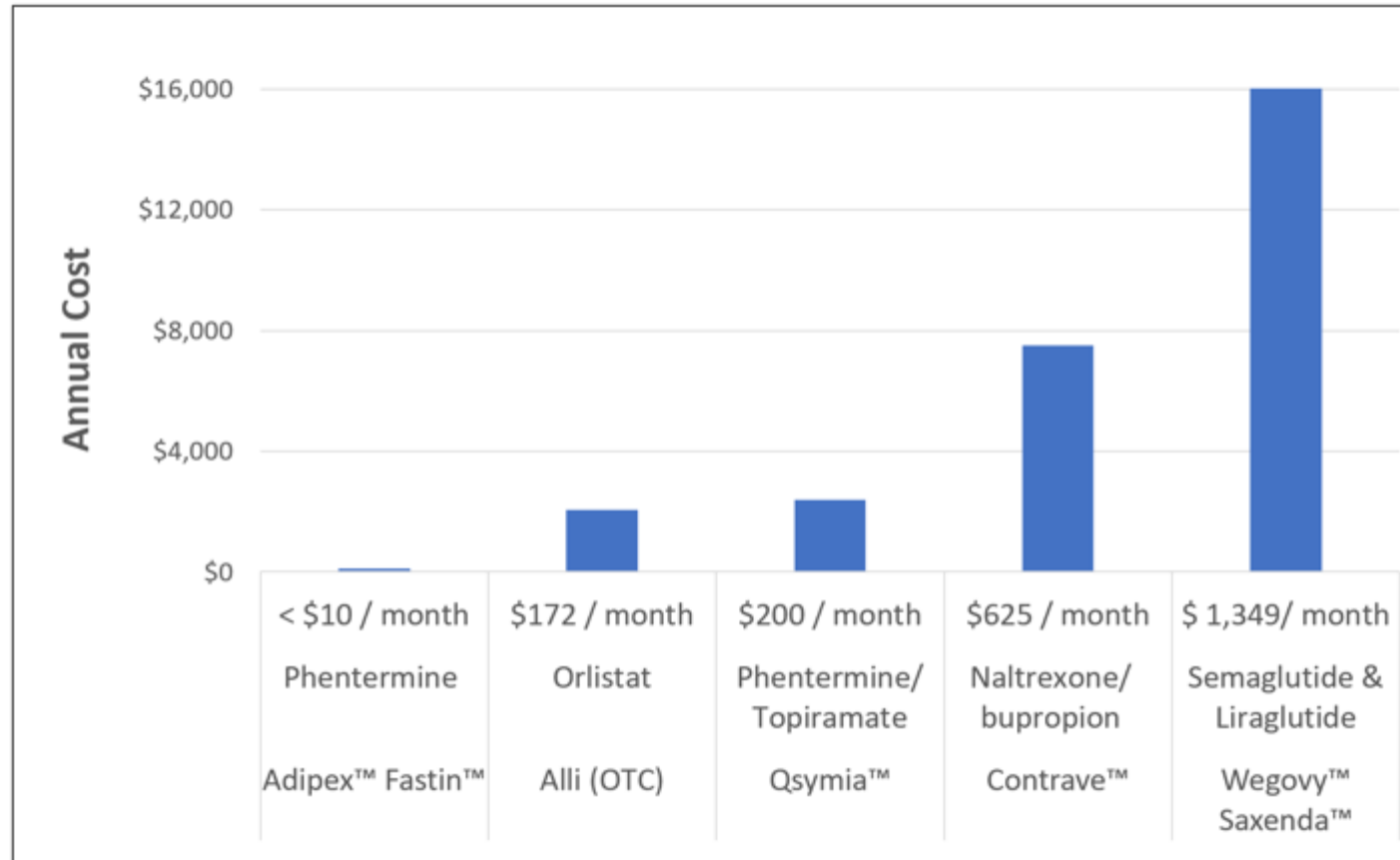
Indications, Efficacy and Cardiovascular Effects

	Phentermine up to 12 weeks	Phentermine/ topiramate (Qsymia™)	Naltrexone/ bupropion (Contrave™)	Liraglutide (Saxenda™)	Semaglutide (Wegovy™)
FDA Indication (adults)	BMI ≥ 30 or BMI ≥ 27 with weight-related condition (e.g. HTN, DM) + reduced-caloric intake and increased physical activity				
Pediatrics	Lack safety & effectiveness < 16 years	≥ 12 years & BMI ≥ 95 th percentile	Not recommended < 18 years	≥ 12 years & BMI ≥ 30 & weight > 60kg	≥ 12 years & BMI ≥ 95 th percentile
Dosing	Once daily oral	Once daily oral	Titrate up to 2 tabs BID	Daily SC	Weekly SC
Efficacy (weight loss - placebo)	6% at 20 weeks	9% at 52 weeks	5% at 52 weeks	6% at 52 weeks	12.5% at 68 weeks
Cardio-vascular	↓ BP with weight loss; ↑ HR > in peds	↓ BP with weight loss; Transient ↑ HR [PMID: 24621808]	No ↑ in CV events or MACE [PMID: 33847068]	↓ CVD events and mortality at lower doses in type 2 DM	

Contraindications / Precautions

	Phentermine up to 12 weeks	Phentermine/ topiramate (Qsymia™)	Naltrexone/ bupropion (Contrave™)	Liraglutide (Saxenda™)	Semaglutide (Wegovy™)
eGFR < 15ml/min	Do not use			No dose reduction required but use with caution due to reports of kidney injury and worsening renal failure	
eGFR 15-30 ml/min					
Contraindications Pregnancy / breast feeding +	CAD, uncontrolled HTN, arrhythmia, hyperthyroidism, glaucoma	Same as phentermine + hx of renal stones; potential pregnancy	Uncontrolled HTN, seizures, bipolar disorder, anorexia, alcoholism	History of medullary thyroid cancer or type 2 multiple endocrine neoplasia syndrome	
Drug interactions (not exhaustive)	MAOIs; SSRI/SNRIs	MAOIs; SSRI/SNRIs; CNS depressants; diuretics	MAOIs; SSRI/SNRIs; opioids; many cyp450 interactions	Beta blockers; drugs associated with hypo/hyperglycemia	
Adverse Effects	Anxiety, irritability, insomnia, xerostomia, ↑HR,	Same as phentermine + depression, dysgeusia, CNS effects	N/V, diarrhea, headache, insomnia, mania, seizures, xerostomia, ↑BP	Abdominal pain, constipation, diarrhea, dyspepsia, headache, N/V, ↑HR	

Anti-Obesity Medication Cost (WAC, 2023)



the **pharma**letter

* Up to date news for the Pharmaceutical and Biotechnology Industries

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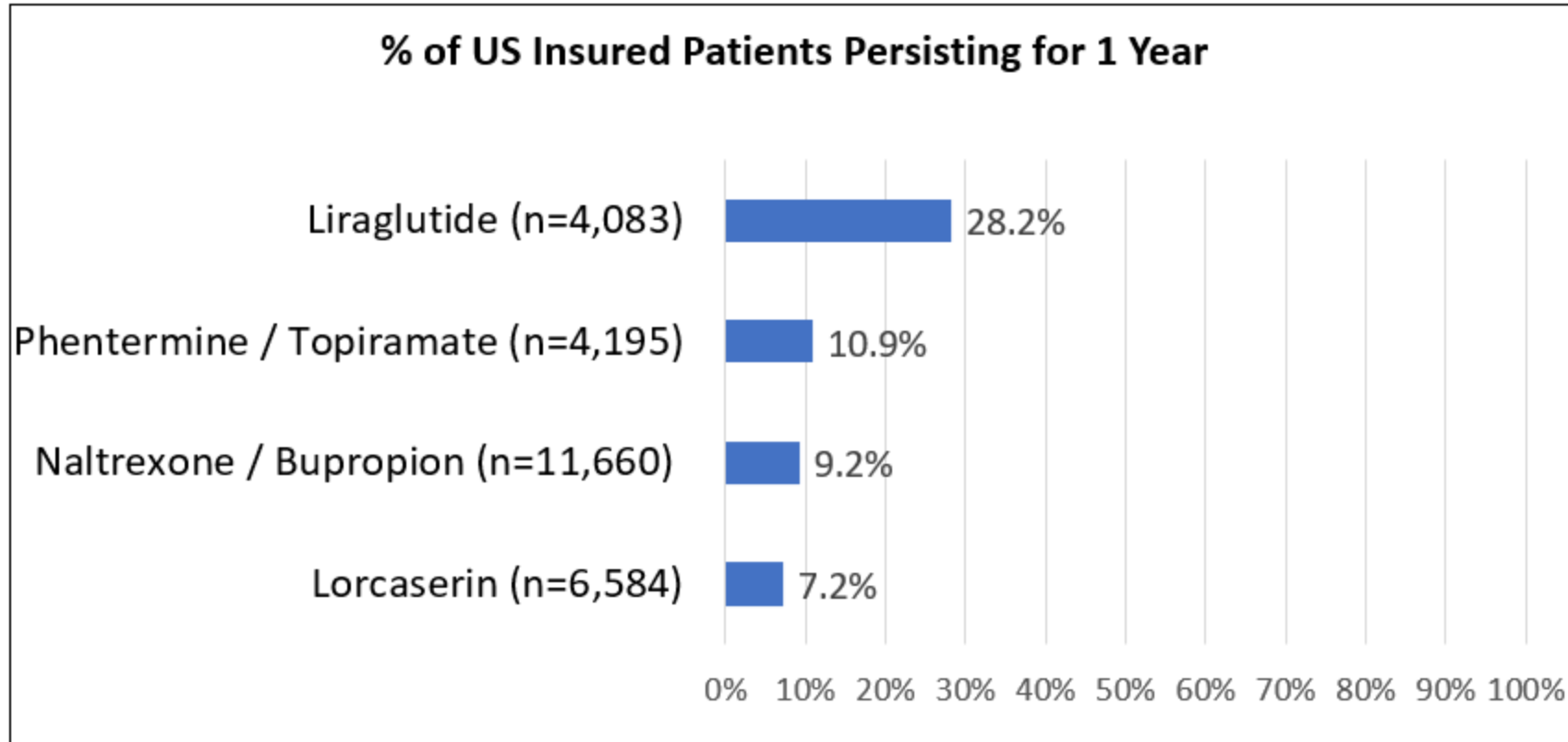
HOME > PHARMACEUTICAL

Pricing watchdog judges Wegovy too pricey in the USA

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Persistence with Anti-Obesity Medication

Adapted from Ganguly R et al. Diab Res and Clin Pract 2018



Data source: Truven Health MarketScan claims, representing US commercial and Medicare plans. Study period was Jan. 2014- Sept. 2016. PMID 30009937.

Anti-Obesity Medication: Barriers

- Difficult topic for providers and patients to discuss
- Maintaining weight loss is challenging
- Obesity drugs have a clouded history
- Bias and stigma
- Provider education
- Treatment complexity
- Insurance coverage
- Disparity → equity



CME Credits & Eval

Reminder to please complete the evaluation in order to claim CME credits!

Claim CME credits here: <https://www.surveymonkey.com/r/ZDZS5HG>



The AAFP has reviewed 'Advancing Comprehensive Primary Care Through Improving Care Delivery Design and Community Health,' and deemed it acceptable for AAFP credit. Term of approval is from 03/18/2022 to 03/18/2023. Physicians should claim only the credit commensurate with the extent of their participation in the activity. NPs and RNs can also receive credit through AAFP's partnership with the American Nurses Credentialing Center (ANCC) and the American Academy of Nurse Practitioners Certification Board (AANPCB).

THANK YOU

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