Attainment of Legerity: Probably the Most Important Health Intervention of the 21st Century.

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Disclosures and Acknowledgments

(Current or within 12 months prior to date shown)

Disclosure	Company
Stockholder	Dexcom Inc.
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1. **The prevalence of obesity and its importance in disease causation**
2. **Our current performance in combating adult obesity**
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5. **Discussion**

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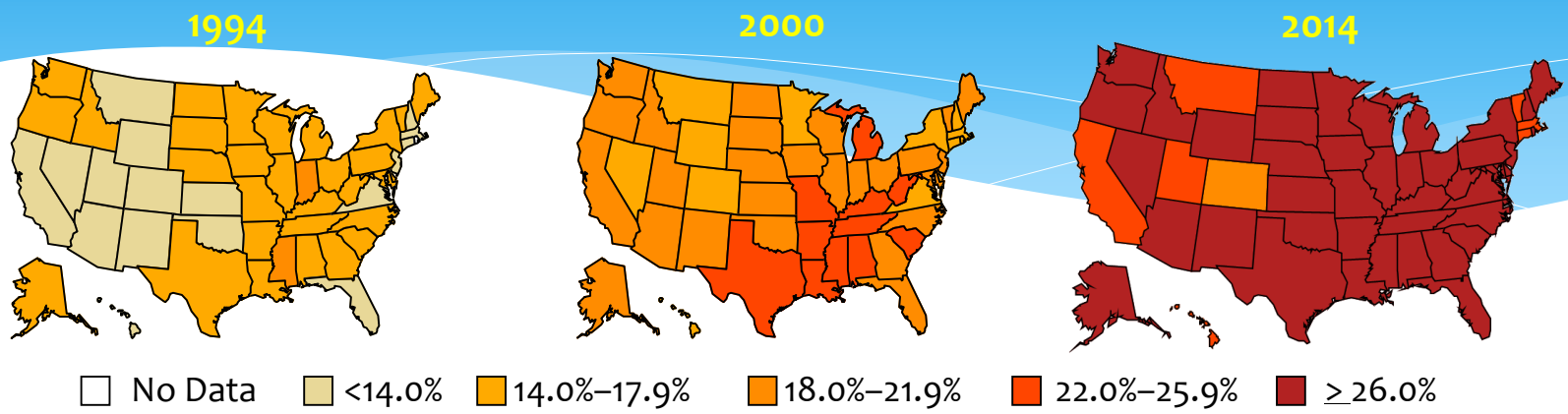
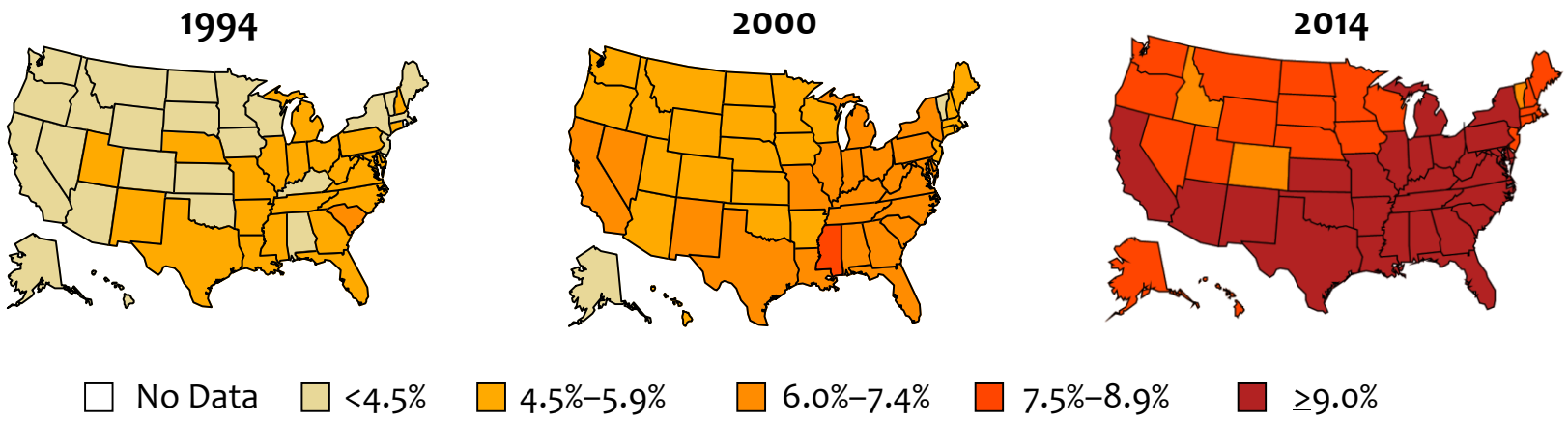
Age-adjusted Prevalence of Obesity and Diagnosed Diabetes Among US Adults

Obesity (BMI ≥30 kg/m²)

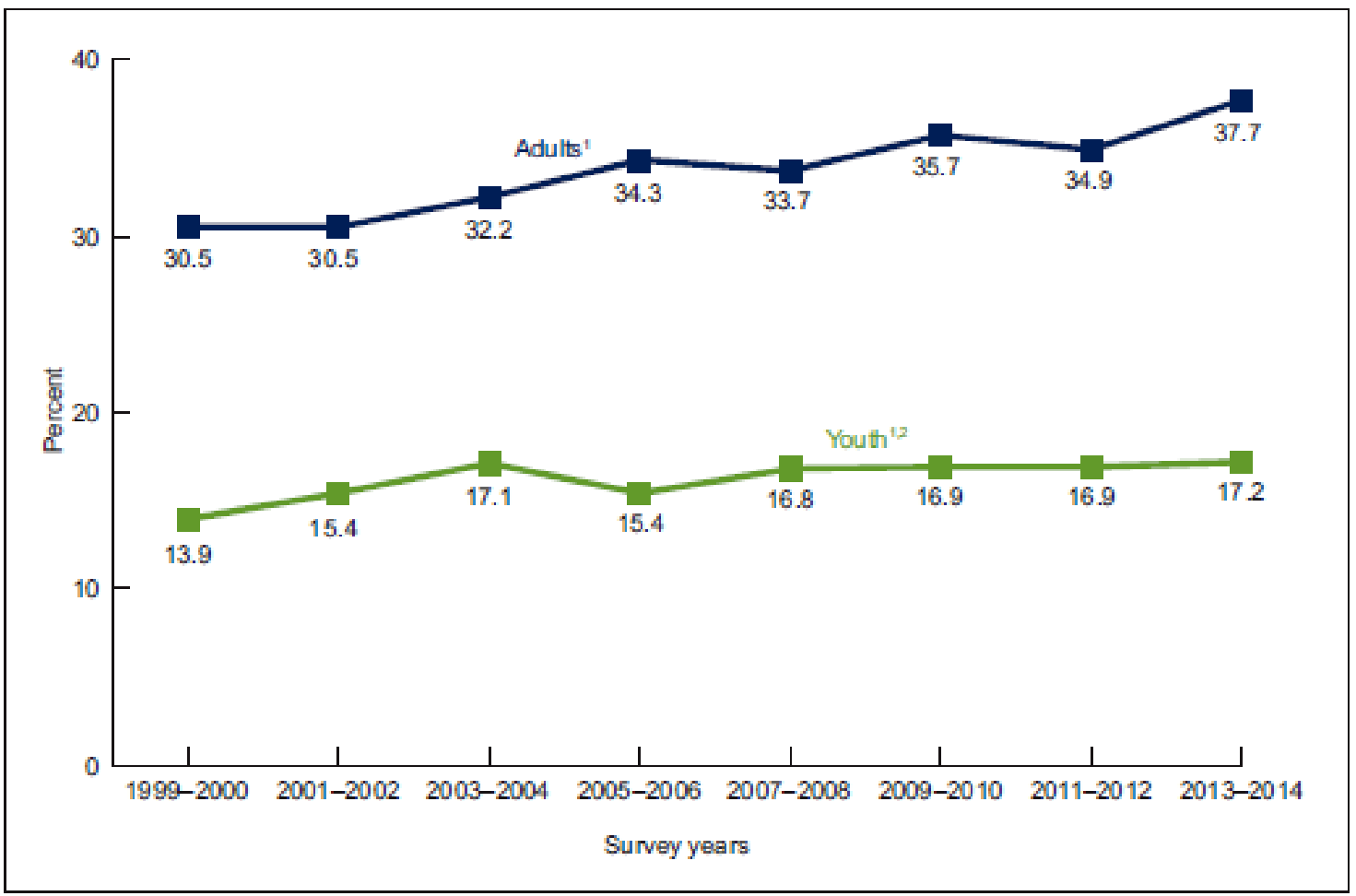


Diabetes



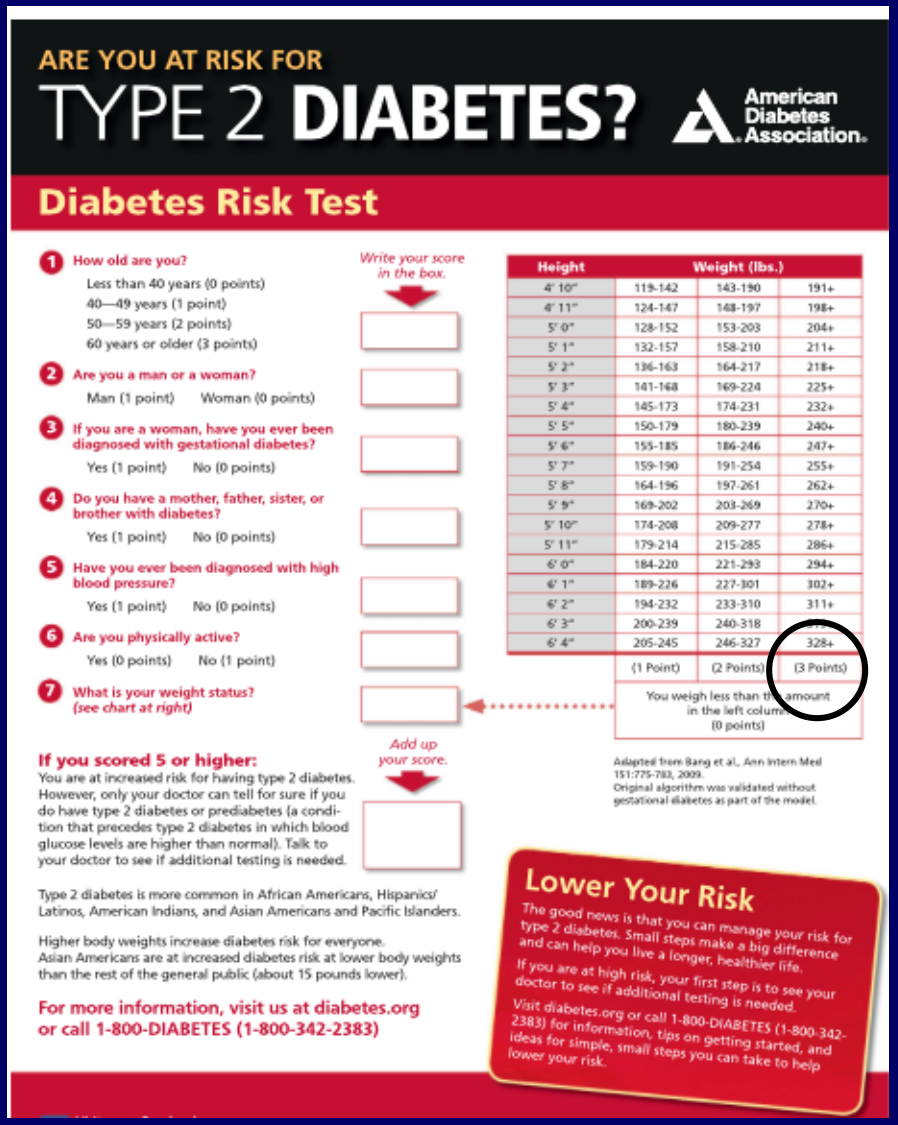
CDC's Division of Diabetes Translation. United States Surveillance System available at http://www.cdc.gov/diabetes/data

Prevalence of Obesity in US 1999-2014



[1]Significant increasing linear trend from 1999–2000 through 2013–2014.
[2]Test for linear trend for 2003–2004 through 2013–2014 not significant ($p > 0.05$).
NOTE: All adult estimates are age-adjusted by the direct method to the 2000 U.S. census population using the age groups 20–39, 40–59, and 60 and over.
SOURCE: CDC/NCHS, National Health and Nutrition Examination Survey.

Weight is the Most Potent Risk Factor for Type 2 Diabetes



ARE YOU AT RISK FOR
TYPE 2 DIABETES?
American Diabetes Association.

Diabetes Risk Test

1. How old are you?
   Less than 40 years (0 points)
   40—49 years (1 point)
   50—59 years (2 points)
   60 years or older (3 points)
2. Are you a man or a woman?
   Man (1 point) Woman (0 points)
3. If you are a woman, have you ever been diagnosed with gestational diabetes?
   Yes (1 point) No (0 points)
4. Do you have a mother, father, sister, or brother with diabetes?
   Yes (1 point) No (0 points)
5. Have you ever been diagnosed with high blood pressure?
   Yes (1 point) No (0 points)
6. Are you physically active?
   Yes (0 points) No (1 point)
7. What is your weight status? *(see chart at right)*

Write your score in the box.

Height	Weight (lbs.)		
4' 10"	119-142	143-190	191+
4' 11"	124-147	148-197	198+
5' 0"	128-152	153-203	204+
5' 1"	132-157	158-210	211+
5' 2"	136-163	164-217	218+
5' 3"	141-168	169-224	225+
5' 4"	145-173	174-231	232+
5' 5"	150-179	180-239	240+
5' 6"	155-185	186-246	247+
5' 7"	159-190	191-254	255+
5' 8"	164-196	197-261	262+
5' 9"	169-202	203-269	270+
5' 10"	174-208	209-277	278+
5' 11"	179-214	215-285	286+
6' 0"	184-220	221-293	294+
6' 1"	189-226	227-301	302+
6' 2"	194-232	233-310	311+
6' 3"	200-239	240-318	
6' 4"	205-245	246-327	328+
	(1 Point)	(2 Points)	(3 Points)

You weigh less than the amount in the left column (0 points)

Add up your score.

If you scored 5 or higher:
You are at increased risk for having type 2 diabetes. However, only your doctor can tell for sure if you do have type 2 diabetes or prediabetes (a condition that precedes type 2 diabetes in which blood glucose levels are higher than normal). Talk to your doctor to see if additional testing is needed.

Type 2 diabetes is more common in African Americans, Hispanics/Latinos, American Indians, and Asian Americans and Pacific Islanders.

Higher body weights increase diabetes risk for everyone. Asian Americans are at increased diabetes risk at lower body weights than the rest of the general public (about 15 pounds lower).

For more information, visit us at diabetes.org or call 1-800-DIABETES (1-800-342-2383)

Adapted from Bang et al., Ann Intern Med 151:775-783, 2009.
Original algorithm was validated without gestational diabetes as part of the model.

Lower Your Risk

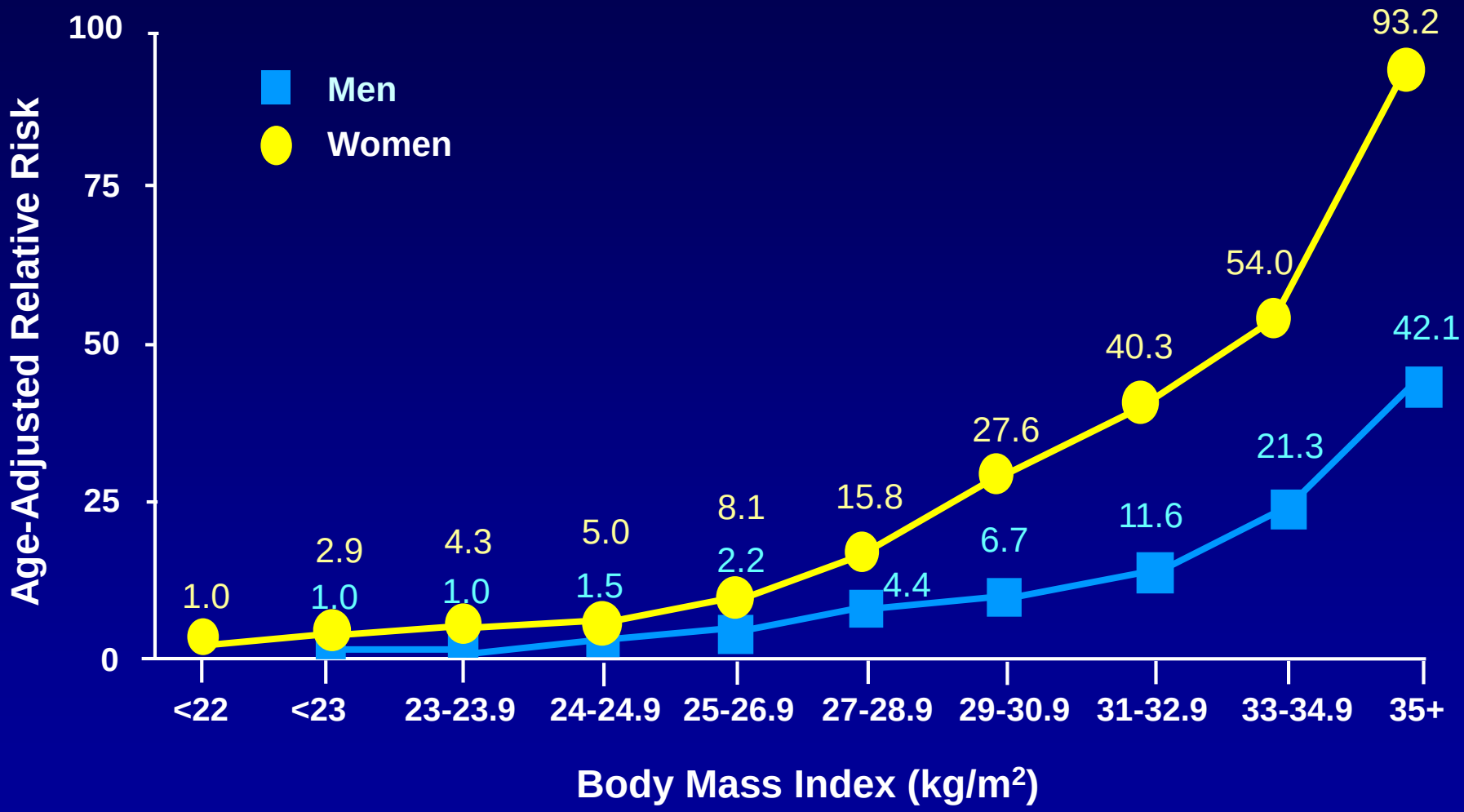
The good news is that you can manage your risk for type 2 diabetes. Small steps make a big difference and can help you live a longer, healthier life.

If you are at high risk, your first step is to see your doctor to see if additional testing is needed.

Visit diabetes.org or call 1-800-DIABETES (1-800-342-2383) for information, tips on getting started, and ideas for simple, small steps you can take to help lower your risk.

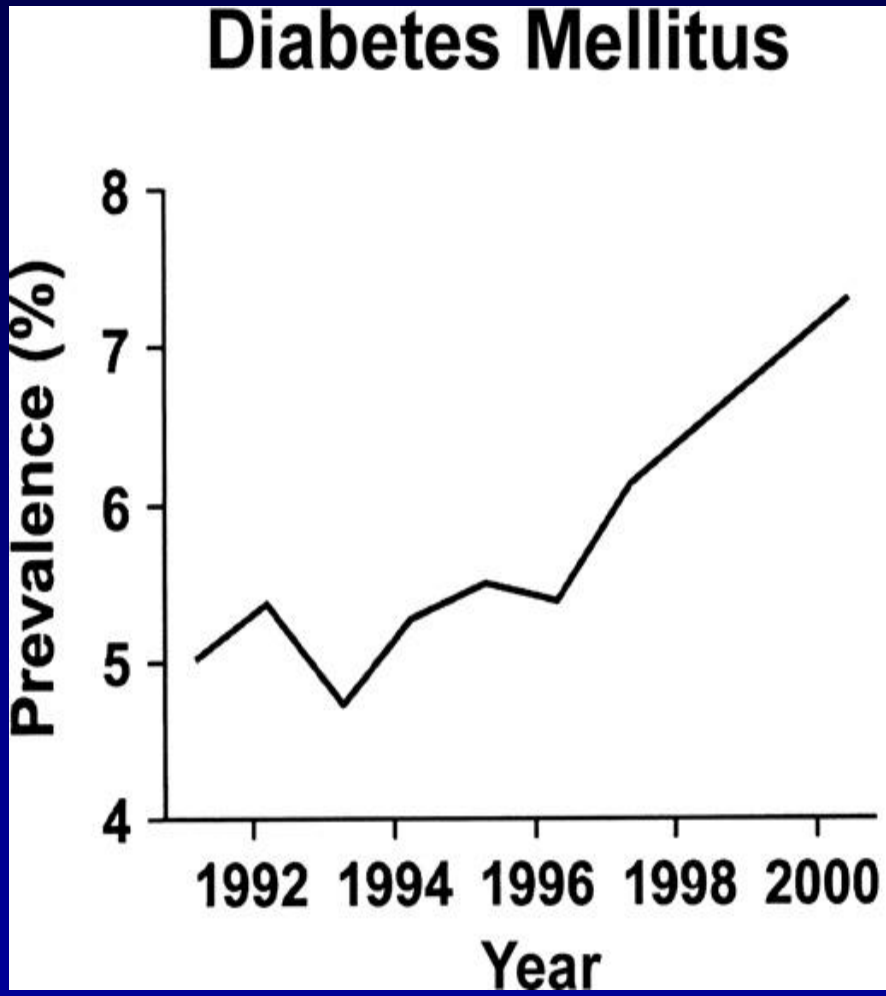
Diabetes Care 2017 Jan; 40 (Supplement 1): S1-S2. https://doi.org/10.2337/dc17-S001

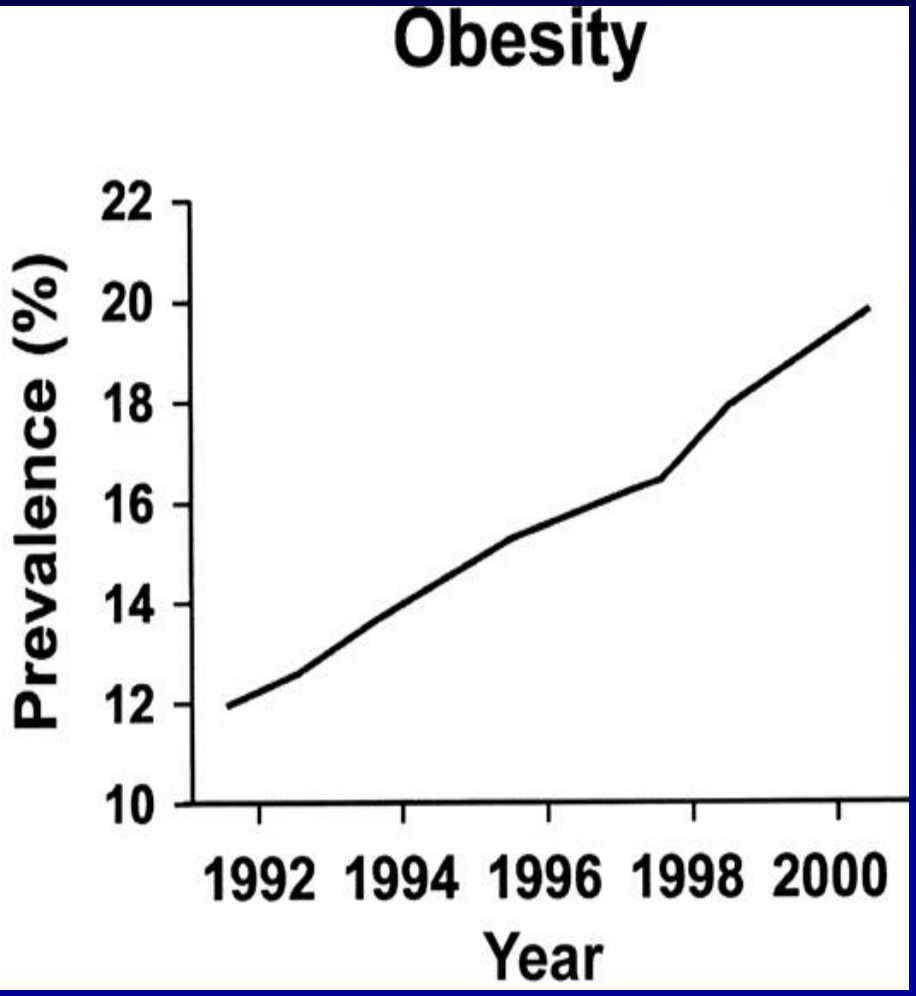
Relationship Between Weight Risk of Type 2 Diabetes



Chan JM et al. *Diabetes Care* 17:961-969, 1994.
Colditz G et al. *Ann Intern Med* 122:481-486, 1995.

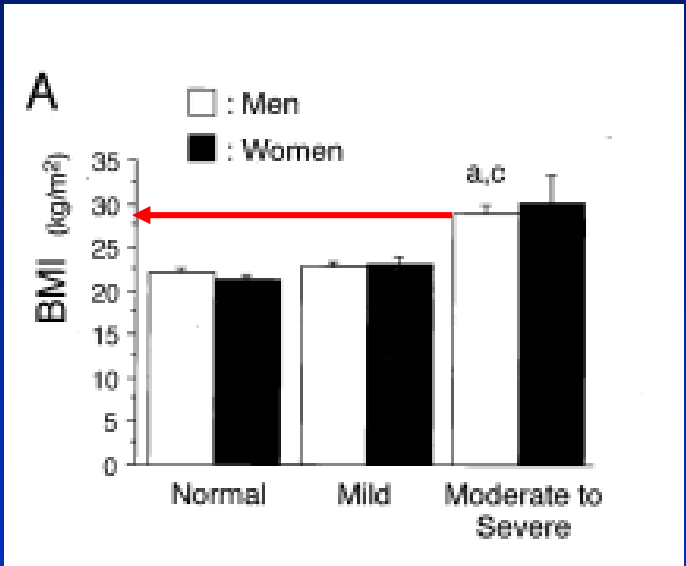
Trends for Diabetes and Obesity in U.S. Adults 1992-2000

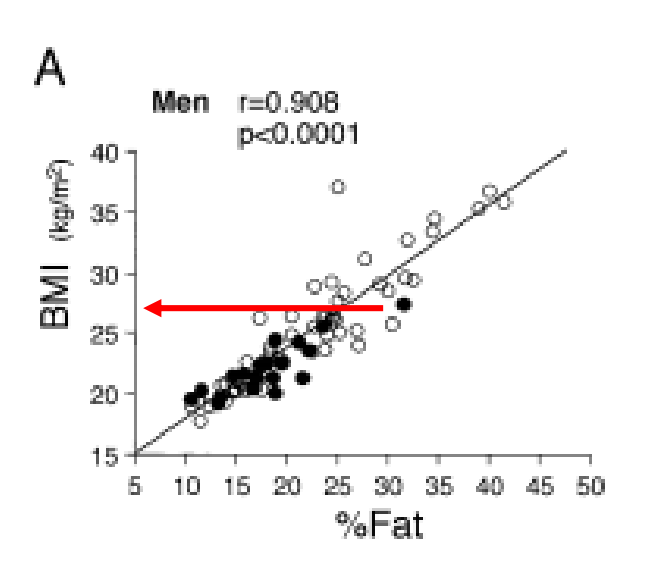




Smith SC Jr. *Am J Med* 120:S3–S11, 2007.

BMI and NAFLD





Nakao K et al. *Am J Gastroenterol 97*:1796-1801, 2002.

Role of Obesity in Cancer

Cancers more prevalent in the overweight and obese:

1. Esophagus
2. Stomach
3. Pancreas
4. Gallbladder
5. Liver
6. Colon
7. Rectal
8. Breast
9. Ovaries
10. Uterus
11. Lymphoma
12. Multiple Myeloma
13. Thyroid

Centers for Disease Control , Oct 2017
International Agency for Research on Cancer

Epidemiology of Obesity and Cancer

- **In 2014, 630,000 people in the U.S. were diagnosed with a cancer linked to overweight/obesity;**
- **Rates of obesity-related cancer rose 7% between 2005 and 2015, except colorectal cancer (down 23%);**
- **Cancers not associated with obesity fell by 13% during this time period;**
- **Obesity-related cancers account for 40% of all cancers in the U.S.**

Centers for Disease Control , Oct 2017
International Agency for Research on Cancer

Other Disorders with Higher Prevalence in Obesity

- Obstructive sleep apnea
- Lower extremity osteoarthritis
- GERD
- Cholelithiasis
- CHF
- Hernia
- Hydradenitis suppurativa
- Dyslipidemia
- PCOS
- Venous stasis
- Plantar fasciitis
- Gout
- Menstrual irregularities and infertility
- Hypertension
- Eating disorders
- Depression

etc…

Costs of care of most major health problems in obese persons are higher & outcomes are poorer

Risk of Most Major Diseases Increases with BMI

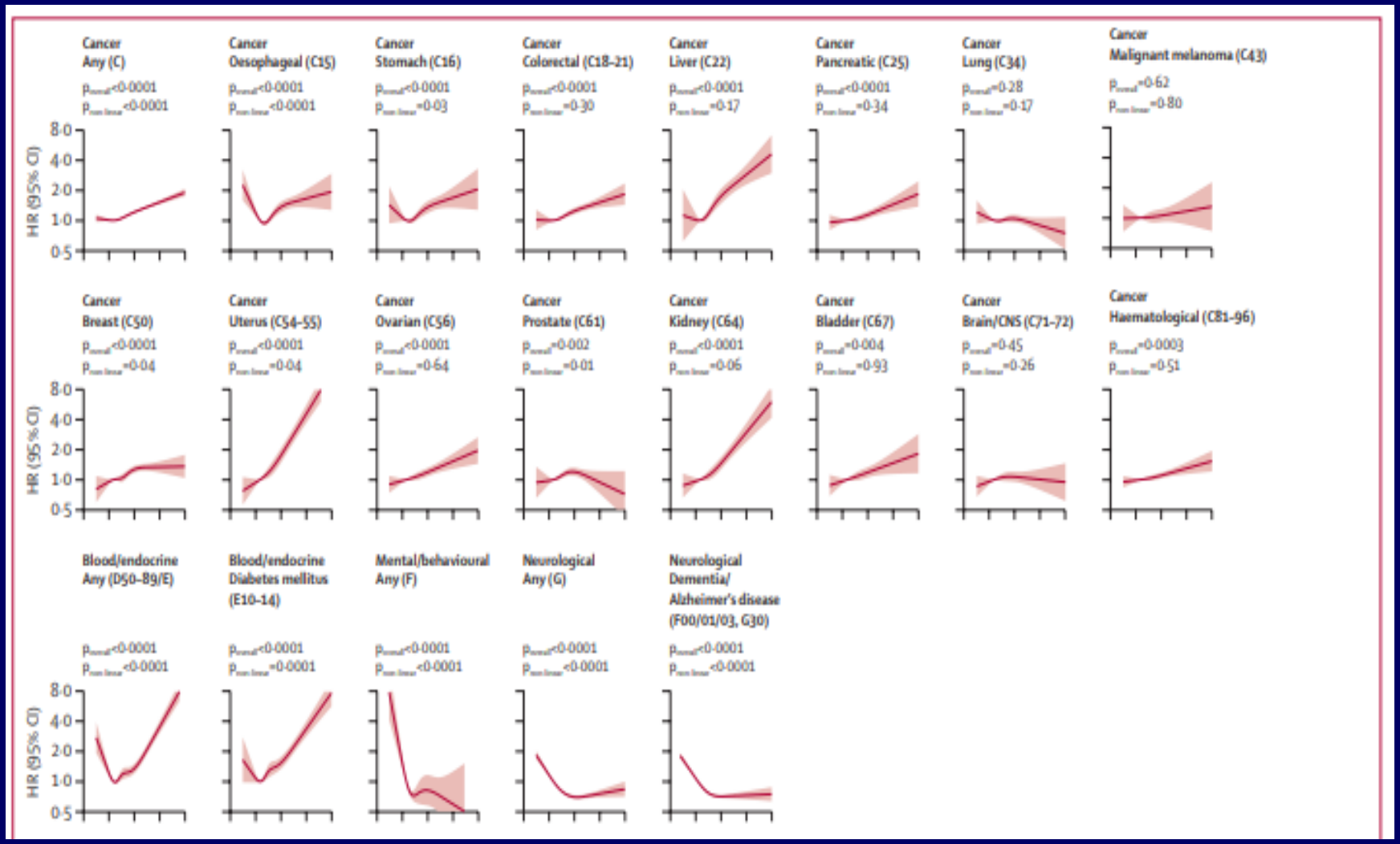
	BMI change point, kg/m² (95% CI)	HR per 5 kg/m² BMI increase below change point* (95% CI)	HR per 5 kg/m² BMI increase above change point (95% CI)
All-cause mortality	25 (25–25)	0·81 (0·80–0·82)	1·21 (1·20–1·22)
Level 1 outcomes			
Communicable diseases	26 (26–26)	0·73 (0·71–0·76)	1·28 (1·24–1·31)
Non-communicable diseases	25 (25–25)	0·83 (0·81–0·84)	1·22 (1·21–1·23)
Injuries and external causes	27 (26–28)	0·75 (0·71–0·80)	1·10 (1·04–1·17)
Level 2 outcomes (ICD-10 chapters/codes)			
Cancers (C)	21 (20–25)	0·88 (0·80–0·97)	1·13 (1·12–1·14)
Blood and endocrine (D50–89, E)	22 (22–29)	0·43 (0·35–0·54)	1·42 (1·37–1·48)
Mental and behavioural (F)	24 (21–25)	0·31 (0·22–0·44)	1·05 (0·86–1·27)
Neurological (G)	26 (25–27)	0·68 (0·66–0·70)	0·98 (0·96–1·01)
Cardiovascular (I)	25 (25–25)	0·89 (0·87–0·91)	1·29 (1·27–1·30)
Respiratory (J23–99)	25 (24–25)	0·53 (0·50–0·56)	1·25 (1·21–1·29)
Liver cirrhosis (K70·3/71·7/74·3–6)	23 (22–27)	0·75 (0·48–1·16)	1·44 (1·33–1·55)
Digestive (K, excluding cirrhosis)	24 (22–25)	0·79 (0·72–0·86)	1·32 (1·28–1·36)
Musculoskeletal (M)	24 (24–25)	0·45 (0·39–0·53)	1·23 (1·15–1·32)
Urogenital (N)	25 (24–25)	0·84 (0·77–0·93)	1·45 (1·39–1·51)
Accident, transport-related (V)	NA*	1·00 (0·90–1·11)	..
Accident, excluding transport (W/X00–59)	27 (26–28)	0·71 (0·66–0·77)	1·17 (1·09–1·26)
Self-harm and interpersonal violence (X60–Y09)	NA*	0·87 (0·80–0·94)	..

HR=hazard ratio. ICD-10=International Classification of Diseases, 10th revision. NA=not available. *For transport-related accidents, and self-harm and interpersonal violence, there was little or no evidence against linearity (figure 2) so a single linear effect without change point was estimated.

Table 2: **Estimated change points in the association between BMI and mortality among never-smokers, and associations with mortality below and above the change point, from piecewise two-line models for the 5-year post-BMI exclusion period**

Bhaskaran K et al. *Lancet Diabetes Endocrinol* Online Oct 30 2018.

Risk of Most Major Diseases Increases with BMI



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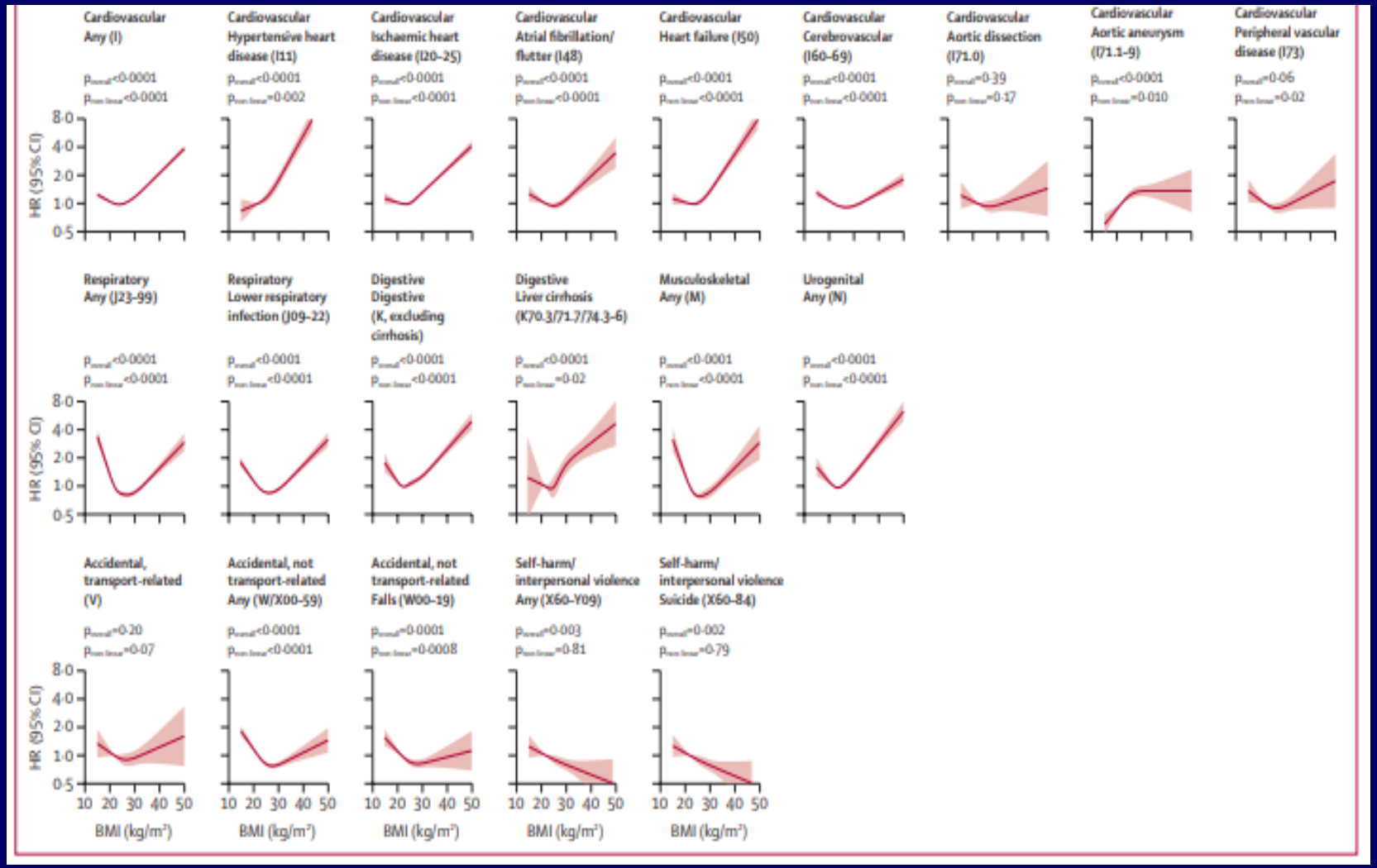

Bhaskaran K et al. *Lancet Diabetes Endocrinol* Online Oct 30 2018.

The Energy Impact of Obesity

It is estimated that there are about 20-25 billion pounds (c. 10 billion kg) of excess body weight carried in U.S.

At 9 calories per fat gram, this represents about 90 trillion calories that are excess to needs;

At 2000 kcal per day, this would nourish 123 million adults for 1 year

<u>Some Considerations in Addition to Health Issues:</u>

What are the costs to the economy of generating and maintaining this excess storage energy?

What are the costs of transporting/supporting this excess weight?

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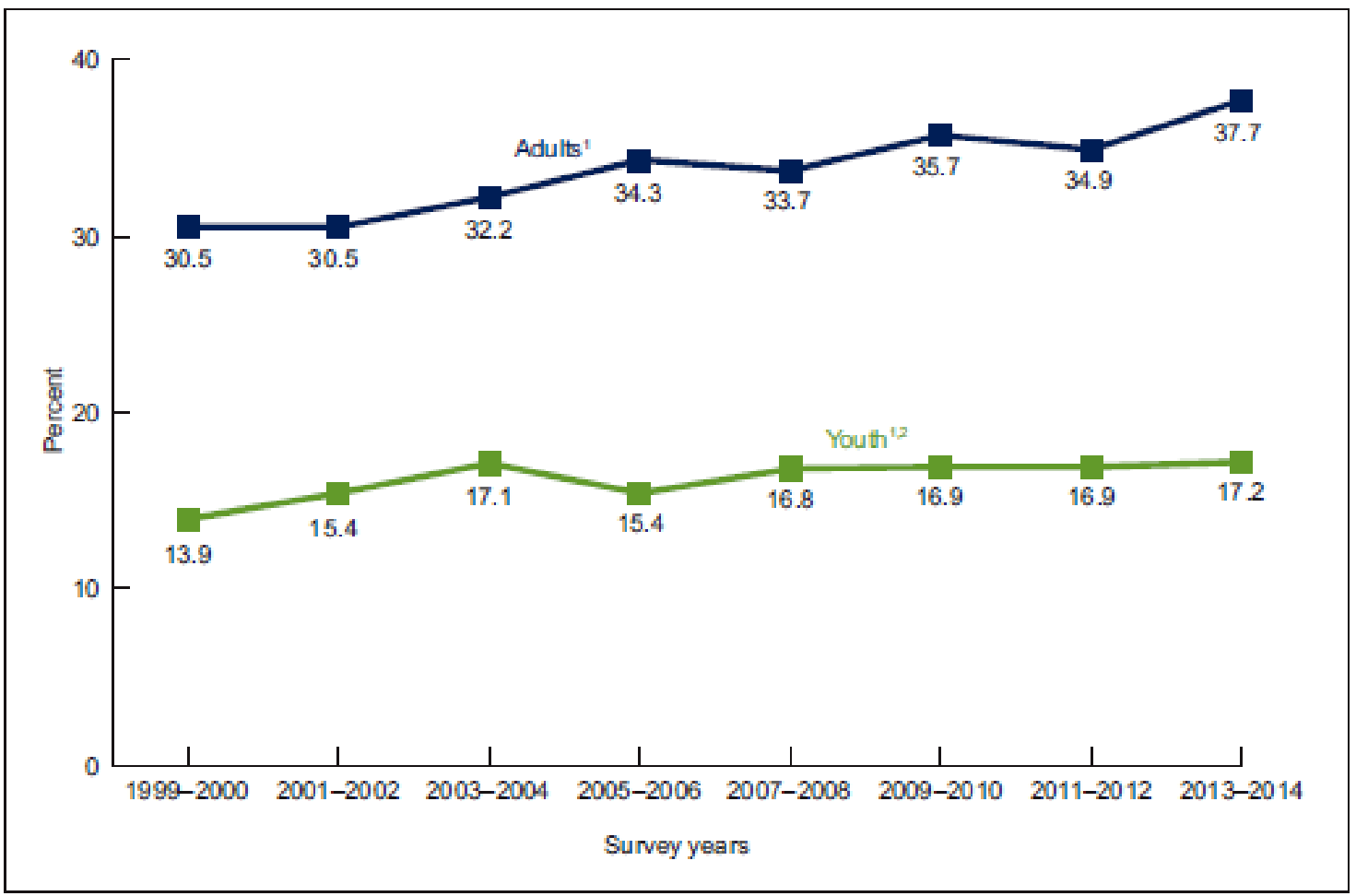
Prevalence of Obesity in US 1999-2014



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SOURCE: CDC/NCHS, National Health and Nutrition Examination Survey.

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Strategies For Management of Obesity

Society/Public Policy/Organization:

Considerations:

When a factor is present in society at a prevalence rate of 68% (other than during an epidemic of contagious disease), does it not represent a normal adaptation to the (changing) environment?

Is obesity the human health equivalent to global warming as an impending environmental apocalypse?

Common Element:

Neither of these trends can be adequately addressed by individual behavior change alone and require global societal commitment to far-reaching change.

Strategies For Management of Obesity

Society/Public Policy/Organization:

1. Tax incentives to promote healthy lifestyles
2. Lower health/life insurance rates to reward healthy behaviors
3. Taxes on undesirable food items
4. Workplace health programs
5. Urban pedestrian only zones
6. Cafeteria and Vending policies to provide healthier options
7. Reintroduction of sports into core school curricula

Strategies For Management of Obesity

Individual/Group:

1. Nutrition education, exercise program, lifestyle modification
2. Medications
3. Bariatric Surgery
4. Gastric balloons

Non-Pharmacological Interventions

Cochrane Review 2010

Long-term non-pharmacological weight loss interventions for adults with prediabetes

9 RCT, n=5168, 1-10yrs

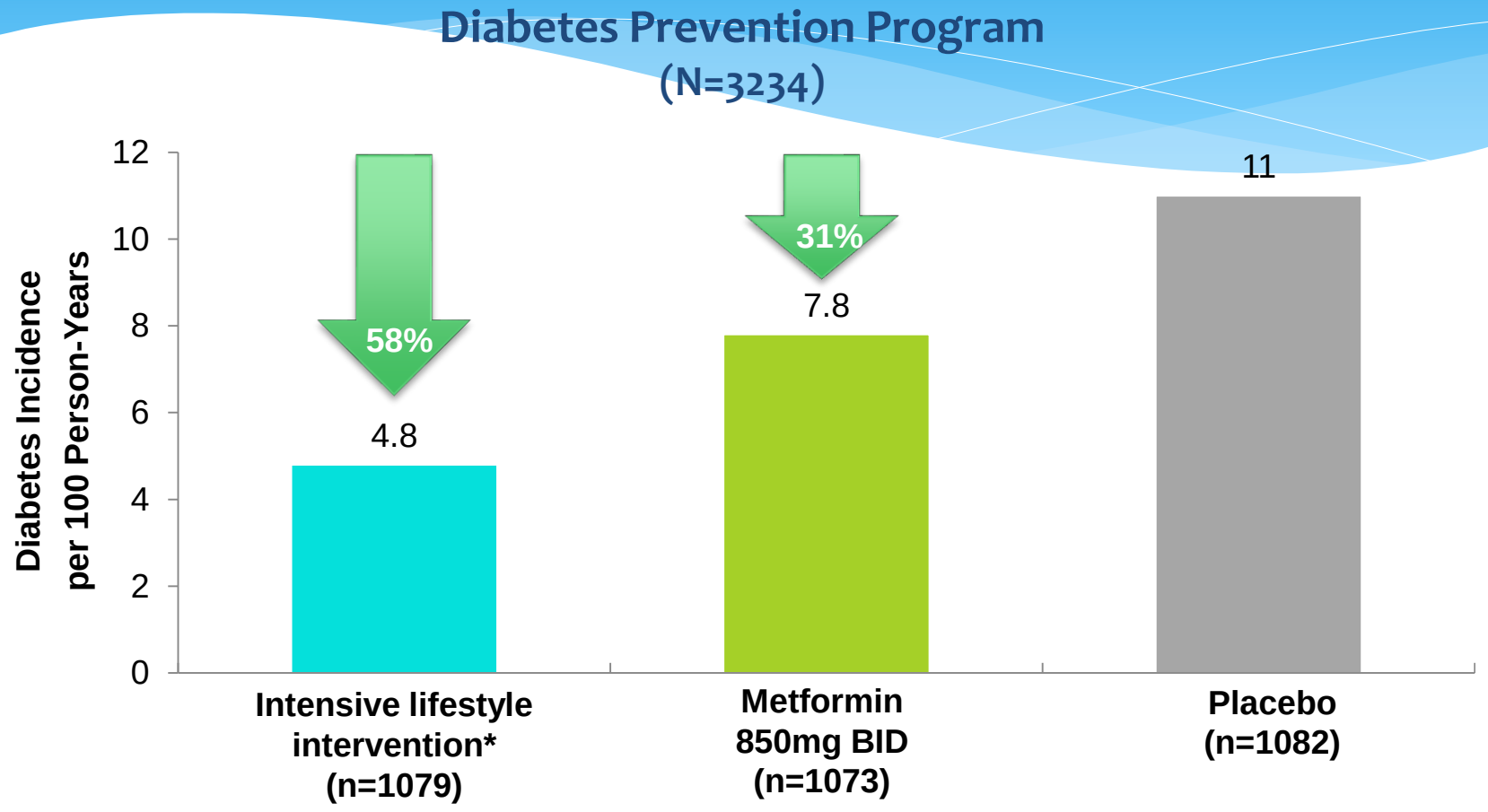
Results:

4 studies reduced weight by 2.8kg (95% CI 1-4.7), BMI by 1.3 kg/m2 (95% CI 0.8-1.9).

3 studies reduced weight by 2.6kg (95% CI 1.9-3.3)

Norris SL, Zhang X, Avenell A, Gregg E, Schmid CH, Lau J. Long-term non-pharmacological weight loss interventions for adults with prediabetes. *Cochrane Database of Systematic Reviews* 2005, Issue 2. Art. No.: CD005270.DOI: 10.1002/14651858.CD005270.

Diabetes Prevention Program

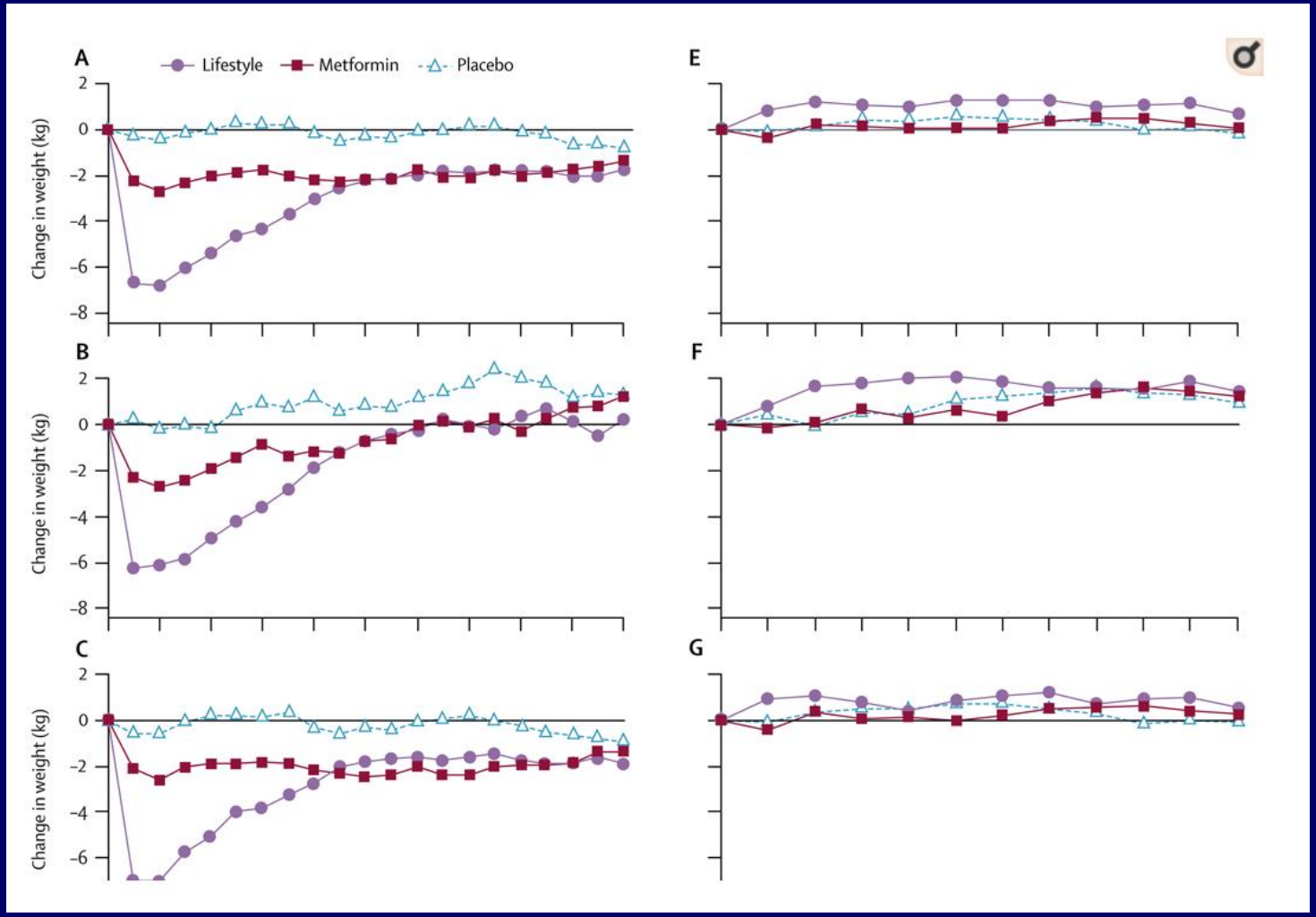


*Goal: 7% reduction in baseline body weight through low-calorie, low-fat diet and ≥150 min/week moderate intensity exercise .

IGT, impaired glucose tolerance; T2D, type 2 diabetes.

DPP Research Group. *N Engl J Med*. 2002;346:393-403.

Weight Loss By Behavioral Interventions Is Very Hard To Sustain



Diabetes Prevention Program **Diabetes Prevention Program Outcomes Study**

The Diabetes Prevention Program Research Group. *Lancet* 14;374(9702):1677-86, 2009.

Metabolic Basis of Recidivism To Lifestyle Weight Loss Interventions

1. Reductions in energy expenditure;
2. Changes in hunger/satiety balance;
3. Changes in insulin sensitivity and adipocyte number favoring fat storage.

These changes may be permanent

Reluctance to Use Approved Medications for Management of Obesity

"Patients go to the pharmacy 15 times more frequently for antidiabetic drugs than for antiobesity medications even though 116 million adults fit the criteria for use of these drugs, compared to less than 30 million for whom antidiabetes drugs are indicated."

Size of the U.S. unregulated commercial weight loss industry:

1992: $30 billion expenditures

2016: $60 billion expenditures

$517 each person

Reluctance to Use Approved Medications For Management of Obesity

1. Belief that weight management is a personal responsibility, similar to e.g. cleanliness, grooming and attire
2. Fear of stigmatization
3. Admission of failure
4. Fear of loss of control
5. Guilt
6. Concern about side-effects

ADA 2017
Standards of Care

Treatment	25-26.9	27-29.9	30-34.9	35-39.9	≥40
Diet, physical activity and BH therapy	Yes	Yes	Yes	Yes	Yes
Pharmacotherapy		Yes	Yes	Yes	Yes
Metabolic surgery			Yes	Yes	Yes

- **Diet, physical activity (>150 minutes/week) and behavioral therapy with goal >7% weight loss with T2DM**
- **Pharmacotherapy should be targeted to lose >5%**
  - **Metformin therapy**

Diabetes Care 2017 Jan; 40 (Supplement 1): S1-S2. https://doi.org/10.2337/dc17-S001

Interventions to Prevent Diabetes

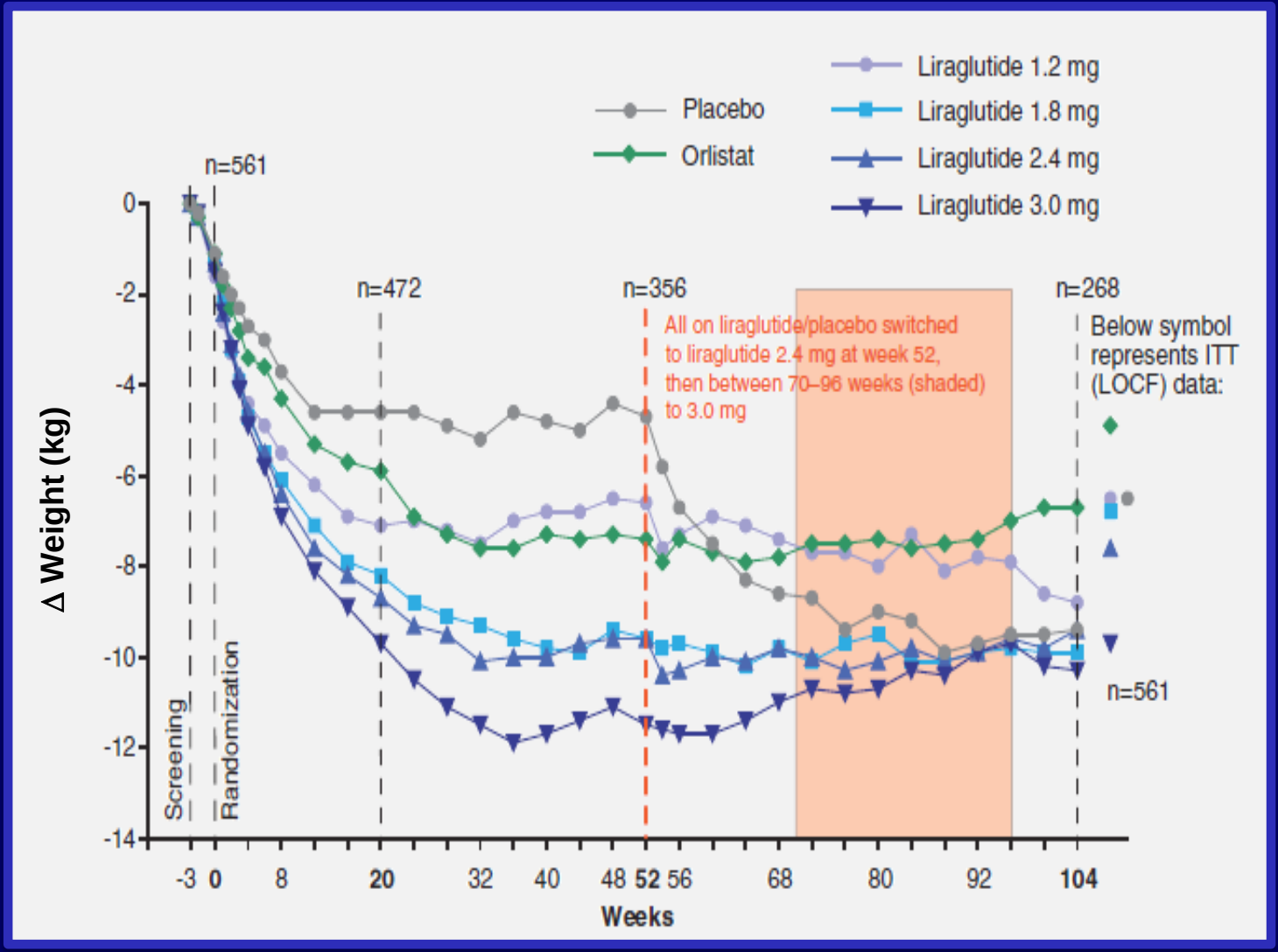
Intervention	Follow-up Period	Reduction in Risk of T2D (P value vs placebo)
Antihyperglycemic agents		
Metformin[1]	2.8 years	31% (P<0.001)
Acarbose[2]	3.3 years	25% (P=0.0015)
Pioglitazone[3]	2.4 years	72% (P<0.001)
Rosiglitazone[4]	3.0 years	60% (P<0.0001)
Weight loss interventions		
Orlistat[5]	4 years	37% (P=0.0032)
Phentermine/topiramate[6]	2 years	79% (P<0.05)
Bariatric surgery[7]	10 years	75% (P<0.001)

T2D, type 2 diabetes.

1. DPP Research Group. *N Engl J Med*. 2002;346:393-403. 2. STOP-NIDDM Trial Research Group. *Lancet*. 2002;359:2072-2077.
3. Defronzo RA, et al. *N Engl J Med.* 2011;364:1104-15. 4. DREAM Trial Investigators. *Lancet*. 2006;368:1096-1105.
5. Torgerson JS, et al. *Diabetes Care*. 2004;27:155-161. 6. Garvey WT, et al. *Diabetes Care*. 2014;37:912-921.
7. Sjostrom L, et al. *N Engl J Med*. 2004;351:2683-2693.

31

Liraglutide for Obesity



Astrup, et al. Effects of liraglutide in the treatment of obesity: a randomized, double-blind placebo controlled study. The Lancet. 2009;374. 1606-1616

Liraglutide in Overweight and Obese Older Persons with Prediabetes

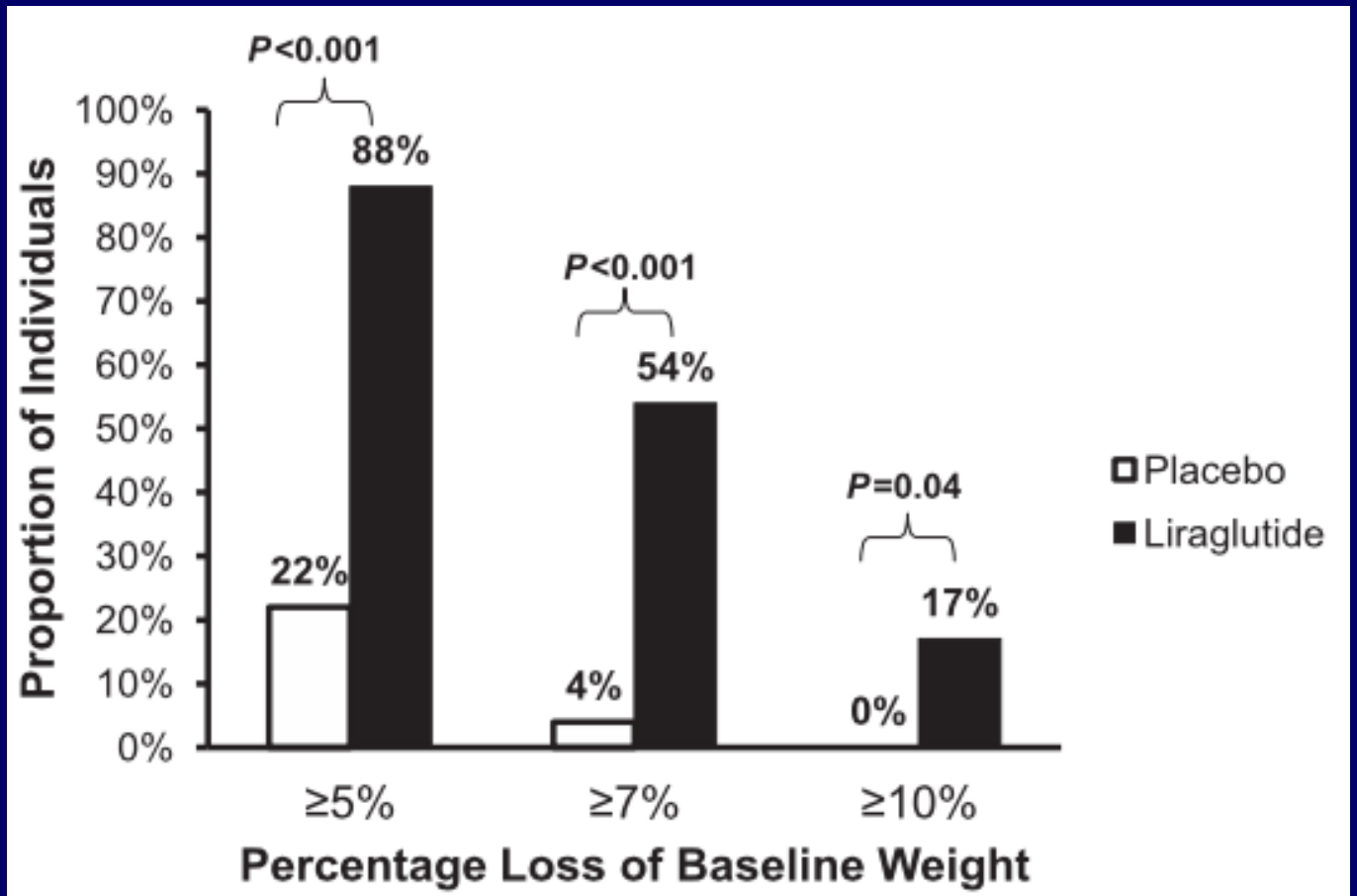
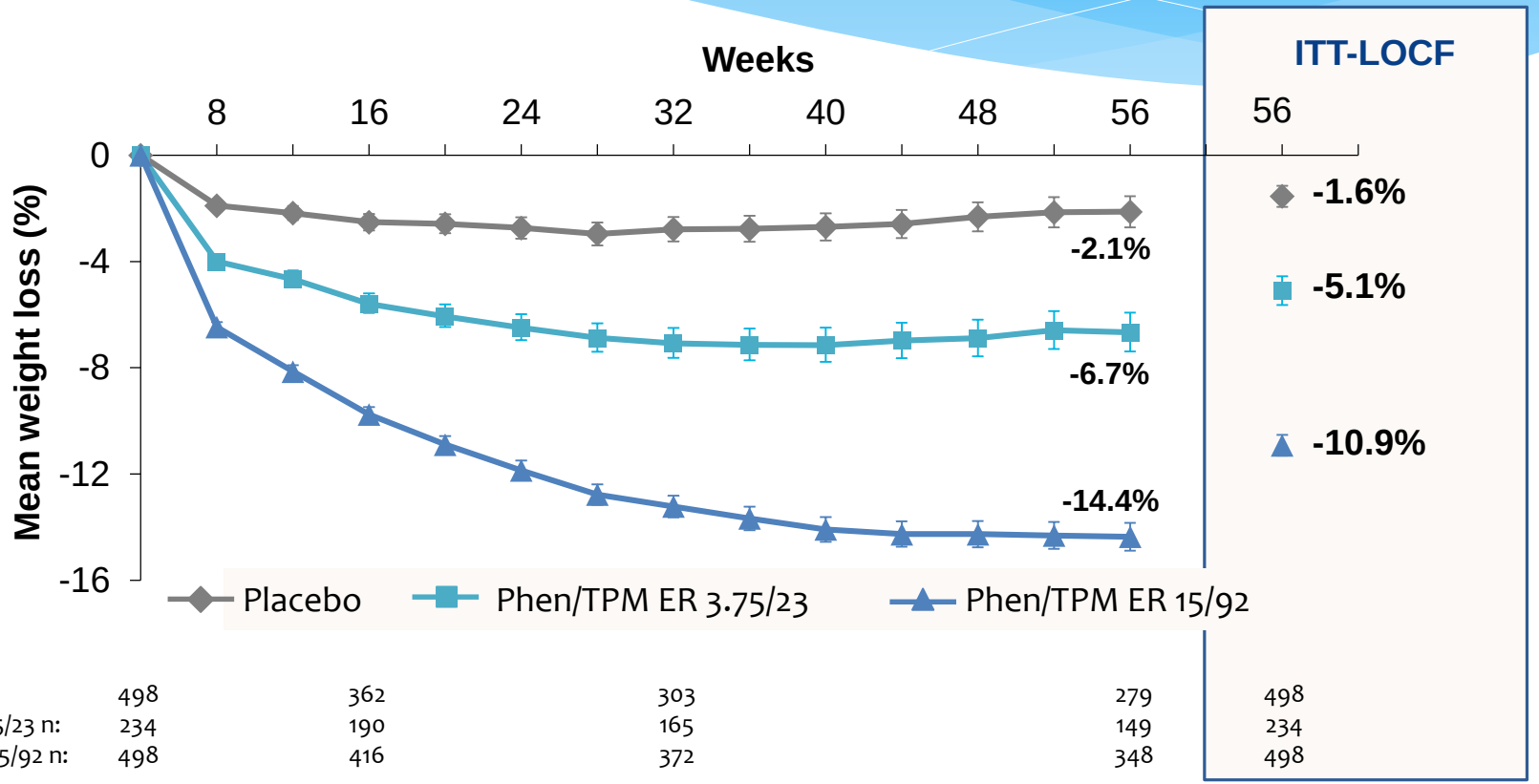


Figure 1—*Proportion of individuals who lost at least 5, 7, and 10% of baseline weight. Liraglutide treatment was associated with greater degree of weight loss compared with placebo.*

Kim et al. Benefits of liraglutide treatment in overweight and obese older individuals with prediabetes. Diabetes Care 36:3276-328, 2013

Phentermine/Topiramate ER EQUIP

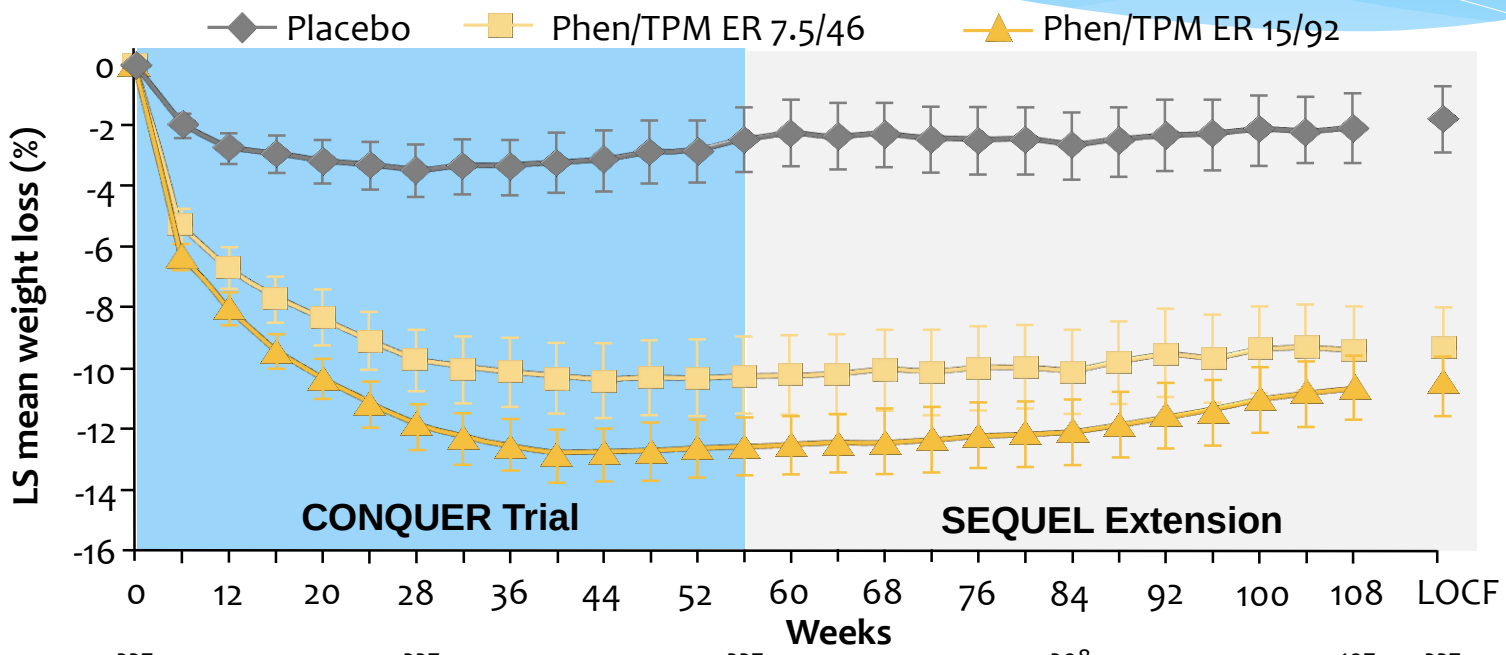


Placebo n:	498	362	303	279	498
en/TPM 3.75/23 n:	234	190	165	149	234
Phen/TPM 15/92 n:	498	416	372	348	498

ITT, intent to treat; LOCF, last observation carried forward; Phen/TPM ER, phentermine/topiramate extended release.

Allison DB, et al. *Obesity (Silver Spring).* 2012;20:330-342.

Phentermine/Topiramate SEQUEL



Placebo n:	227	227	227	208	197	227
Phen/TPM 7.5/46 n:	153	152	153	137	129	153
Phen/TPM 15/92 n:	295	295	295	268	248	295

Data are shown with mean (95% CI).

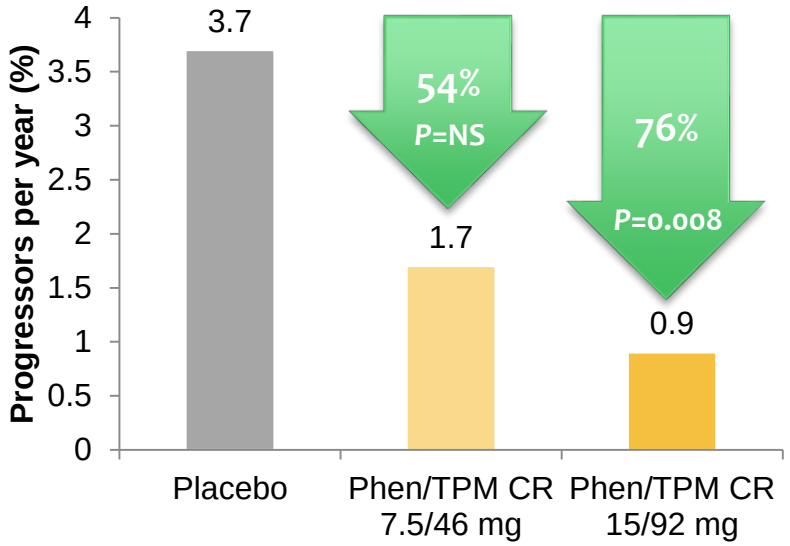
Phen/TPM ER, phentermine/topiramate extended release.

Garvey WT, et al. *Am J Clin Nutr*. 2012;95:297-308.

Phentermine/Topiramate SEQUEL

Glucose and Insulin

Annualized Incidence of T2D



Placebo Phen/TPM ER 7.5/46 mg Phen/TPM ER 15/92 mg

*$P \leq 0.005$ vs placebo.

NS, not significant; Phen/TPM ER, phentermine/topiramate extended release; T2D, type 2 diabetes.

Garvey WT, et al. *Am J Clin Nutr*. 2012;95:297-308.

Generic Components of Brand Name Combinations

Example: Phentermine/Topiramate ER:

Branded combination: ***Qsymia***

Dosages: **3.75/23, 7.5/46, 11.25/69, 15/92**

Generic Phentermine: **15, 30, 18.75, 37.5**

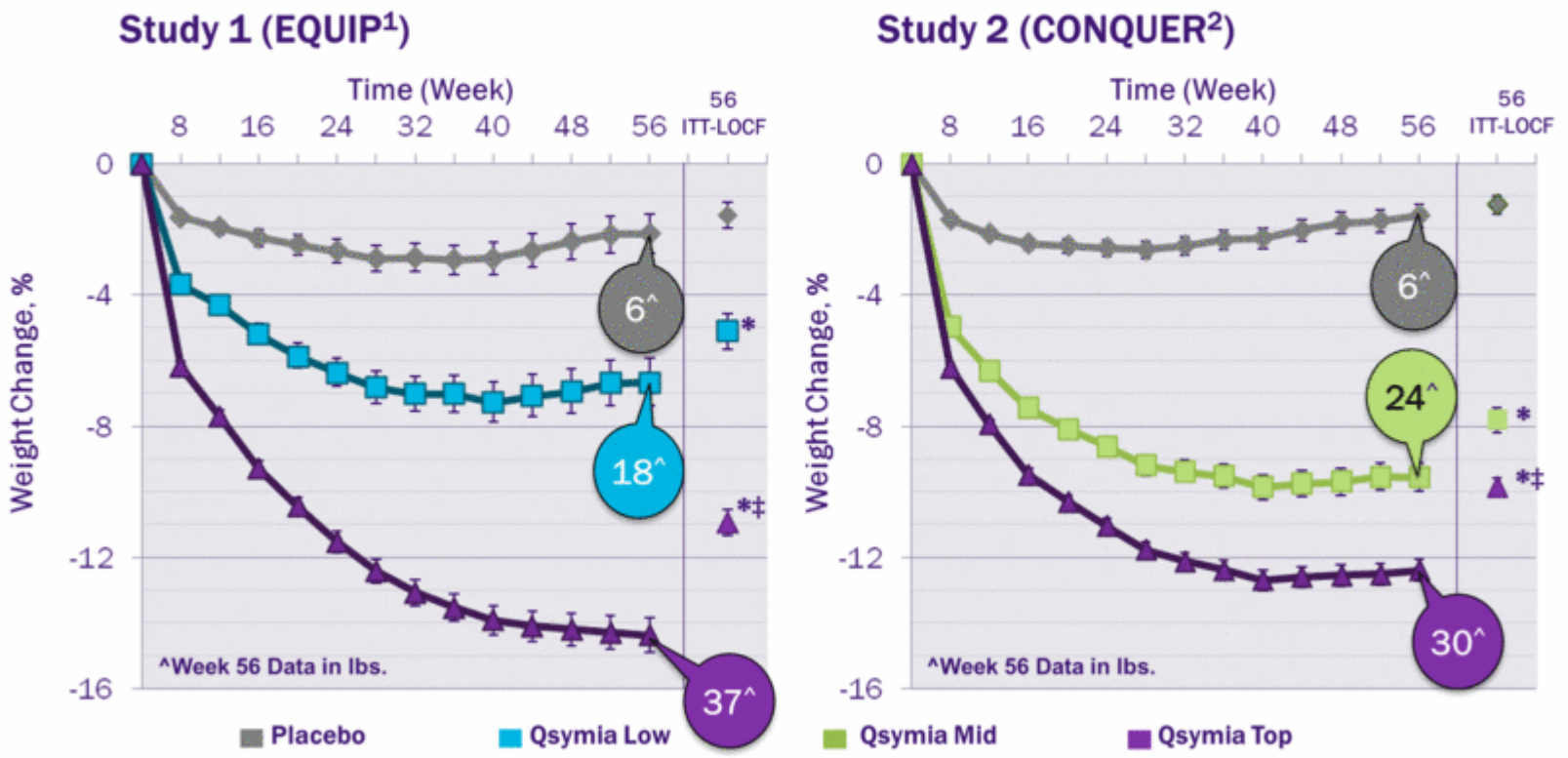
Generic Topiramate: **25, 50, 100, 200**

Qsymia Marketing Claim for Weight Reduction

QSYMIA MAGNITUDE OF EFFECT

PIVOTAL 1-YEAR STUDIES: WEIGHT LOSS OVER TIME (OBSERVED/ITT DATA)

VIVUS



All observed data; *p<0.0001 vs placebo; ‡p<0.0001 vs. Qsymia Mid or Low

The most commonly observed side effects in controlled clinical studies, 5% or greater and at least 1.5 times placebo, include paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth.

SOURCE: (1) Obesity (2011) doi:10.1038/oby.2011.330; (2) www.thelancet.com Published online April 11, 2011 DOI:10.1016/S0140-6736(11)60205-5

6

Orlistat
XENDOS

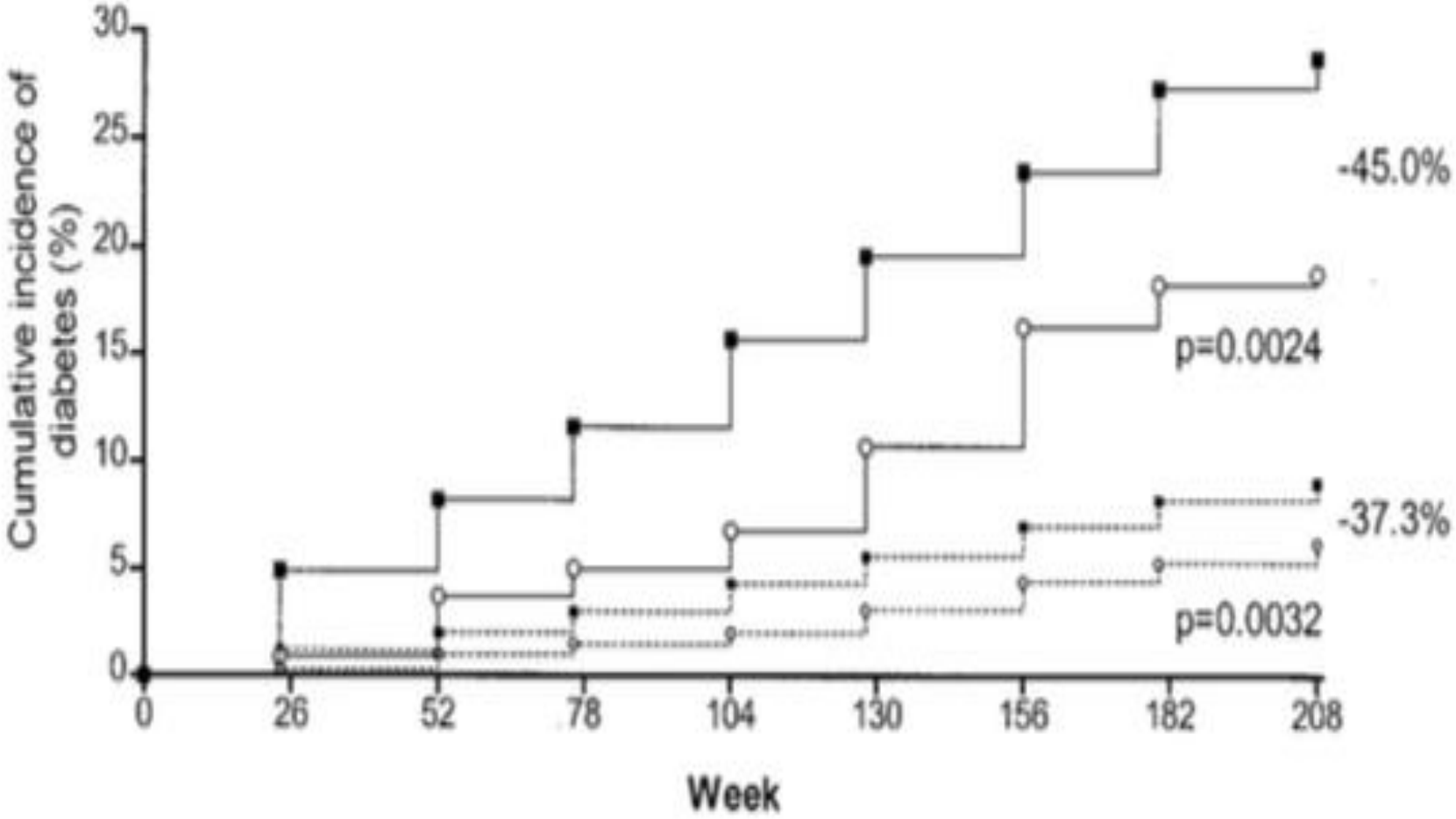
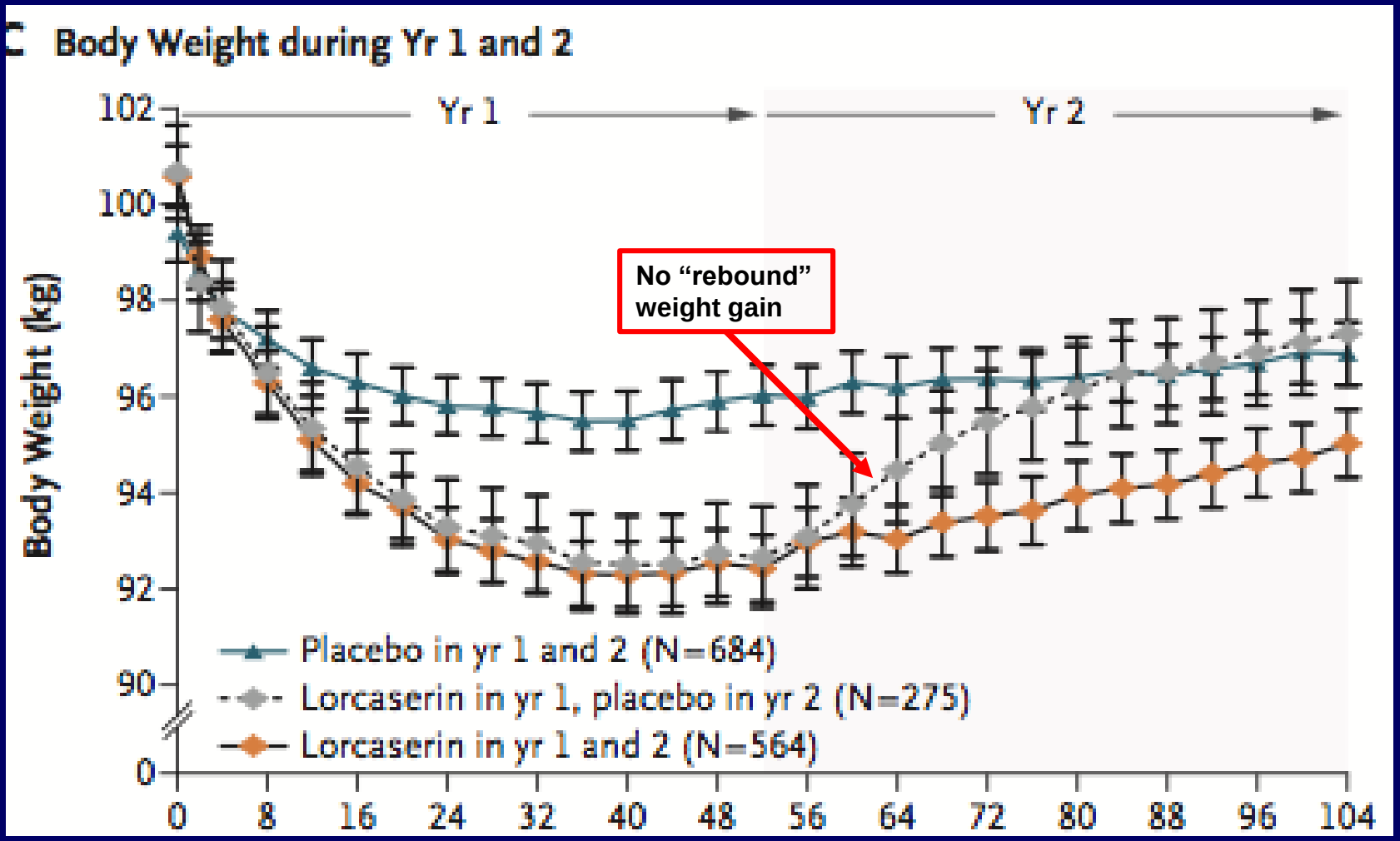


Figure 1—*Cumulative incidence of diabetes by study group in all obese patients (IGT or NGT at*

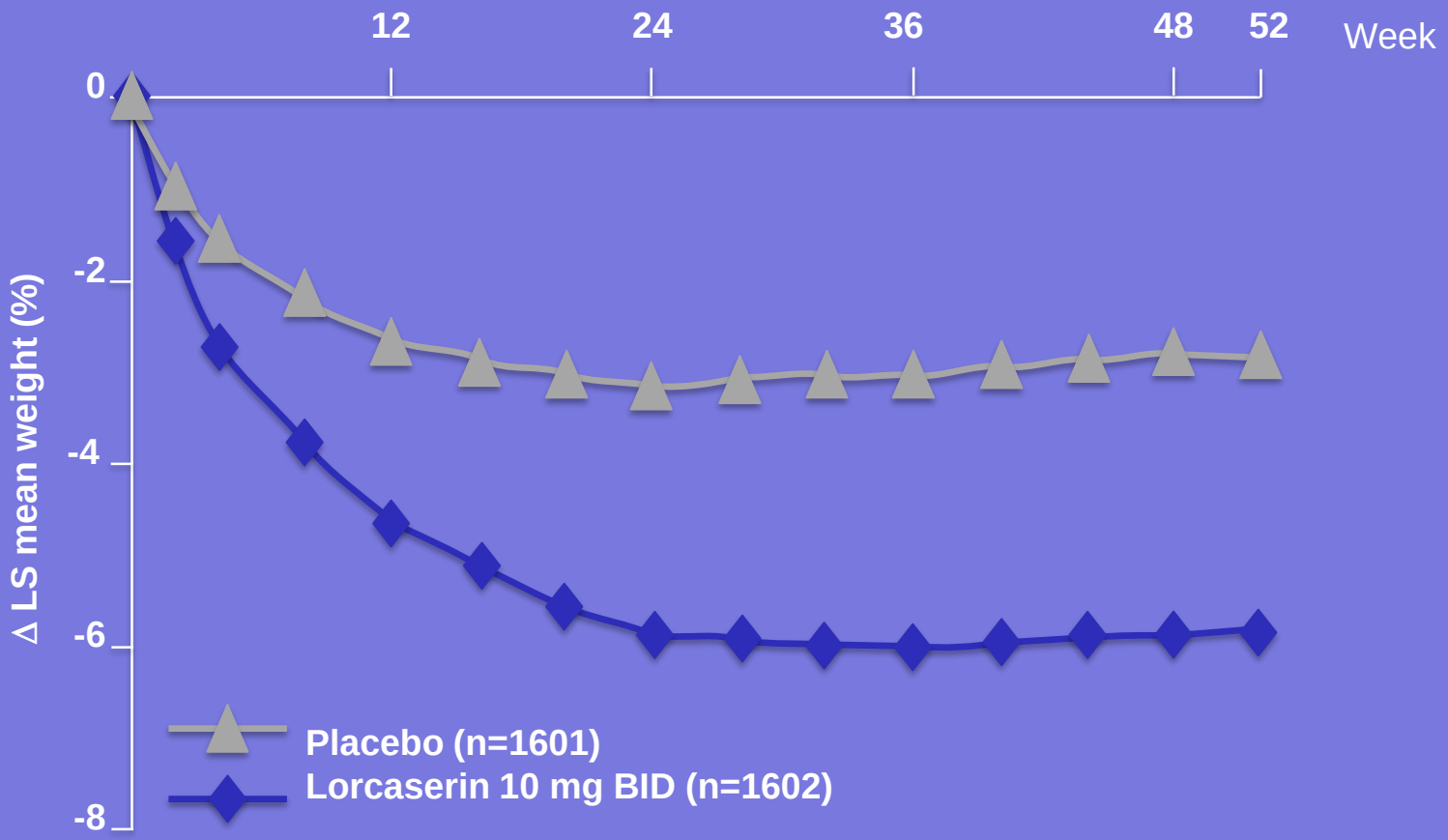
Torgerson et al. Xenical in the prevention of diabetes in obese subjects (XENDOS) stud. Diabetes Care. 2004; 27(1):155-161

Lorcaserin
BLOOM



Smith et al. Multicenter, placebo-controlled trial of lorcaserin for weight management. The NEJM. 2010;363(3):245-256

Lorcaserin
BLOSSOM



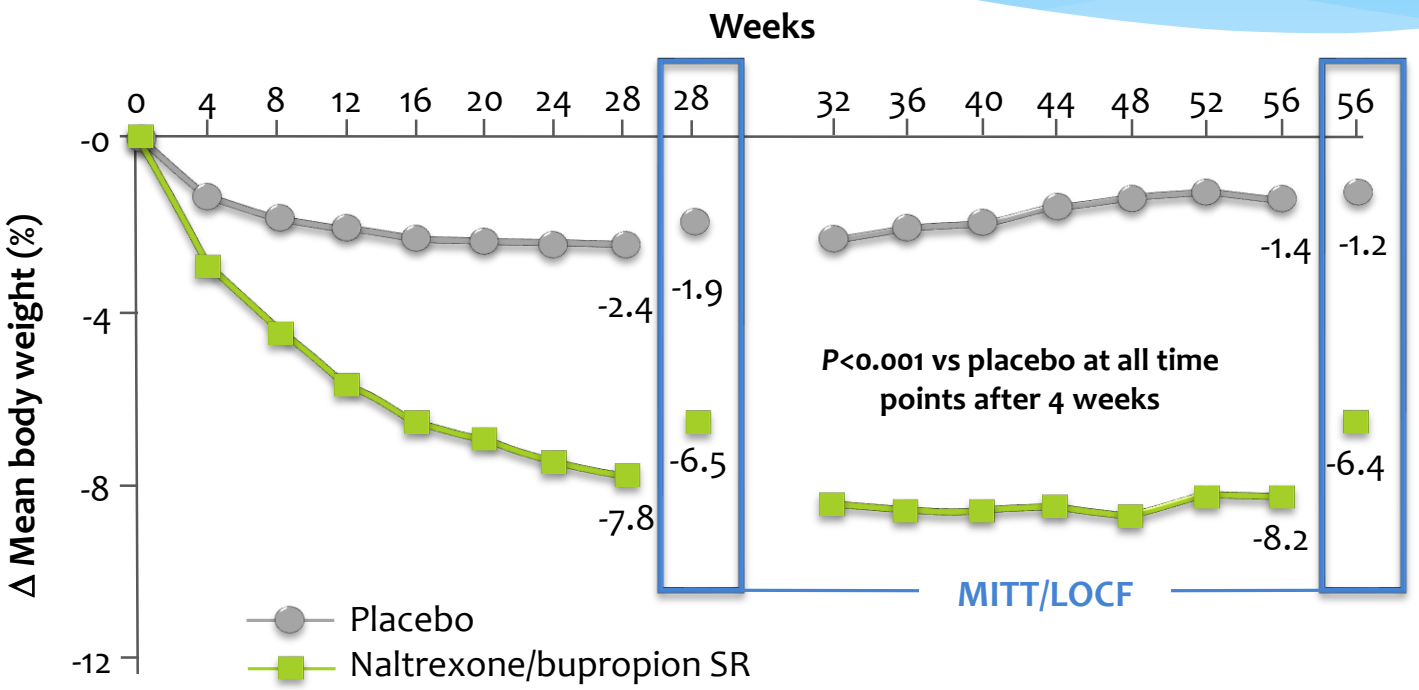
BID, twice daily; LS, least squares.

Fidler MC, et al. *J Clin Endocrinol Metab.* 2011;96:3067-3077.

41

Naltrexone/Bupropion SR COR II

(N=1496)



COR II, CONTRAVE Obesity Research II; LOCF, last observation carried forward; MITT, modified intent to treat; SR, sustained release.

Apovian C, et al. *Obesity (Silver Spring)*. 2013;21:935-943.

Strategies For Management of Obesity in Diabetes

When possible, choose antidiabetic agents that promote weight reduction:

Promote weight ↓	Promote weight ↑	Weight ↔
Metformin	Sulfonylureas	DPP-IV inhibitors
SGLT-2 inhibitors	Insulins	Acarbose
GLP-1 agonists	Pioglitazone	
Bromocriptine		

Objectives

To Review and Discuss:

1. **The prevalence of obesity and its importance in disease causation**
2. **Our current performance in combating adult obesity**
3. **Available strategies to combat obesity**
4. **Reappraisal of current priorities – define Legerity**
5. **Discussion**

UA-BUMC-Phoenix Legerity Program

The BUMC-Phoenix Legerity Program Opens A New Era in Weight Management

'Legerity' means lightness or 'having little weight'.

***'Obesity' defines the problem, but 'Legerity' defines the goal*.**

The BUMC Legerity Program is a novel, health-positive, non-stigmatizing, affirming goal-oriented approach to weight management.

<u>The Problem:</u> Obesity affects almost 40% of US adults and confers increased risk of many major diseases, with worse and more costly treatment outcomes.

<u>The goals:</u>
1) To achieve prompt weight reduction as a *primary means* to prevent progression of comorbid diseases to an advanced, irreversible stage.
2) To enhance knowledge by outcomes data collection and clinical trials plus community engagement to achieve a less obesogenic environment.

<u>The Program:</u> Utilizes a triage-based approach to treatment of comorbid diseases in obese persons by a stratified, rapid stepwise medical management protocol to achieve prompt and sustained weight reduction, while closely monitoring outcomes in associated conditions.

Clinical protocol with monitoring of comorbid disease outcomes + **Clinical trials and translational research collaborations** + **Partnerships with community to achieve environmental change**

Banner Health

Triage Approach of Proposed BUMC Legerity Program

Pts recognized in BUMC Clinics with Obesity who are otherwise healthy without qualifying comorbidities.

Pts recognized in BUMC Clinics with Obesity (BMI >35) contributing to severity of their primary/comorbid disease with failure of sustained response to lifestyle intervention

Evaluate in BUMC Legerity Program

Pts recognized in BUMC Clinics with Obesity (BMI >35) who have irreversible complications of their primary/comorbid disease.

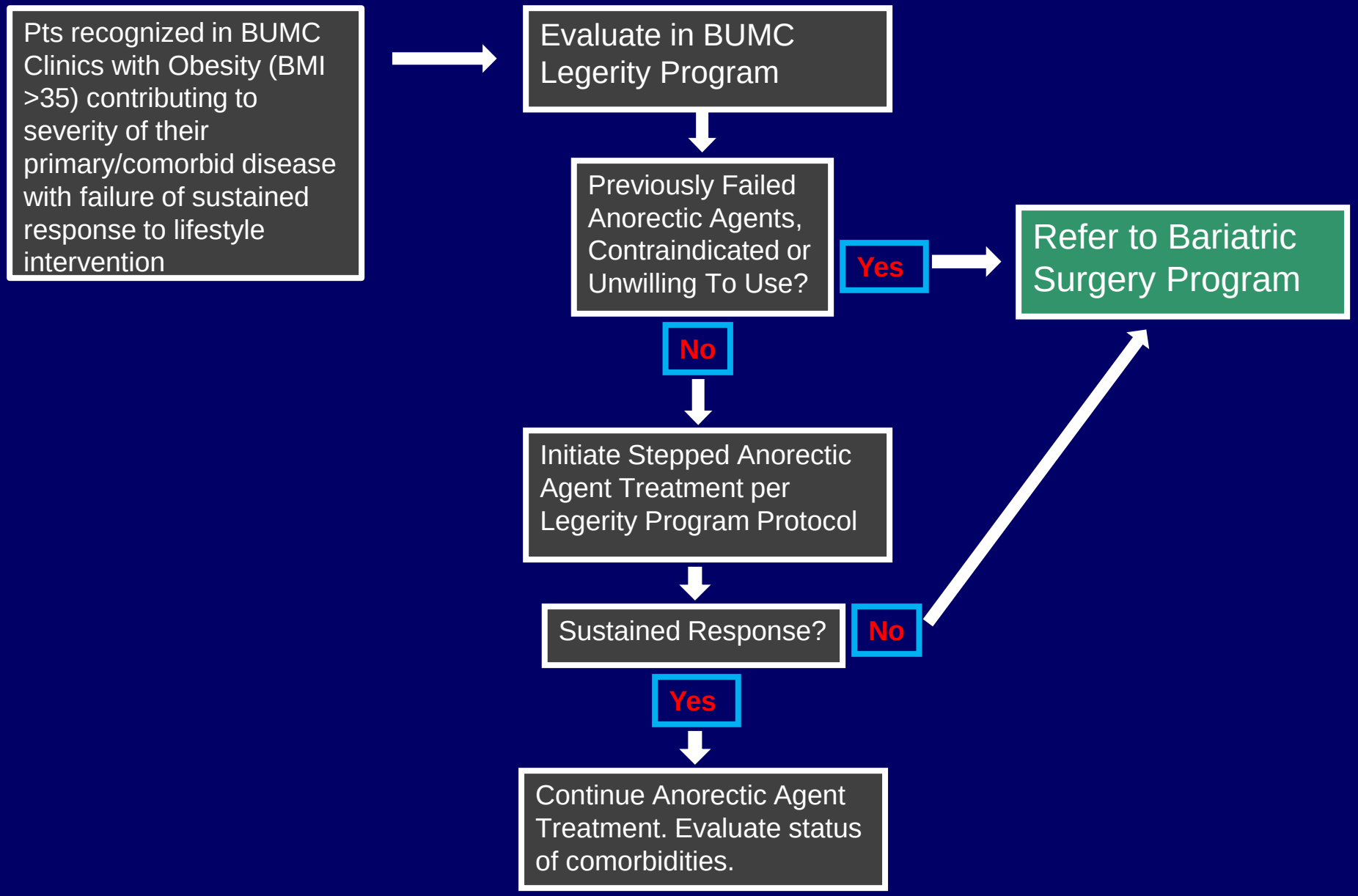
Classification of Obesity

Classification		BMI (kg/m^2)	Disease Risk* Waist Circumference (>40in men, >35in women)
Normal		18.5-24.9	
Overweight		25-29.9	High
Obesity	Class I	30-34.9	Very High
→	Class II	35-39.9	Very High
→	Class III	>40	Extremely High

*Risk of Type 2 Diabetes, Hypertension, CV disease relative to normal Weight and Waist Circ.

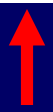
http://www.nhlbi.nih.gov/

Proposed BUMC Legerity Program Protocol



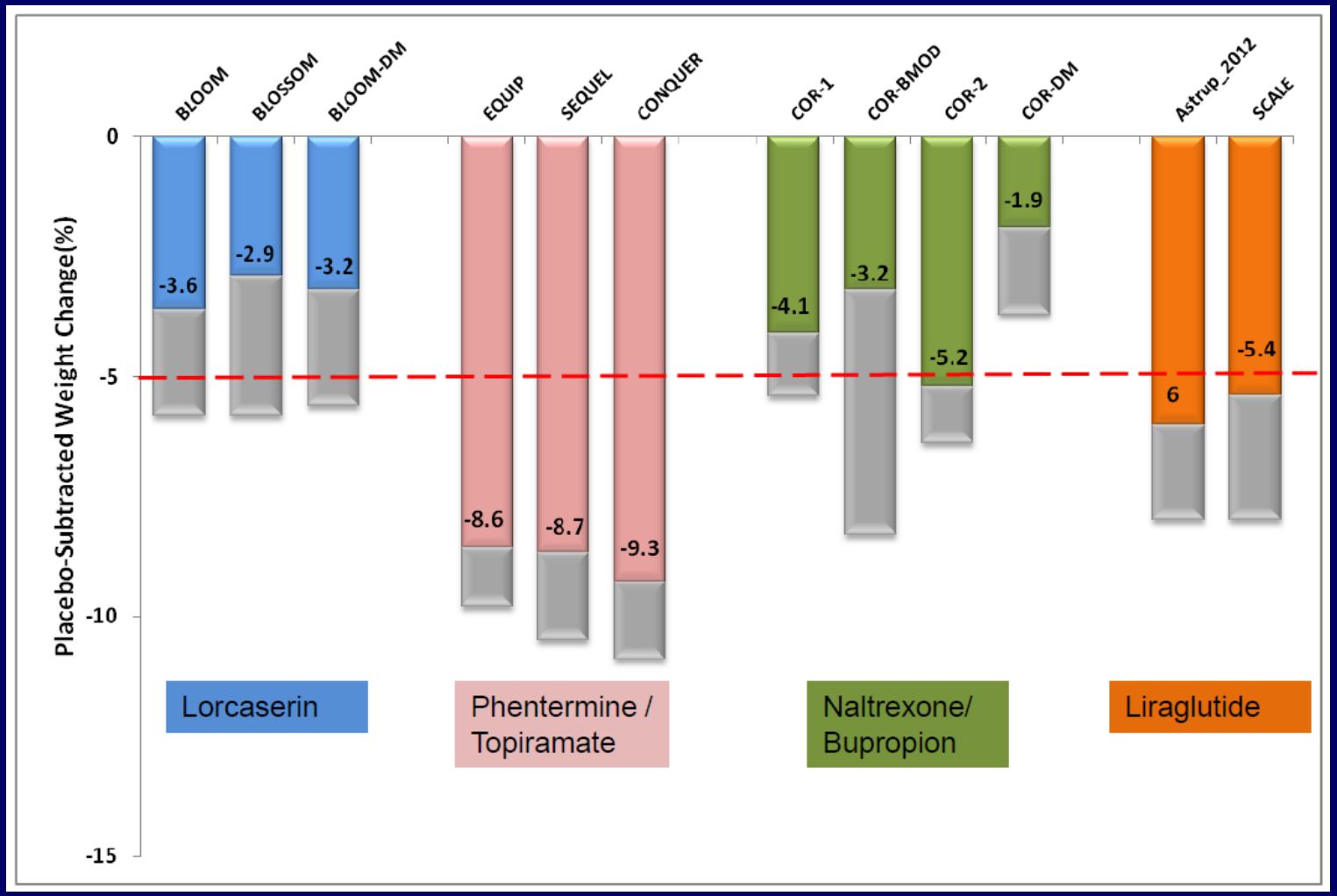
The Minimum Weight Loss Targets Are Achievable with Medical Therapy

TERTIARY PREVENTION			
Metabolic syndrome		10%	Prevention of T2DM
Prediabetes		10%	Prevention of T2DM
T2DM		5-15% or more	• Reduction in A1C • Reduction in number and/or doses of glucose-lowering medications • Diabetes remission especially when diabetes duration is short
Dyslipidemia		5-15% or more	• Lower triglycerides • Raise HDL-c • Lower non-HDL-c
Hypertension		5-15% or more	• Lower systolic and diastolic BP • Reductions in number and/or doses of antihypertensive medications
Nonalcoholic fatty liver disease	Steatosis	5% or more	Reduction in intrahepatocellular lipid
	Steatohepatitis	10-40%	Reduction in inflammation and fibrosis
Polycystic ovary syndrome		5-15% or more	• Ovulation • Regularization of menses • Reduction in hirsutism • Enhanced insulin sensitivity • Reduced serum androgen levels
Female infertility		10% or more	• Ovulation • Pregnancy and live birth
Male hypogonadism		5-10% or more	Increase in serum testosterone
Obstructive sleep apnea		7-11% or more	• Improved symptomatology • Decreased apnea-hypopnea index
Asthma/reactive airway disease		7-8% or more	• Improvement in forced expiratory volume at 1 second • Improved symptomatology
Osteoarthritis		• ≥10% • 5-10% or more when coupled with exercise	• Improved symptomatology • Increased function
Urinary stress incontinence		5-10% or more	Reduced frequency of incontinence
Gastroesophageal reflux disease		10% or more	Improved symptomatology
Depression		Uncertain	• Improved symptomatology • Improvement in depression scores



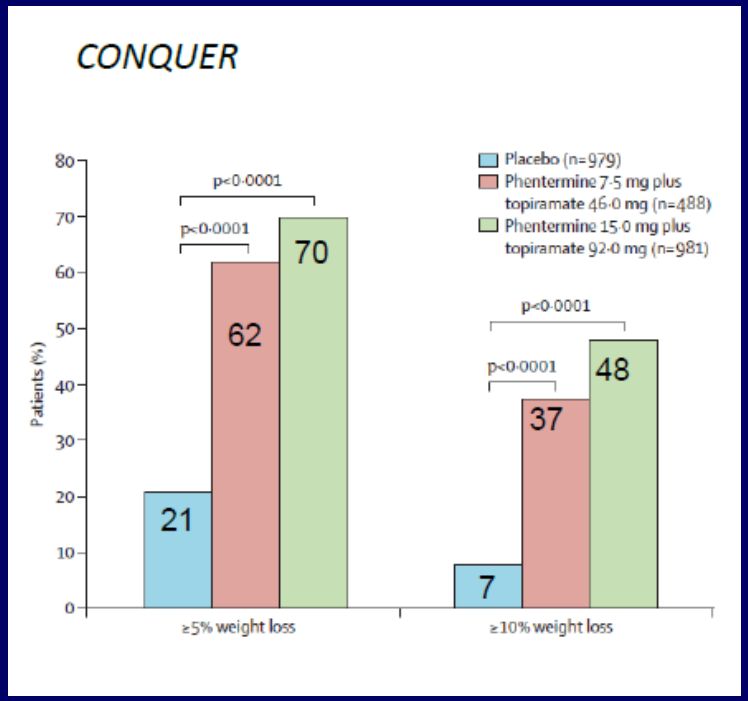
AACE Consensus Guidelines For Medical Care of Patients with Obesity 2016

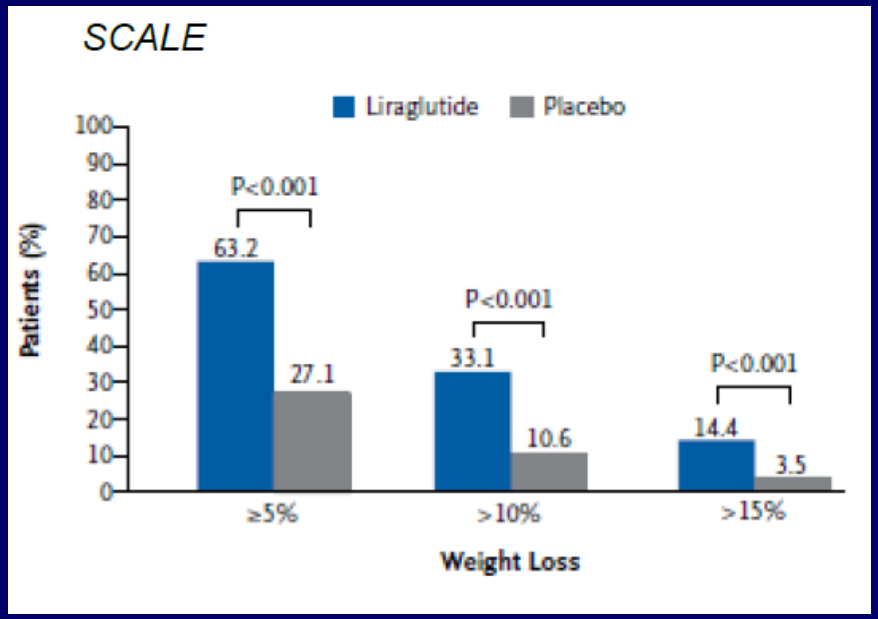
Efficacy of Newer Anorexiant Weight Control Medications



Rueda-Clausen CF et al. *Nat Rev Endo* 9:467, 2013
AstrupA et al. *Int J Obesity* 36:843, 2012
Pi-SunyerX et al. *New Engl J Med* 373, 2015

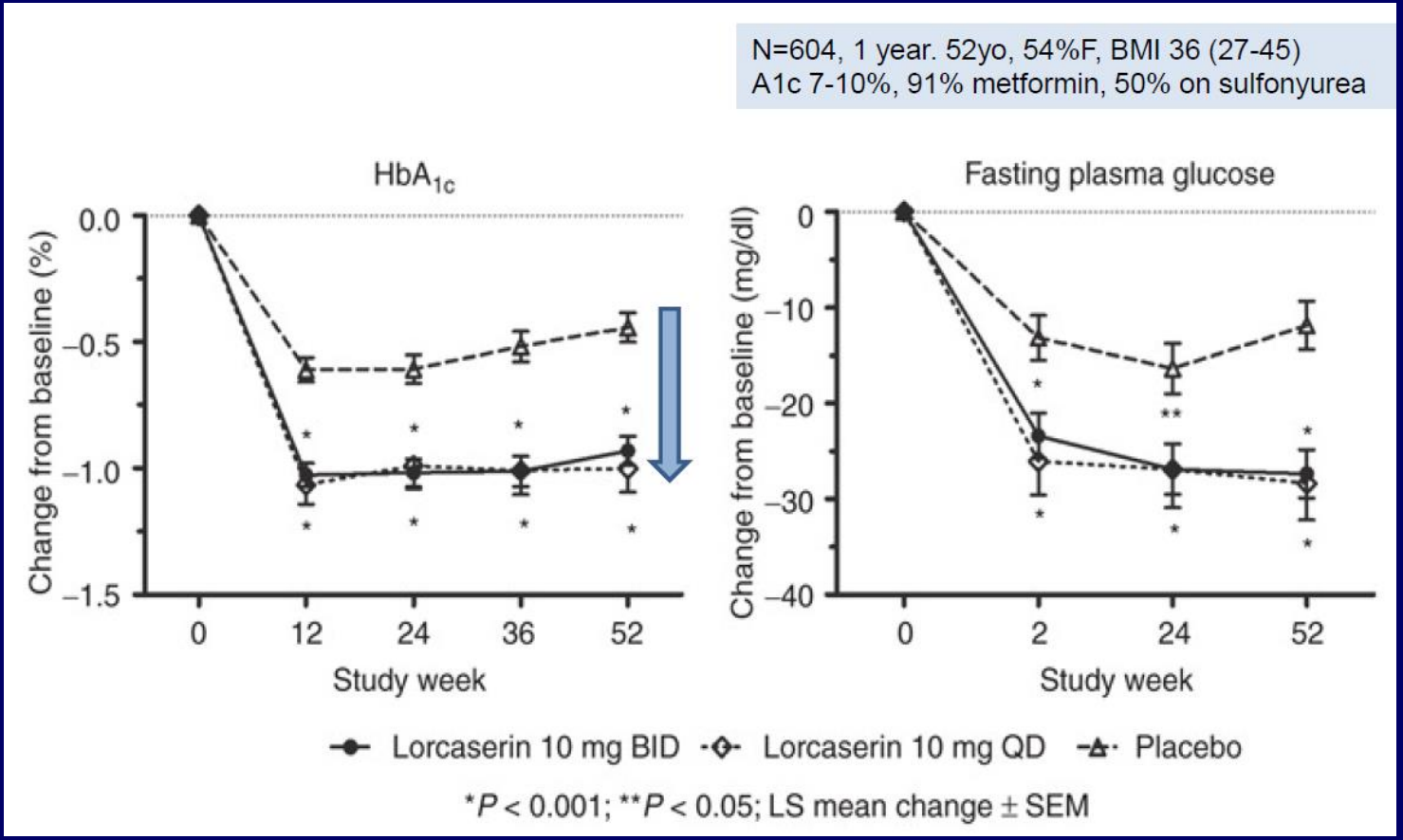
Efficacy of Newer Anorexiant Weight Control Medications





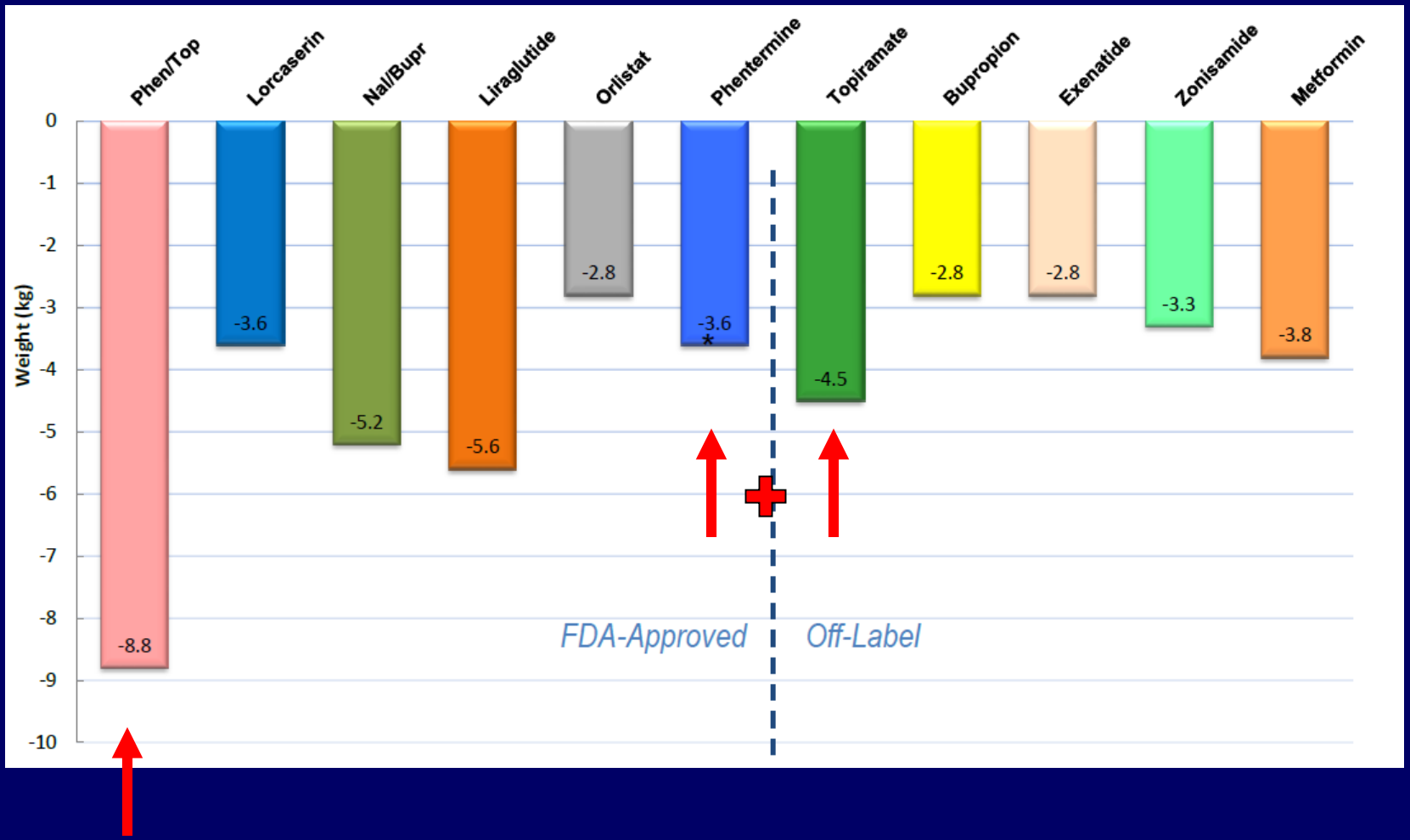
Gadde KM et al. *Lancet* 377:1341-1352, 2011
Pi Sunyer et al. New Engl J Med, 2015

Ancillary Benefit of Weight Loss on Comorbidities



O'Neil PM et al. *Obesity,* 2012

Significant Weight Reduction Can Be Achieved With Generic Medications



Can The Fight For Legerity Be Won?

We have mobilized the great army of diabetes educators, nutritionists, dietitians and exercise specialists. They are fully engaged, but in the world at large our air force and navy remain at base.

Army: Lifestyle Adjustment Interventions

Air Force: Obesity Medications

Navy: Bariatric Surgery

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Discussion