

EMPOWERMENT AND SELF-MANAGEMENT OF DIABETES: THE PHARMACIST AND DIABETES CARE

SESSION 2: NUTRITION, DIETARY CHOICES AND LIFESTYLE CHANGES





MUTE



CHAT



RAISE HAND



Q&A

NATIONAL CENTER FOR HEALTH IN PUBLIC HOUSING (NCHPH)

- The National Center for Health in Public Housing (NCHPH), a project of North American Management, is supported by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) under grant number U30CS09734, a National Training and Technical Assistance Cooperative Agreement (NCA) for \$608,000, and is 100% financed by this grant. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government.
- The mission of the National Center for Health in Public Housing (NCHPH) is to strengthen the capacity of federally funded Public Housing Primary Care (PHPC) health centers and other health center grantees by providing training and a range of technical assistance.



Training and
Technical
Assistance



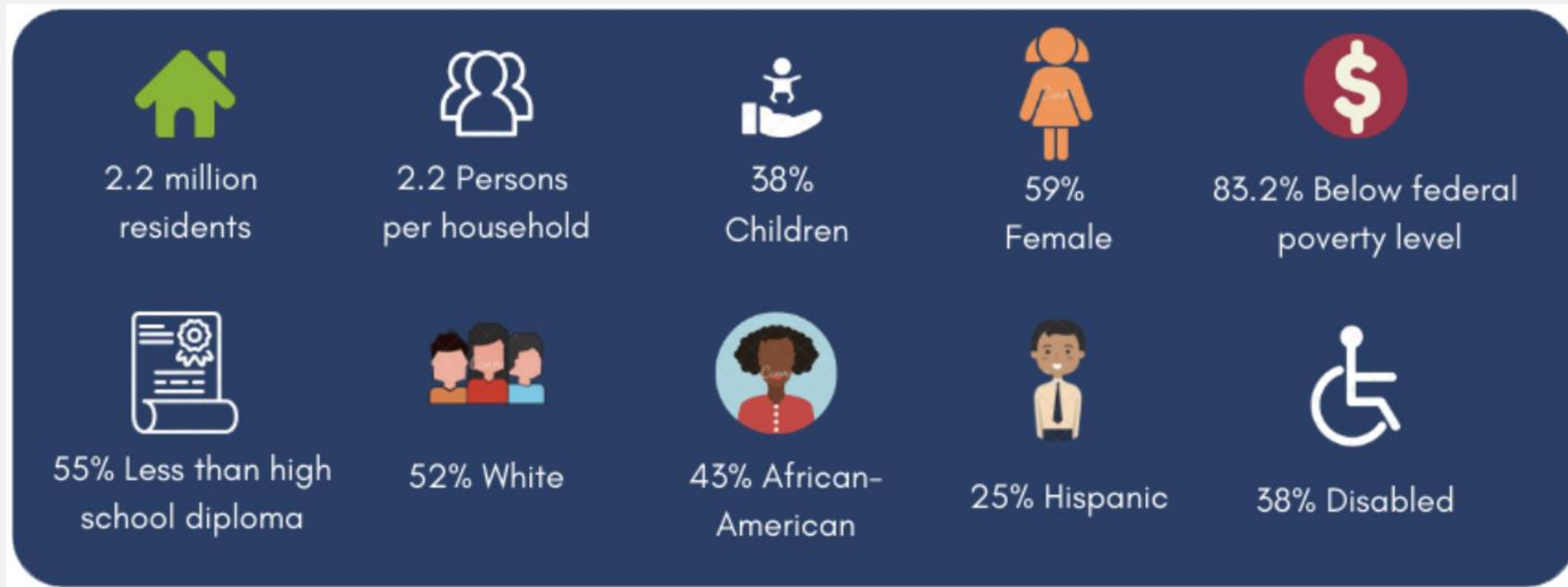
Research and
Evaluation



Outreach
and
Collaboration

Increase access, quality of health care, and improve health outcomes

PUBLIC HOUSING DEMOGRAPHICS



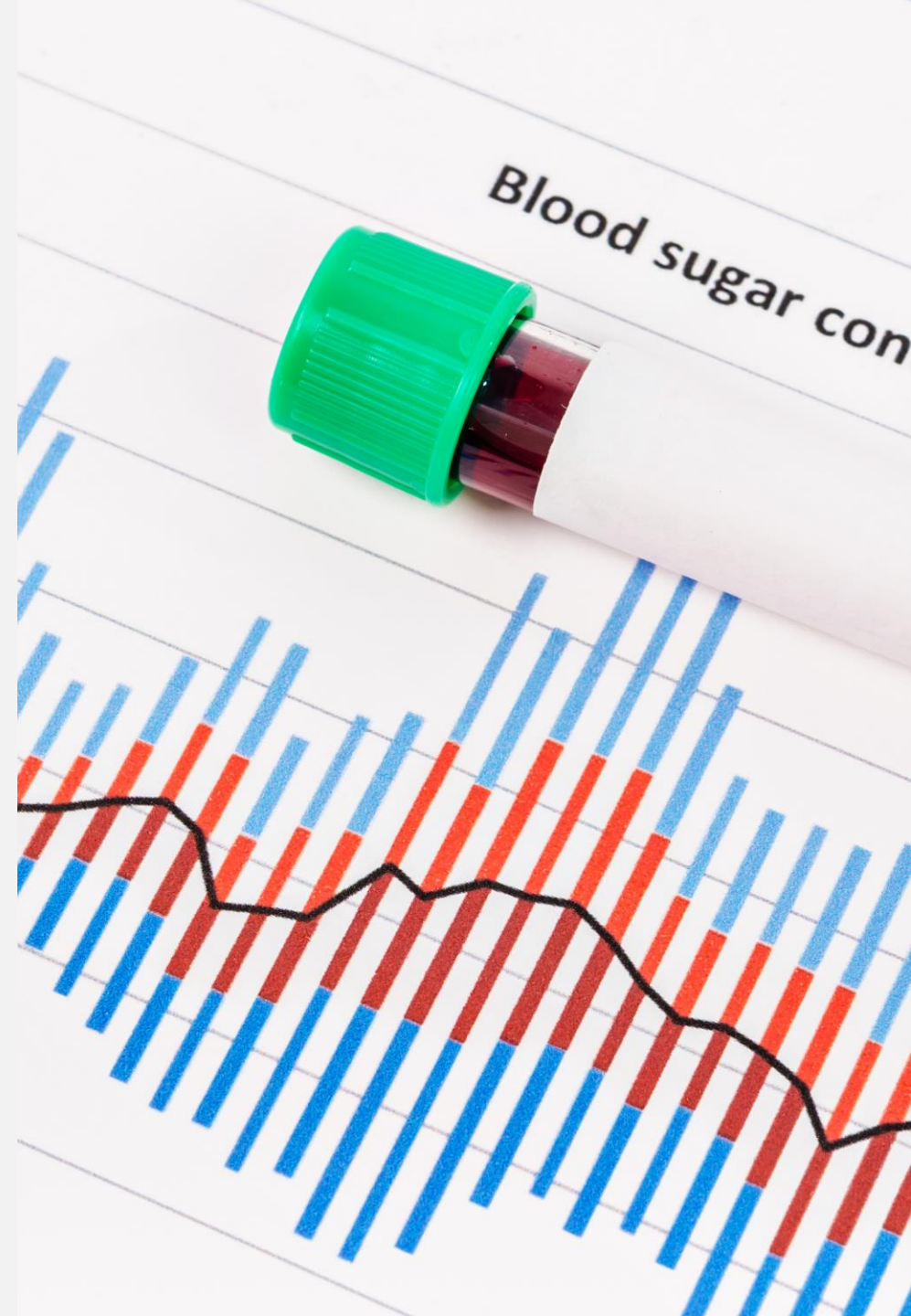
DIABETES IN HEALTH CENTERS

A little over 15% of health center (HC) patients have diabetes

32% of HC patients have Poorly Controlled Hemoglobin A1c (HbA1c > 9%)

9% of Public Housing Grantee patients have diabetes

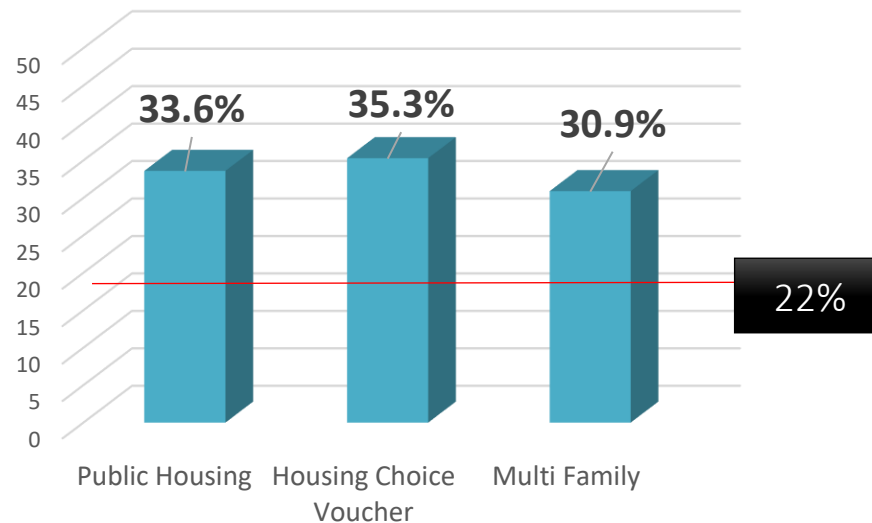
Source: UDS, 2018



A Health Picture of HUD-Assisted Adults, 2006-2012

Adults in HUD-assisted housing have higher rates of chronic health conditions and are greater utilizers of health care than the general population. * Updated version expected in Summer 2020

Adult Smokers with Housing Assistance



Source: Helms VE, 2017

	HUD-Assisted	Low-income renters	All Adults
Fair/Poor Health	35.8%	24%	13.8%
Overweight/Obese	71%	60%	64%
Disability	61%	42.8%	35.4%
Diabetes	17.6%	8.8%	9.5%
COPD	13.6%	8.4%	6.3%
Asthma	16.3%	13.5%	8.7%



TERRY LAWSON, RPH, CDCES





Obesity Management

The Pharmacist's Approach



Objectives

- Discuss the prevalence of obesity in the United States
- Discuss the prevalence of food insecurity and its impact on special and vulnerable populations
- Apply patient assessment techniques in the management of obesity
- Discuss recommendations regarding pharmacotherapy in the management of obesity
- Describe recent guidelines regarding pharmacologic and non-pharmacologic management of obesity
- Apply patient centered considerations when selecting a pharmacotherapeutic approach in the management of obesity

Prevalence- CDC Data Among Adults: United States, 2017–2018

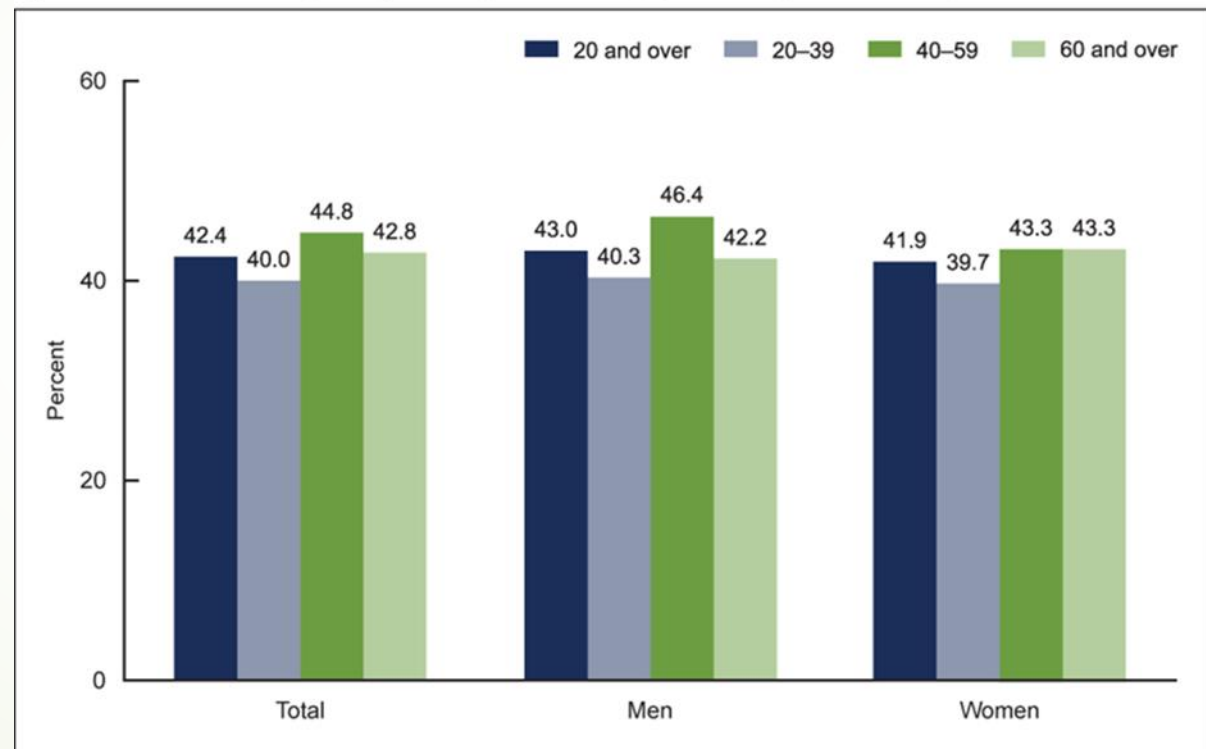
- ❖ **42.4%**, no significant differences between men and women among all adults or by age group

Rise in Obesity:

- Easy access to unhealthy food choices
- Sedentary lifestyle
- Environmental factors – food insecurity and access to exercise


Jordan MA, Harmon J. Pharmacist interventions for obesity: improving treatment adherence and patient outcomes. *Integr Pharm Res Pract.* 2015;4:79-89. Published 2015 Jul 8. doi:10.2147/IPRP.S72206

Figure 1. Prevalence of obesity among adults aged 20 and over, by sex and age: United States, 2017–2018



NOTES: Estimates for adults aged 20 and over were 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. Crude estimates are 42.5% for total, 43.0% for men, and 42.1% for women. Access data table for Figure 1 at: https://www.cdc.gov/nchs/data/databriefs/db360_tables-508.pdf#1.

SOURCE: NCHS, National Health and Nutrition Examination Survey, 2017–2018.



Prevalence- CDC Data Among Adults: United States, 2017–2018

- 9.2% severe obesity in adults - higher in women than in men
- From 1999–2000 through 2017–2018, the prevalence of obesity increased from 30.5% to 42.4%, and the prevalence of severe obesity increased from 4.7% to 9.2%.
- Obesity affects some groups more than others - Prevalence of obesity was highest in non-Hispanic black adults at 49.6% followed by Hispanics (44.8%), non-Hispanic whites (42.2%) and non-Hispanic Asians (17.4%)
- Severe obesity was highest among adults aged 40–59 compared with other age groups
- Socioeconomic ties – in general more education had lower obesity prevalence
- Obesity-related conditions include heart disease, stroke, type 2 diabetes and certain types of cancer that are some of the leading causes of preventable, premature death
- The estimated annual medical cost of obesity in the United States was \$147 billion in 2008 US dollars; the medical cost for people who have obesity was \$1,429 higher than those of normal weight.

Patient Assessment

- Measure height and weight and calculate BMI at annual visits or more frequently.
- Can be manually **calculated** Weight in kilograms divided by square of height in meters (kg/m²) OR by **online calculator** OR **chart**
- NIH- chart-Visual tool – patient engagement- facilitates the conversation

https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmi_tbl.htm

BMI	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
Height (inches)	Body Weight (pounds)																
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223
68	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230
69	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272
75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287

Visual Tool

Food Insecurity

- Assess food insecurities -Food availability should be queried In 2018, an estimated 1 in 9 Americans were food insecure, equating to over 37 million Americans, including more than 11 million children
- The U.S. Department of Agriculture (USDA) defines food insecurity as a lack of consistent access to enough food for an active, healthy life. More information and resources can be found at Hunger + Health “Feeding America” website: <https://hungerandhealth.feedingamerica.org/resources/>



- Assess other cultural circumstances that could affect dietary patterns.

Food Insecurity COVID 19 Impact-Handout

**Pops more
Likely to be
impacted,
those with:
Low income
Low Health
Literacy
Low English
proficiency
Migrant
workers
Seniors**

- ▶ Many food-insecure individuals have characteristics that put them at a higher risk for severe illness associated with COVID-19
- ▶ Workers who have service occupations or work in the leisure and hospitality industry are more likely to be food insecure and are at risk of further hardship as many businesses have been forced to close and lay off staff
- ▶ If unemployment and poverty increase to the level of the Great Recession, 9.9 million more people may experience food insecurity. In a more extreme scenario, the number of food-insecure individuals could rise by 17.1 million increasing the deficit to over 55 million people
- ▶ Individuals who experience food insecurity are more likely to have poorer health, and to have diet-related conditions like diabetes.
- ▶ An estimated 5.5 million seniors age 60 and older are food insecure, as are 4.8 million adults age 50-59
- ▶ Seniors typically have mobility and transportation limitations, and with social distancing measures in place, these challenges are likely to be heightened
- ▶ Hoarding is not an option - many struggle to afford what they need for the immediate future, much less large shopping purchases to prepare for a quarantine

Food Insecurity – Resources- Find a Food Bank



Search

Need Help

Sign Up

DONATE

HUNGER
IN AMERICA

OUR
WORK

TAKE
ACTION

FIND A
FOOD BANK

HUNGER
BLOG

The Feeding America nationwide network of food banks secures and distributes 4.3 billion meals each year through food pantries and meal programs throughout the United States and leads the nation to engage in the fight against hunger. Contact your local community food bank to find food or click here to [read about public assistance programs](#).

Search by
Zip Code or State

Zip Code:

or

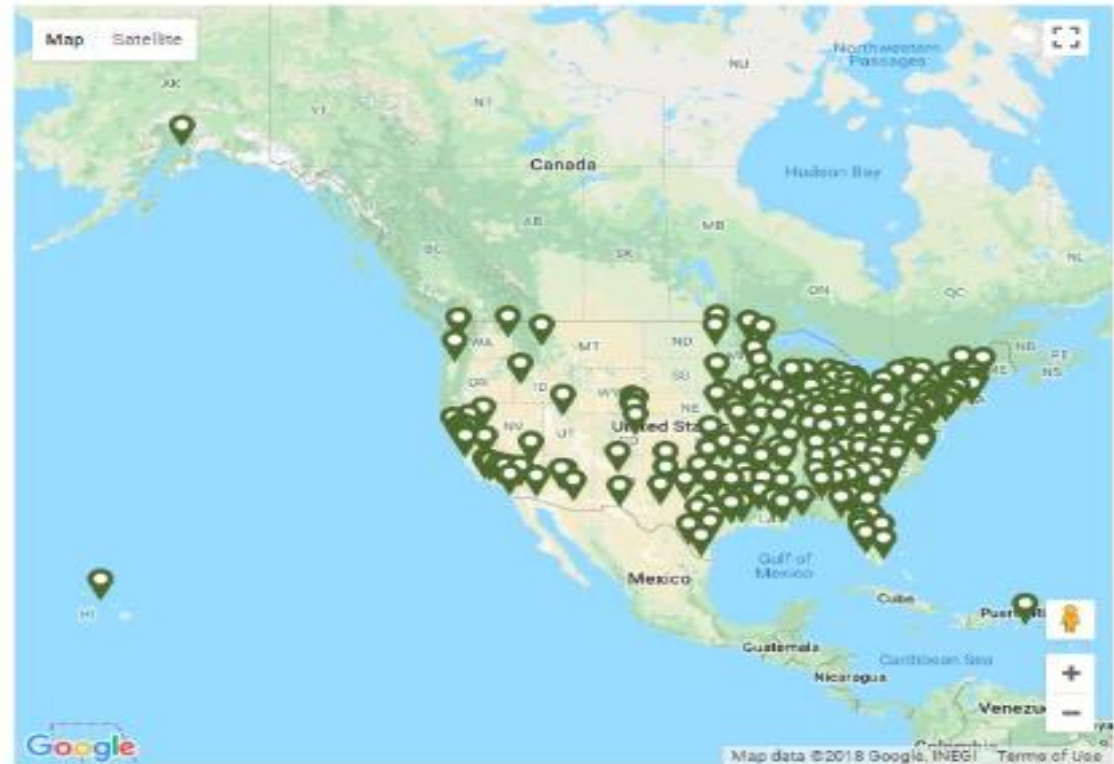
State

GO

[View Feeding America's full Member Food Bank Network >](#)

1 Feeding America Food Bank that serves 07047

Feeding America food banks serve large areas and will be able to find a feeding program in your local community.



<https://hungerandhealth.feedingamerica.org/resources/>

Find a Food Bank

Food Insecurity- Resources

What is a Feeding America National Program Model?

- A distribution model that provides access to meals, groceries or benefits for a target population (children, families, seniors).
- Programs are measurable, scalable and contribute to organizational outcomes.
- Models are supported through fundraising and capacity building activities.

[Contact your local food bank](#) to find out how you can get involved in programs that are already underway. Individual food banks do not necessarily operate all national programs, but all food banks are working in their local communities to serve people in need. For more information on specific national programs click below:

- [BackPack Program](#)
- [Kids Cafe](#)
- [School Pantry](#)
- [Senior Grocery Program](#)
- [SNAP Application Assistance](#)



Poll Question:

Besides finding a food bank for a food insecure patient what other community centered options can you look for to help close the gap of food insecurity?

- a. Senior community centers
- b. Churches and community health workers
- c. Community partnerships
- d. All of the above

Patient Assessment

- Once calculated, BMI should be classified to determine the presence of overweight or obesity, discussed with the patient, and documented in the patient record.
- NIH online calculator:
https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm

Table 8.1—Treatment options for overweight and obesity in type 2 diabetes

Treatment	BMI category (kg/m ²)		
	25.0–26.9 (or 23.0–24.9*)	27.0–29.9 (or 25.0–27.4*)	≥30.0 (or ≥27.5*)
Diet, physical activity, and behavioral therapy	†	†	†
Pharmacotherapy		†	†
Metabolic surgery			†

*Recommended cut points for Asian American individuals (expert opinion). †Treatment may be indicated for select motivated patients.

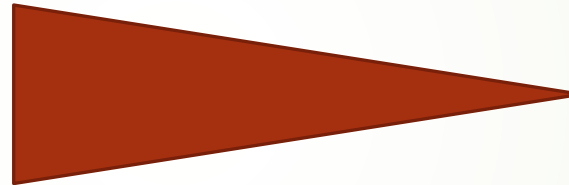
Clinical and Practical Considerations

- ▶ Educate patients on risks associated with overweight/obesity- Providers should advise patients with overweight or obesity that, in general, higher BMIs increase the risk of cardiovascular disease and all-cause mortality, as well as other adverse health and quality of life outcomes i.e. Cancer, Osteoarthritis, Gallbladder disease, sleep apnea and other respiratory conditions
- ▶ Clinical considerations may warrant more frequent evaluation. Significant unexplained weight gain or loss – needs closer evaluation- more frequent monitoring i.e. heart failure
- ▶ If deterioration of medical status is associated with significant weight gain or loss, inpatient evaluation should be considered, specifically focused on the association between medication use, food intake, and glycemic status
- ▶ For patients with a high level of weight-related distress, special accommodations should be made to ensure privacy during weighing- empathetic approach, patient preference, sensitivity
 - ▶ Side Note: some of my patients were so distressed we could not weigh them BUT they were willing to keep a weight/diet journal

SMART Goals - Strategies

- Strategies/Interventions include:

- Dietary changes
- Physical activity
- Behavioral therapy
- **Pharmacologic therapy**
- **Metabolic surgery**



Carefully selected patients as adjuncts to diet, physical activity, and behavioral

- **Start the conversation- Ruler Method** - Assess each patient's readiness to engage in behavioral changes for weight loss and jointly determine weight-loss goals and patient appropriate intervention strategies. **Individual's motivation**, life circumstances, and willingness to make lifestyle changes to achieve weight loss dictate goals

Guidance - Recommendations – Standards of Care

- Diet, physical activity, and behavioral therapy designed to achieve and maintain $\geq 5\%$ weight loss is recommended for patients with type 2 diabetes who have overweight or obesity and are ready to achieve weight loss.
- Greater benefits in control of diabetes and cardiovascular risk factors may be gained from even greater weight loss.
- Interventions should be high intensity ≥ 16 sessions for 6 months - achieve a 500–750kcal/day energy deficit
- For patients who achieve short term weight-loss goals, long-term (≥ 1 year) weight maintenance programs are recommended when available. Such programs should at minimum provide monthly contact, as well as encourage ongoing monitoring of body weight (weekly or more frequently) and other self-monitoring strategies, including high levels of physical activity (200–300 min/week).



Guidance - Recommendations – Standards of Care

- ▶ Significant weight loss can be attained with lifestyle programs that achieve a 500–750 kcal/day energy deficit, which in most cases is approximately 1,200–1,500 kcal/day for women and 1,500 to 1,800 kcal/day for men
- ▶ Weight loss of 3 to 5% is the minimum necessary for clinical benefit
- ▶ Weight-loss benefits are progressive; more intensive weight-loss goals (>5%, >7%, >15%, etc.) may be pursued if needed to achieve a healthy weight and/or if the patient is more motivated and more intensive goals can be feasibly and safely attained.

Weight Management Programs

- ▶ Help patients select the right program for them and avoid programs that are not reputable – **Beware of those that boast no exercise needed**
- ▶ Pharmaceutical service program should incorporate features below
- ▶ Key features to look for: whether on-line or in person program - <https://www.niddk.nih.gov/health-information/weight-management/choosing-a-safe-successful-weight-loss-program>
 - ▶ **Lifestyle counseling** – behavioral programs that promote healthy habits and how to maintain them - food and activity journals
 - ▶ **Stress management** and sleep patterns – yoga, meditation, mindfulness
 - ▶ **Ongoing support** – online, chat rooms, in person groups- provide feedback and monitoring
 - ▶ **Sustainable weight loss goals** – slow and steady - usually 1 to 2 pounds per week
 - ▶ **Planning for the future** – how to keep the weight off – developing healthy habits such as food journaling

Weight Management Programs

- **Refer to Medical Care Settings-** To achieve weight loss of >5%, short-term (3-month) interventions that use very low-calorie diets (≤ 800 kcal/day) and meal replacements may be prescribed for carefully selected patients by trained practitioners in **medical care settings** with close medical monitoring. To maintain weight loss, such programs must incorporate long-term comprehensive weight-maintenance counseling.
- **Metabolic surgery-** should be recommended in **screened adult candidates** with BMI ≥ 40 (37.5 in Asian pop) and in BMI between 35 – 39.9 (32.5-37.5 Asian pop) who do not achieve durable weight loss and improvement in co-morbidities including hyperglycemia i.e. HTN, LIPIDs
 - **Very promising- Multiple RCTs** – demonstrating superior glycemic control and reduction of cardiovascular risk factors in patients with type 2 diabetes and obesity compared with various lifestyle/medical interventions
- **Screening-** People with diabetes presenting for metabolic surgery also have increased rates of depression and other psychiatric disorders. Screen by a mental health professional with expertise in obesity management in those with a history of:
 - alcohol, tobacco, or substance abuse
 - significant depression
 - suicidal ideation and other mental health conditions

Surgery should be postponed until these conditions are fully addressed. Furthermore, assessment should take place regularly following metabolic surgery to optimize mental health and to ensure that psychiatric symptoms do not interfere with weight loss and lifestyle changes



Poll Question

An adult patient who weighs 260lbs (BMI = 33 kg/m²) asks you how much weight at a minimum he should loose in order to gain clinical benefit?

- a. 20-30 lbs.
- b. 5-10 lbs.
- c. 8-13 lbs.
- d. 2- 7 lbs.

Useful tips to help motivate your patients

- There is strong and consistent evidence that obesity management can delay the progression from prediabetes to type 2 diabetes
- For Type 2 with overweight or obesity - Modest and sustained weight loss produce clinically meaningful reductions in blood glucose, A1C, and triglycerides
- Greater benefits in control of diabetes and cardiovascular risk factors may be gained from even greater weight loss.
- Look AHEAD trial and other large cardiovascular outcome studies document other benefits of weight loss in patients with type 2 diabetes, including improvements in mobility, physical and sexual function, and health-related quality of life
- In patients with type 2 diabetes who also have overweight or obesity, modest and sustained weight loss has been shown to improve glycemic control and to reduce the need for glucose-lowering medications
- Greater weight loss produces even greater benefits, including reductions in blood pressure, improvements in LDL and HDL cholesterol, and reductions in the need for medications to control blood glucose, blood pressure, and lipids, and may result in achievement of glycemic goals in the absence of glucose-lowering agent use in some patients

Recommendations for Pharmacotherapy

- ▶ When choosing glucose-lowering medications for patients with type 2 diabetes and overweight or obesity, **consider a medication's effect on weight**
- ▶ Whenever possible, minimize medications for comorbid conditions that are associated with weight gain
- ▶ Weight-loss medications **are effective as adjuncts** to diet, physical activity, and behavioral counseling for selected patients with type 2 diabetes and BMI ≥ 27 kg/m². Potential benefits must be weighed against potential risks of medications

Monitor all weight loss medications for safety and intolerabilities at least monthly for the first 3 months

- ▶ If response to weight loss medications is $< 5\%$ weight loss after 3 months or if there are significant safety or tolerability issues at any time, the medication should be discontinued, and alternative medications or treatment approaches should be considered.
- ▶ **All patients with diabetes on antidiabetic agents should be closely monitored for hypoglycemia while on weight management programs and especially those that include pharmacotherapy – dietary restrictions may lower requirements – adjust antidiabetic agents accordingly**

Recommendations for Pharmacotherapy

- Agents associated with varying degrees of weight loss- in obese patients agents like GLPs, SGLT2, pramlintide can be added
 - Metformin- neutral but potential for modest loss
 - alpha-glucosidase inhibitors- acarbose (Precose)
 - GLP1-RAs – Byetta, Victoza
 - SGLT2 inhibitors – Invokana (canagliflozin)
 - Amylin mimetics – pramlintide (Symlin)
- Agents associated with weight gain
 - Insulin – Analogs, Human- have the highest
 - Sulfonylureas – Glipizide, Glimepiride (Less so)
 - Thiazolidinediones- TZDs - pioglitazone (Actos)

Recommendations for Pharmacotherapy

Concomitant medications- whenever possible, minimize or provide alternatives for medications that promote weight gain. Endocrine Society recommends use of shared decision making.

Medications associated with weight gain:

- Antipsychotics (clozapine, olanzapine, risperidone, quetiapine)
- Antidepressants (TCA, SSRIs, MAOIs) – amitriptyline, fluoxetine, phenelzine
- Glucocorticoids – prednisone
- Injectable progestins –greater weight gain with depot-medroxyprogesterone than oral contraceptives.
- Anticonvulsants – gabapentin, pregabalin, carbamazepine, and valproate have been found to cause weight gain-
- Antihistamines/anticholinergics – diphenhydramine

- Alternative- Ziprasidone found to cause significantly less weight gain when compared with other atypical antipsychotics
- Alternative-Bupropion can be considered as an alternative agent since it is associated with weight loss
- Alternative -Use NSAIDs where appropriate
- Intrauterine devices and barrier methods are also options
- Alternative - topiramate and zonisamide may lead to weight loss
- Alternative - loratadine

Weight Loss Medications

- ▶ FDA has approved medications for both short-term and long-term use in weight management **as adjuncts** to diet and exercise and behavioral therapy in patients who have at least one other weight related co-morbidity i.e. HTN, Hyperlipidemia
- ▶ Nearly all have shown **improvement in glycemic control in Type 2** and to **delay** progression to type 2 in patients at high risk
- ▶ The logic behind the use of agents to promote weight loss:
 - ▶ Help patients **adhere more consistently** to low-calorie diets
 - ▶ **Reinforce** lifestyle changes
- ▶ These agents are **contraindicated** in pregnancy and in those trying to get pregnant
- ▶ Women of childbearing age **must receive counseling** regarding the use of reliable methods of contraception
- ▶ Efficacy and safety should be **assessed at least monthly for the first 3 months**
- ▶ **Discontinue medication** - If response is insufficient or LESS THAN 5% after 3 months or if there are significant safety or tolerability issues at any time- alternative medications or treatment approaches should be considered

Lorcaserin- Potential Risk of Cancer

- ▶ Lorcaserin- 2/2020- The U.S. Food and Drug Administration (FDA) has requested that the manufacturer of Belviq, Belviq XR (lorcaserin) voluntarily withdraw the weight-loss drug from the U.S. market because a safety clinical trial shows an increased occurrence of cancer. The drug manufacturer, Eisai Inc., has submitted a request to voluntarily withdraw the drug.
- ▶ Patients should stop taking lorcaserin and talk to your health care professionals about alternative weight-loss medicines and weight management programs. It's best to dispose of unused lorcaserin using a drug take back location, but if you can't get to one you can dispose of lorcaserin in your household trash (after mixing with undesirable substance like used cat litter, put into plastic bag and container and discard). Remove PHI.
- ▶ Health care professionals should stop prescribing and dispensing lorcaserin to patients. Contact patients currently taking lorcaserin, inform them of the increased occurrence of cancer seen in the clinical trial, and ask them to stop taking the medicine. Discuss alternative weight-loss medicines or strategies with your patients.

Phentermine-

Amphetamine-related anorexigenic agent; action in reducing appetite may be secondary to CNS effects that may involve stimulation of hypothalamus to release norepinephrine

- Indicated for short term - \leq 12 weeks
- Contraindications –
 - Pregnancy (Category X) and in lactation,
 - History of cardiovascular disease (e.g., arrhythmias, heart failure, coronary artery disease, stroke, **uncontrolled** hypertension); hyperthyroidism; glaucoma; agitated states; history of drug abuse
 - Concomitant or Use of monoamine oxidase inhibitors (MAOIs) within preceding 14 days;
 - Concomitant administration of other CNS stimulants
 - Hypersensitivity or idiosyncratic reaction to sympathomimetic amines
- Elderly are at high risk for myocardial infarction, hypertension, angina, or becoming dependent on phentermine with prolonged use
- Drug interactions – MAOIs, Alcohol, Insulin & antidiabetic agents (Hypoglycemia), adrenergic neuron blocking agents
- Caution in hypertension; risk of increase in blood pressure
- Use with caution in patients with seizure disorders or Tourette syndrome
- Advise patients to avoid late evening administration - take in the morning before breakfast or 1 to 2 hours after breakfast

Orlistat

- Inhibits gastric and pancreatic lipases, prevents triglyceride hydrolysis resulting in decreased absorption of dietary fats

- Long-term >12 weeks - **weight loss and weight maintenance** also indicated to reduce the risk for weight regain after prior weight loss
- Taken **in conjunction with meals up to three times a day-** (during or up to 1 hour after the meal)- If a meal is skipped or if a meal contains no fat no need to take orlistat
- Advise patients to take a nutritionally balanced, reduced-calorie diet that contains approximately **30% of calories from fat** evenly distributed across three meals - An increase in gastrointestinal events when taking a diet high on fat (>30% total daily calories from fat)
- **Advise patients to take a multivitamin** containing fat-soluble vitamins to ensure adequate nutrition (A, D, E, **K**)- take at least 2 hours after or before orlistat
- **By far most common side effect is GI symptoms** but most clinical trial patients reported SE subsided after several weeks on the medication. Oily spotting, flatus with discharge, fecal urgency fatty/oily stool, oily evacuation, increased defecation and fecal incontinence
- Substantial weight loss can increase risk of cholelithiasis
- Post marketing reports of severe liver injury with hepatocellular necrosis or acute hepatic failure with some cases resulting in liver transplant or death
- Contraindications- Pregnancy (Category X)-also not recommended in lactation, Chronic malabsorption syndrome, cholestasis, hypersensitivity

Orlistat- Malabsorption

- **Thyroid hormone** - separate by 4 hours and monitor for changes in thyroid function
- **Cyclosporin** separate by 3 hours.
- **Warfarin and Other Anticoagulants**
 - Vitamin **K** absorption may be decreased with orlistat
 - Reports of decreased prothrombin, increased INR, and unbalanced anticoagulant treatment resulting in change of hemostatic parameters have been observed with coadministration of orlistat and anticoagulants
 - Patients on chronic stable doses of warfarin or other anticoagulants who are prescribed orlistat should be monitored closely for coagulation parameters changes
- **Antiepileptic drugs (AEDs)** - Convulsions reported with coadministration of AEDs and orlistat; monitor serum AED levels
- **Amiodarone PO-** A pharmacokinetic study showed reduced amiodarone and desethylamiodarone systemic exposure when co-administered with orlistat
- **Antiretroviral drugs (ART)** - Loss of virological control has been reported in HIV-infected patients taking orlistat concomitantly with antiretroviral drugs - if HIV viral load increases, discontinue orlistat

Phentermine/topiramate- induces anorexic CNS

effect/topiramate- Effect may be through appetite suppression and satiety enhancement

- If discontinuation is recommended **gradually** discontinue therapy to avoid possible seizures (e.g., 1 dose every other day for at least 1 week)
- If patient does not respond to lower dose the dosage can be escalated
- **To escalate the dose:** Increase to 11.25 mg/69 mg PO qDay for 14 days; followed by dosing 15 mg/92 mg qDay; evaluate weight loss following dose escalation to 15 mg/92 mg after an additional 12 weeks of treatment
- Do not exceed 7.5 mg/46mg dose for patients with moderate or severe renal impairment or patients with moderate hepatic impairment

Phentermine/topiramate

- Contraindications
 - Hypersensitivity or idiosyncrasy to sympathomimetic amines
 - Pregnancy (Category X) and lactation
 - Glaucoma
 - Hyperthyroidism
 - Within 14 days following MAOIs (risk hypertensive crisis)
- Caution in patients with history of cardiac or cerebrovascular disease
- Use of Antidiabetic Medications: Weight loss may cause hypoglycemia. Measure serum glucose before/during treatment
- Increase in the risk of suicidal thoughts and ideation or behavior CNS effects: Cognitive dysfunction and psychiatric disturbances - Risk may be increased in patients with a history of depression; dose reduction or discontinuation may be necessary
- Post marketing and/or case reports: Acute angle-closure glaucoma

Phentermine/topiramate

➤ Drug Interactions

- Oral contraceptives - Altered exposure may cause irregular bleeding but not increased risk of pregnancy. Advise patients not to discontinue oral contraceptives if spotting occurs and check with their physician if condition does not resolve or worsens
- CNS depressants including alcohol: Potentiate CNS depressant effects. Avoid concomitant use of alcohol
- Non-potassium sparing diuretics: May potentiate hypokalemia. Measure potassium before/during treatment

Naltrexone/bupropion-

Combination may regulate activity in the dopamine reward system of the brain that helps control food cravings and overeating behaviors

- Dosing escalation schedule is recommended

	Morning Dose	Evening Dose
Week 1	1 tablet	None
Week 2	1 tablet	1 tablet
Week 3	2 tablets	1 tablet
Week 4 – Onward	2 tablets	2 tablets

- Contraindications

- **Black Box Warning:** closely monitor children, adolescents, young adults for **suicidal thoughts and behaviors**. Serious neuropsychiatric reactions reported in patients taking bupropion for smoking cessation.
- Uncontrolled hypertension
- Seizure disorder or a history of seizures
- Bulimia or anorexia nervosa, which may increase risk of seizures
- Long-term opioid or opiate agonists use or acute opiate withdrawal
- Patients undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, or antiepileptic drugs
- Within 14 days of monoamine oxidase inhibitor therapy
- Hypersensitivity
- Pregnancy (Category X)

Naltrexone/bupropion

- ▶ Monitor patients for suicidal ideation or behavior and for unusual changes in behavior - screen for depression - agitation, depressed mood, or changes in behavior or thinking that are not typical for patient are observed
- ▶ **Discontinue therapy and do not restart if seizure** occurs while on therapy; use caution when prescribing to patients with predisposing risk factors for seizures
- ▶ Discontinue therapy if long-term opiate therapy required
- ▶ **Following therapy, patients may be more sensitive to opioids, even at lower doses**
- ▶ **Screen for substance abuse history:** A patient should not attempt to overcome naltrexone opioid blockade by administering large amounts of exogenous opioids; may lead to fatal overdose
- ▶ Opioid-dependent patients, including those being treated for alcohol dependence, **should be opioid-free (including tramadol) before therapy is initiated;** opioid-free interval of a minimum of 7-10 days is recommended for patients previously dependent on short-acting opioids; patients transitioning from buprenorphine or methadone may need as long as 2 weeks

Naltrexone/bupropion

- ▶ Blood pressure and pulse should be measured prior to starting therapy and should be monitored at regular intervals, particularly among patients with controlled hypertension prior to treatment
- ▶ Discontinue therapy if symptoms or signs of acute hepatitis occur
- ▶ Use caution in hepatic impairment
- ▶ May precipitate a manic, mixed, or hypomanic episode; risk higher in patients with bipolar disorders or have risk factors for bipolar disorder, including family history of bipolar disorder, suicide, or depression
- ▶ Measure blood glucose levels prior to and during therapy; patients who develop hypoglycemia after initiating therapy should adjust antidiabetic drug regimen

Liraglutide

- Trade Name for weight loss Saxenda – not indicated for Type 2 diabetes
- Higher dose than Victoza- Initiate at 0.6 mg SC qDay for 1 week; increase by 0.6 mg/day in weekly intervals until a dose of 3 mg/day is achieved
- Discontinue if a patient cannot tolerate the 3-mg dose, as efficacy has not been established at lower doses (e.g., 0.6, 1.2, 1.8, 2.4 mg)
- Drug Interactions- Consider reducing dose of the insulin secretagogue (i.e., by one-half) or insulin to reduce the risk for hypoglycemia, and monitor blood glucose and if discontinuing monitor for hyperglycemia
- **Black Box Warning:** Causes thyroid C-cell tumors in rodents; human risk could not be determined. Contraindicated in patients with personal or family history of medullary thyroid carcinoma (MTC) or in patients with multiple endocrine neoplasia syndrome type 2 (MEN 2).
- Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed; studied in a limited number of patients with a history of pancreatitis; unknown if patients with a history of pancreatitis are at higher risk for development of pancreatitis

Liraglutide

- ▶ Resting heart rate may increase by 2-3 bpm; up to 10-20 bpm increases also reported
- ▶ **Suicidal ideation**; monitor for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior; discontinue in patients who experience suicidal thoughts or behaviors; avoid in patients with a history of suicidal attempts or active suicidal ideation
- ▶ **May cause a delay of gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications; exercise caution when oral medications are concomitantly administered with liraglutide**
- ▶ Most common adverse reactions, reported in greater than or equal to 5% are: nausea, hypoglycemia, diarrhea, constipation, vomiting, headache, decreased appetite, dyspepsia, fatigue, dizziness, abdominal pain, and increased lipase. **Also monitor for injection site reactions and proper administration technique**
- ▶ Severe Hypersensitivity reactions have been reported post marketing- **angioedema**
- ▶ Use caution in renally impaired - acute renal failure or worsening of chronic renal failure, sometimes requiring hemodialysis has also been reported- monitor closely with dose adjustments



Poll Question

What advise is not recommended in a patient taking orlistat for weight maintenance?

- a. Skip a dose if you are eating a meal that contains no fat
- b. Separate your thyroid medication dose by at least 4 hours
- c. You should include a dose of orlistat with a fat containing snack
- d. Maintain a diet that contains 30% of calories from fat

Studies of Weight Management Programs with Pharmacists

Author	Design	Intervention	Total participants (n) enrolled	Patient outcomes
Community pharmacy based weight management pharmaceutical care services				
Bescoby [36]	6 month, pre/post study	Weight management pharmaceutical care program	21	Participant satisfaction with the program
Ahrens [37]	12 week, randomized, controlled, open-label study	Meal-replacement program with a conventional weight loss diet comparing outcomes for participants on a reduced calorie diet to those on a meal replacement product	88	Phase 1: Meal replacement: avg 4.90 kg avg weight loss; reduced calorie diet: 4.30 kg avg weight loss Phase 2: Meal replacement: additional 0.7 kg, total 5.2 kg weight loss (6.36 % decrease from baseline); reduced calorie diet: additional 0.9 kg, total 4.3 kg weight loss(5.63 % from baseline)
Malone [38]	Pre/post study	Pharmaceutical care services provided for patients on orlistat therapy	30	Control group: 0.5 kg avg weight loss Intervention group: 2.5 kg avg weight loss Participants in the intervention group stayed on therapy on average 18.5 weeks vs. 7.8 for the control group
Botomino [39]	1 year ,stratified, randomized pre/post study	Weight management counseling (standard, intensive, high risk) provided to patients in a nationwide diabetes screening campaign	3,800	≥5 % initial body weight lost in: 16.7 % standard counseling pts; 24.5 % intensive counseling pts; 24.5 % high-risk counseling pts (p<0.05 High risk vs intensive and standard groups)
Morrison [40**]	12 month, pre/post study	Weight management pharmaceutical care program	458	10.2 % of participants enrolled for 12 months (n=314) achieved ≥5 % weight loss from baseline.
Winter [41]	24 week, pre/post study	Weight management pharmaceutical care program	60	18 participants completed 24 weeks in the program. 1.82 kg avg weight loss per patient
Weight management programs involving pharmacists				
Lloyd [18]	Pre/post retrospective study	Pharmacist-led weight management program provided to university employees	289	3.6 kg avg weight loss/participant 1 % change in BMI averaged
Malone [42]	20 week, pre/post study	Multidisciplinary, weight management program	90	After 20 weeks, average participant weight loss was 17.1 %
Milton-Brown [43*]	6 month, pre/post study	Meal-replacement program provided to patients through a hospital outpatient pharmacy	37	Average weight loss 10.2 lbs at 3 months and 14.17 lbs at 6 months

Studies

Models either in community pharmacies alone or as part of collaborative agreements between pharmacists, physicians, and other health care providers- all showed positive results

- ▶ Botomino et. al. – (<https://www.ncbi.nlm.nih.gov/pubmed/18046620>) **Change of body weight and lifestyle of persons at risk for diabetes after screening and counselling in pharmacies**
- ▶ In conjunction with a **community pharmacy** screening for type 2 diabetes, Botomino and colleagues evaluated the effectiveness of providing weight-loss counseling **immediately** after the diabetes screening
- ▶ The pharmacists **received training over two evenings**
- ▶ n= 3800 overweight were randomly screened for Type 2 diabetes - counseling sessions were one-time sessions. Patients were **followed-up afterwards through mail questionnaires.**
 - ▶ Standard Counseling- general lifestyle modifications
 - ▶ Intensive Counseling- nutrition recommendations and goals to achieve target weight loss as well as physical activity recommendations
 - ▶ High Risk Counseling- general lifestyle modifications and advised to follow-up with their physician
- ▶ $\geq 5\%$ initial body wt. lost in 16.7% of SC, 24.5% IC, and 24,5% HRC All groups achieved weight loss – HRC group achieved the greatest weight loss
- ▶ **Study shows that even limited involvement by a pharmacist can complement existing clinical services for chronic diseases in which weight loss may have direct impact such as diabetes**

Studies

- Morrison et. al. – Hand out- (<https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-13-282>) Scotland – incorporated the Counterweight Programme-the Counterweight Programme was introduced into community pharmacies in Fife, Scotland in 2009 for patients with a BMI ≥ 30 kg/m² or a BMI ≥ 28 kg/m² with a co-morbidity in localities in which Counterweight was not available at GP practice. It has been evaluated for use in routine National Health Service primary care in the UK
- Counterweight specialist dietitians delivered training, support and patient information materials to community pharmacies
- Initial visit and nine 10-30-minute follow-up visits within 12 months. Initial visit included height and weight measurements
- 458 patient enrolled
- The pharmacies extended their business hours to provide time for these appointments
- Follow-up visits, pharmacists provided counseling on nutrition and behavioral changes, established caloric goals and checked weight
- Weight data recorded at each weight management session were used to estimate weight change and attendance at 3, 6 and 12 months
- 10.2% of participants enrolled for 12 months (n=314) achieved $\geq 5\%$ weight loss from baseline
- Attendance at the pharmacy-based service was comparable to general practice-based services and had similar effectiveness to other primary care-based weight management programs in successful outcomes achieved.

Studies

Limitations and Barriers Reported

- ▶ Knowledge and training- most pharmacist report little training received in obesity management in pharmacy schools at the time of the studies. CPE courses are filling in this gap
- ▶ Caveat- Newer Graduates - The standards from ACPE only became effective in 2007- Standard 12 requires curricula to include population-based health, wellness, disease prevention. Appendix 1 of the 2016 standards – includes not only that students be able to interpret/analyze lab tests but also perform health screenings and physical assessments
- ▶ Pharmacist perceptions – Texas study pharmacist comfort level or lack there of correlated with the frequency of counseling
- ▶ Current practice models – Time, workflow and resources
- ▶ Legal considerations – limitations on state scopes of practice- most states allow collaborate practice agreements
- ▶ Reimbursement for services – Social Security Act - lack of provider status- continued advocacy from the field – COVID 19 has opened more opportunities
- ▶ Facility design - hinder effective individualized counseling - privacy

Role Hand out

- “**Pharmacists** are again among the **most** highly **trusted** people in their **occupations**, according to a recent Gallup poll. The poll ranked **pharmacists** third among professionals in the United States for honesty and ethical standards, with 66% of respondents rating their trustworthiness as “**very high**” or “**high.**””
(<https://www.pharmacytimes.com/publications/career/2019/CareersWinter19/public-perceives-pharmacists-as-some-of-the-most-trusted-professionals>)
- Extensive training in pharmacotherapy and in most curriculums include physical assessment training
- Accessible - Integrated into a variety of pharmaceutical care services – Diabetes, Asthma, Lipids, HTN, Coagulation
- Pharmacists already see their patients at least once a month - Type 2 diabetes- pharmacists already integrate, directly or indirectly, discussions on physical activity and weight loss

Role

- Pharmacists can utilize point-of-care devices and provide more direct weight management services separately or in conjunction with other disease state management programs - reading nutrition labels, health risks associated with obesity, nutrition and exercise support, and medication monitoring
- Point-of-care devices for weight management - scales, height measures, measuring tape, body composition analyzers, pedometers, blood pressure/heart rate monitors, and calorie counters, and A1C for people living with diabetes and obesity
- Pharmacists can provide information and recommendations on both over-the-counter products as well as prescription medications - over-the-counter products such as vitamins, herbals, supplements, or nonprescription drug options specifically marketed for weight loss such as Alli (orlistat)

Role

Pharmacists can effectively provide intensive behavioral therapy for obesity in a manner consistent with the CMS guidelines

- 2011- the US Department of Health and Human Services Centers for Medicare & Medicaid introduced a new policy allowing for more opportunities in the treatment of obesity for Medicare beneficiaries
- Although pharmacists are not covered providers yet- provider status will close the reimbursement gap – also
 - Obesity is defined as an “Essential Health Benefit” within the Affordable Care Act and preventive care is gaining traction with payers- likely that services will be covered in the future
- 2014- CMS has informed the American Academy of Family Physicians (AAFP) that a physician may bill the Medicare program for pharmacist-provided services **as incident-to services** if all the legal requirements are met. Codes – 99211-99215- <https://www.pharmacist.com/article/cms-tells-family-physicians-pharmacist-provided-services-may-be-billed-incident-0>



Poll Question

In the absence of provider status, which of the following are options for reimbursement of services?

- a. Grants and/or Fee for service
- b. Collaborate practice agreements
- c. Incident to billing
- d. All of the above

Design the Program as per CMS Guidelines

- ▶ Medicare covers intensive behavioral therapy for obese patients defined as $BMI > 30 \text{ kg/m}^2$. The covered therapy includes screening for obesity, nutritional assessment, and counseling
- ▶ According to CMS, therapy for obesity consists of: Screening for obesity in adults using measurement of BMI calculated by dividing weight in kilograms by the square of height in meters (expressed kg/m^2);
- ▶ Dietary (nutritional) assessment; and Intensive behavioral counseling and behavioral therapy to promote sustained weight loss through high intensity interventions on diet and exercise.

CMS Guidelines- utilize the 5As

Additionally, the NCD states that the intensive behavioral intervention for obesity should be consistent with the 5-A framework that has been delineated by the USPSTF:

- **Assess:** Ask about/assess behavioral health risk(s) and factors affecting choice of behavior change goals/methods.
- **Advise:** Give clear, specific, and personalized behavior change advice, including information about personal health harms and benefits.
- **Agree:** Collaboratively select appropriate treatment goals and methods based on the patient's interest in and willingness to change the behavior.
- **Assist:** Using behavior change techniques (self-help and/or counseling), aid the patient in achieving agreed-upon goals by acquiring the skills, confidence, and social/environmental supports for behavior change, supplemented with adjunctive medical treatments when appropriate.
- **Arrange:** Schedule follow-up contacts (in person or by telephone) to provide ongoing help and support and to adjust the treatment plan as needed, including referral to more intensive or specialized treatment.



SESSION 3: Current Standards of Care

DATE:

May 29, 2020 at 1:00 – 2:15
pm EDT

Registration Link:

<https://attendee.gotowebinar.com/register/4005408015980884236>

COMING UP NEXT:

Q&A



If you would like to ask the presenter a question, please submit it through the questions box on your control panel.



If you are dialed in through your telephone and would like to verbally ask the presenter a question, use the “raise hand” icon on your control panel and your line will be unmuted.



LET US KNOW YOUR THOUGHTS! |

CORONAVIRUS PHPC WEEKLY UPDATES

May 8, 2020
Numbers as of May 1, 2020
Number of PHPC respondents= 76 (71% of all PHPCs)

**IN 2018, THERE WERE 107 PHPCs
SERVING 817,123 PATIENTS LIVING
IN OR IMMEDIATELY ACCESSIBLE
TO PUBLIC HOUSING.**

*PHPC Adequate Supply of Personal Protective Equipment
(PPE) for the next week:*

93.42%

Surgical Masks

90.79%

N95/PPR Masks

82.89%

Gowns

97.37%

Gloves

93.42%

Face Masks & Goggles



PHPC WORKFORCE:

58.75% Health Center Weekly Visits (Versus Pre-COVID-19 Weekly Visits)

211 PHPC Sites Closed

**PATIENT
TESTING**

**PHPCs with
COVID-19
Testing Capacity
86.84%**

**Drive-up/Walk Up
Testing Capacity
69.73%**

PHPCs COVID-19 SPREAD :

22,542

Total Tested

80.78%

Racial or Ethnic
Minority Tested

7.000

WHAT'S NEW FROM NCHPH

Bridging the Digital Divide:

Using Technology to Improve Access to Health Care for Public Housing Residents

April 2020

National Center for Health in Public Housing



Developing Cross-Sector Partnerships

April 2020



Published in partnership with:



SOCIAL DETERMINANTS OF HEALTH FOR PUBLIC HOUSING RESIDENTS:

ACCESS TO HEALTHY FOOD

Using data and maps created by National Center for Health in Public Housing (NCHPH) and other national data sources, this publication is one in a series that identifies the prevalence of social factors and population health indicators that affect public housing residents. It is intended for non-clinical health center staff, decision makers, and public housing stakeholders.

April 2020

JOIN OUR MAILING LIST AT [NCHPH.ORG/CONTACT](https://www.nchph.org/contact) AND RECEIVE:



HRSA Updates



Medicare Updates



Funding Opportunities



Senior Programs



Resources and Services



Webinars

VISIT OUR WEBSITE: [NCHPH.ORG](https://www.nchph.org)

Webinars

Monographs

Publications

Interactive Maps

Provider and Resident-Centered Factsheets

Training Manuals

Newsletters

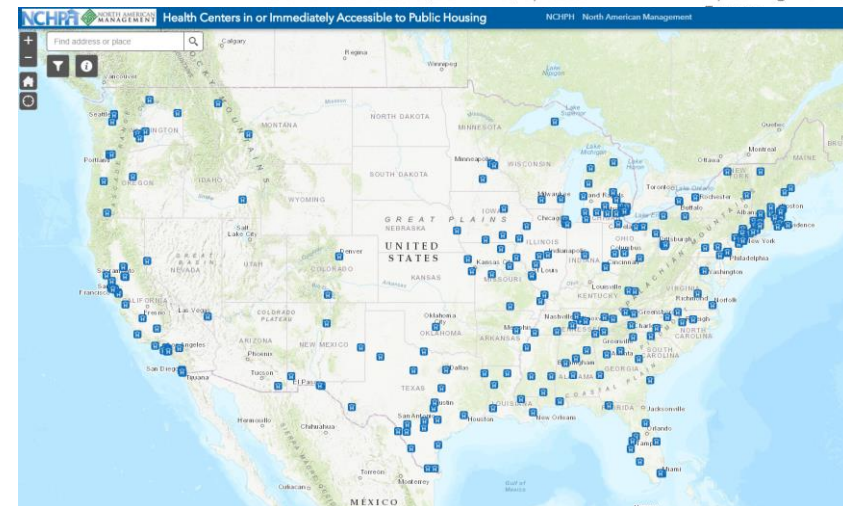
Annual symposiums

One-on-One



Coronavirus Disease (COVID-19) Updates

Upcoming Training & Technical Assistance



CONTACT US

Robert Burns
Director of Health
Bobburns@namgt.com

Dr. Jose Leon
Chief Medical Officer
jose.leon@namgt.com

Saqi Maleque Cho DrPH, MSPH
Manager of Policy, Research, and Health
Promotion
Saqi.cho@namgt.com

Fide Pineda Sandoval
Health Research Assistant
Fide@namgt.com

Chantel Moore
Communications Specialist
Cmoore@namgt.com

Please contact our team for Training and Technical
Support
703-812-8822

THANK YOU!

