Pharmacist Opportunity: Nutrition, Lifestyle & the Obese Patient

Presented By:
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Take Charge Nutrition

Disclosures

Terry Forshee “declare(s) no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.”

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Learning Objectives

At the conclusion of this program, the participating pharmacist or technician will be able to:

- Define obesity and health conditions associated with a sedentary lifestyle and/or poor diet.
- Outline and explore reasons that pharmacists are the health care professionals to best address obesity treatment.
- Identify market opportunities for treatment of obesity and related health conditions.
- Outline general nutritional guidelines for weight loss and good health.
- Discuss the opportunities of implementing Obesity programs as a profitable niche in the pharmacy and potential competitive edge with 3rd party/ACO contracts.

"People who have the answer to 'how' are going to be highly sought after in the new economy"

Former President Bill Clinton, NCPA

Keynote Address 10/14/2014

Who will make the $$ under the ACA?

- ACA mandates free preventative healthcare
- *"Chronic diseases, such as heart disease, cancer, and diabetes, are responsible for seven of 10 deaths each year and account for 75% of the nation's health spending -- and often are preventable."* **Health and Human Services Secretary Kathleen Sebelius**
- ***Who will make the $$? Those who save the "system" $$!***
- Where are these savings?

What is the current health condition of the U.S. population?

OBESITY

- >70% overweight (www.cdc.gov)
- 34.9% obese (78.6 million adults) (www.cdc.gov)
- Obesity higher among 40-59 years old (39.5%)
- Blacks 47.8%, Hispanics 42.5%
- >$147 billion cost to US healthcare system each year (www.cdc.gov)
- If 1/3 Americans are obese, and over 7/10 overweight, how many do you see in your pharmacies each month?

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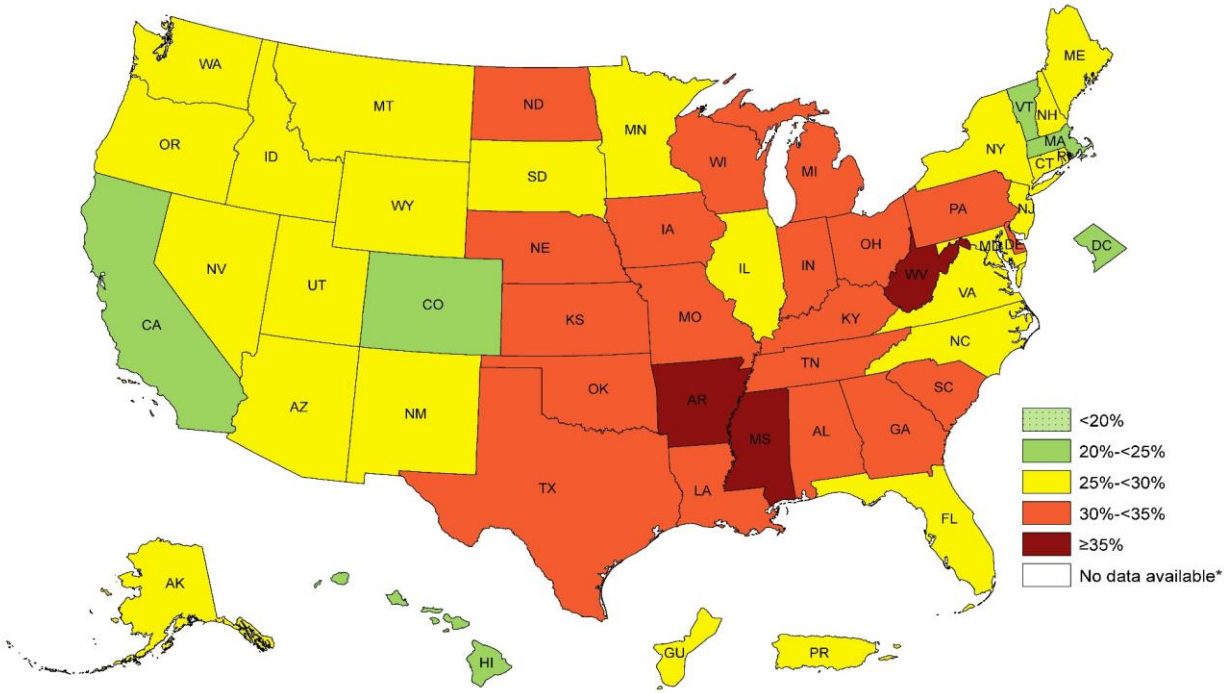
Prevalence¶ of Self-Reported Obesity Among U.S. Adults by State and Territory, BRFSS, 2014

¶ Prevalence estimates reflect BRFSS methodological changes started in 2011. These estimates should not be compared to prevalence estimates before 2011.



***Sample size <50 or the relative standard error (dividing the standard error by the prevalence) ≥ 30%.**

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Prevalence¶ of Self-Reported Obesity Among U.S. Adults by State and Territory, BRFSS, 2014

State	Prevalence	95% Confidence Interval
Alabama	33.5	(32.1, 35.0)
Alaska	29.7	(27.8, 31.7)
Arizona	28.9	(27.7, 30.2)
Arkansas	35.9	(33.8, 38.0)
California	24.7	(23.5, 25.9)
Colorado	21.3	(20.4, 22.2)
Connecticut	26.3	(24.9, 27.7)
Delaware	30.7	(28.6, 32.8)
District of Columbia	21.7	(19.5, 24.0)
Florida	26.2	(25.0, 27.5)
Georgia	30.5	(28.9, 32.1)
Guam	28.0	(25.6, 30.5)
Hawaii	22.1	(20.7, 23.5)
Idaho	28.9	(27.1, 30.8)
Illinois	29.3	(27.6, 31.1)
Indiana	32.7	(31.6, 34.0)
Iowa	30.9	(29.6, 32.3)
Kansas	31.3	(30.3, 32.2)
Kentucky	31.6	(30.2, 33.1)
Louisiana	34.9	(33.4, 36.4)
Maine	28.2	(26.9, 29.5)
Maryland	29.6	(28.1, 31.1)
Massachusetts	23.3	(22.3, 24.4)
Michigan	30.7	(29.4, 32.0)
Minnesota	27.6	(26.8, 28.5)
Mississippi	35.5	(33.4, 37.6)

State	Prevalence	95% Confidence Interval
Missouri	30.2	(28.6, 31.9)
Montana	26.4	(24.9, 27.9)
Nebraska	30.2	(29.2, 31.3)
Nevada	27.7	(25.4, 30.1)
New Hampshire	27.4	(25.8, 29.1)
New Jersey	26.9	(25.7, 28.1)
New Mexico	28.4	(27.0, 30.0)
New York	27.0	(25.6, 28.5)
North Carolina	29.7	(28.4, 31.0)
North Dakota	32.2	(30.5, 34.0)
Ohio	32.6	(31.2, 34.1)
Oklahoma	33.0	(31.7, 34.3)
Oregon	27.9	(26.3, 29.6)
Pennsylvania	30.2	(28.9, 31.4)
Puerto Rico	28.3	(26.8, 29.8)
Rhode Island	27.0	(25.4, 28.6)
South Carolina	32.1	(30.9, 33.3)
South Dakota	29.8	(27.9, 31.8)
Tennessee	31.2	(29.3, 33.2)
Texas	31.9	(30.6, 33.3)
Utah	25.7	(24.9, 26.6)
Vermont	24.8	(23.5, 26.1)
Virginia	28.5	(27.2, 29.7)
Washington	27.3	(26.0, 28.5)
West Virginia	35.7	(34.2, 37.2)
Wisconsin	31.2	(29.6, 32.8)
Wyoming	29.5	(27.5, 31.5)

¶ Prevalence estimates reflect BRFSS methodological changes started in 2011. These estimates should not be compared to prevalence estimates before 2011.
Source: Behavioral Risk Factor Surveillance System, CDC.

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New Obesity Projections

- If current trends continue, 43% of U.S. adults will be obese and **obesity spending will quadruple to $344 billion by 2018**
- **However, if obesity rates are instead held at current levels, the U.S. would save nearly $200 billion per year in health care costs**
- In the "worst states" the obesity rate is projected to be >50%
- In the "best states" the obesity rate is projected to be >33%

http://www.fightchronicdisease.org/media/statements/pfcd/ObesityRates.cfm

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Co-Morbid Conditions to Obesity

Type 2 Diabetes

- In 2012 there were 86 million people in U.S. w/pre-diabetes (up 7 million from 2010) www.diabetes.org
- 29.1 million type 2 diabetics (11.3% of adult population w/8.1 million undiagnosed) www.diabetes.org
- $218 billion per year total economic impact of diabetes (10% of all healthcare exp)
- http://www.diabetes.org/diabetes-basics/diabetes-statistics/
- Estimated more than 250,000 deaths per year related to diabetes (7th leading cause of death) http://www.diabetes.org/diabetes-statistics.jsp
- How many of these patients are yours?

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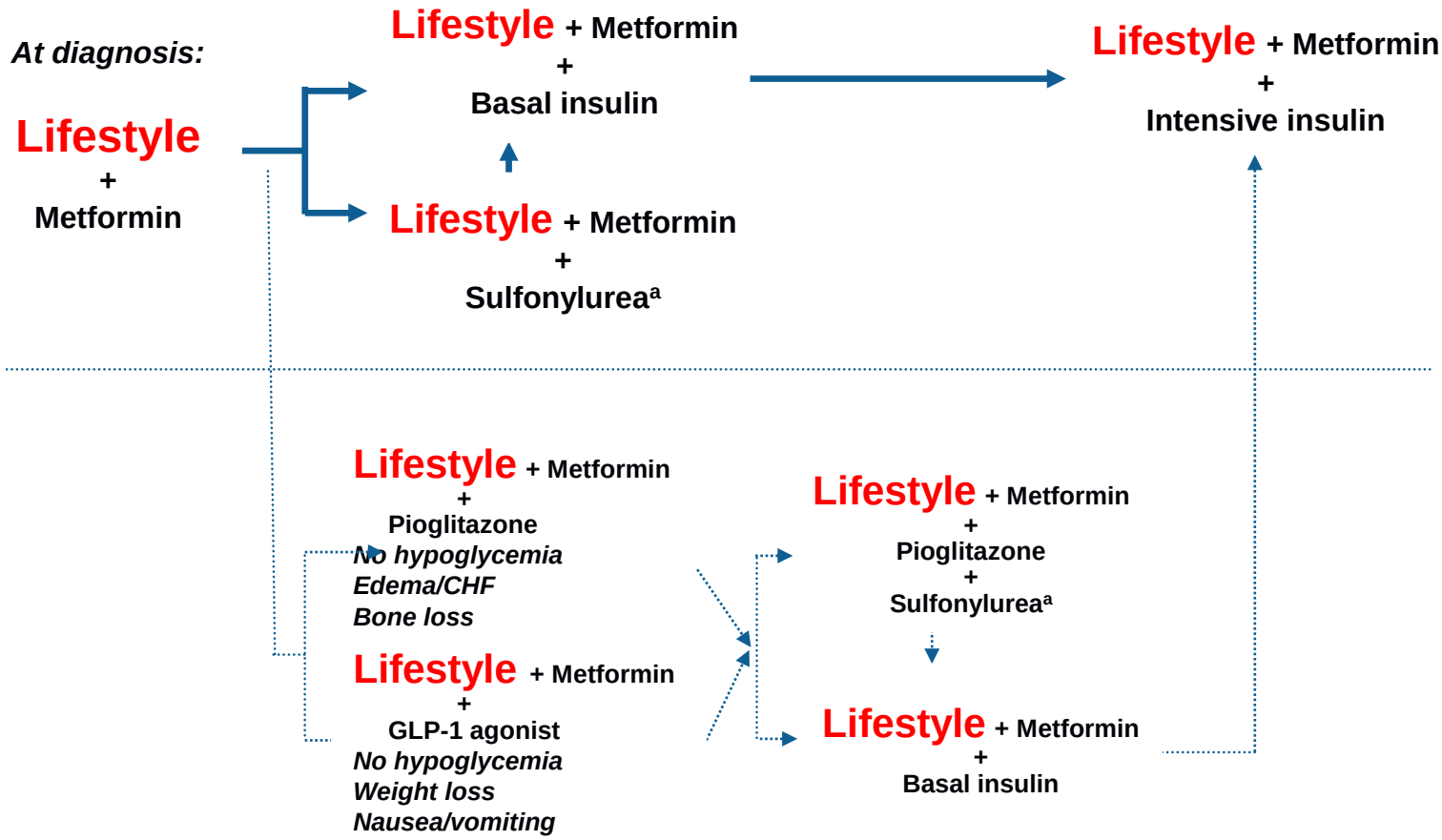
ADA/EASD treatment algorithm for Type 2 diabetes



Reinforce lifestyle interventions at every visit

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Metformin Package Insert

- GLUCOPHAGE (metformin hydrochloride tablets) and GLUCOPHAGE XR (metformin hydrochloride extended-release tablets), as monotherapy, *are indicated as an adjunct to diet and exercise* to improve glycemic control in patients with type 2 diabetes. GLUCOPHAGE is indicated in patients 10 years of age and older, and GLUCOPHAGE XR is indicated in patients 17 years of age and older.
- GLUCOPHAGE or GLUCOPHAGE XR may be used concomitantly with a sulfonylurea or insulin to improve glycemic control in adults (17 years of age and older).

www.rxlist.com

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Januvia® Package Insert

- **HIGHLIGHTS OF PRESCRIBING INFORMATION**
- **These highlights do not include all the information needed to use**
- **JANUVIA safely and effectively. See full prescribing information**
- **for JANUVIA.**
- **JANUVIA® (sitagliptin) Tablets**
- **Initial U.S. Approval: 2006**
- **----------RECENT MAJOR CHANGES ----------**
- Dosage and Administration
- Patients with Renal Insufficiency (2.2) 04/2011
- Warnings and Precautions
- Renal Impairment (5.2) 04/2011
- **----------INDICATIONS AND USAGE----------**
- JANUVIA is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
- http://www.januvia.com/sitagliptin/januvia/consumer/prescribing-information-for-januvia/index.jsp

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Tradjenta® Package Insert

- TRADJENTA is a dipeptidyl peptidase-4 (DPP-4) inhibitor that is used along with diet and exercise to lower blood sugar in adults with type 2 diabetes. TRADJENTA is not for people with type 1 diabetes or for people with diabetic ketoacidosis (increased ketones
- in the blood or urine). It is not known if TRADJENTA is safe and effective when used with insulin.
- Please read the Important Safety Information and Patient Information.

http://www.tradjenta.com/?sc=TRAWEBGOOGLE10&utm_source=google&utm_medium=cpc&utm_term=tradjenta&utm_campaign=decision_-_branded

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Hyperlipidemia

- 107 million people w/high cholesterol http://www.americanheart.org/presenter.jhtml?identifier=4506
- 37 million w/readings of 240mg/dL (high risk) or higher http://www.americanheart.org/presenter.jhtml?identifier=4506
- *Average* blood cholesterol level in adult Americans is about 203 mg/dL http://www.cdc.gov/nchs/hus.htm
- Approximately 17% of all Americans have high cholesterol regardless of race
- How many are your patients already?

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Is Current Treatment Method Working?

- 70% of high-risk patients w/CHD are not achieving the NCEP ATP III-recommended goal of LDL-C ≤70 mg/dL
  http://www.medscape.org/viewprogram/31866?src=cmemp
- ≈ 2/3 of people with a high risk of CHD who meet the criteria for lipid-lowering drug therapy are not taking medication
  http://www.medscape.org/viewprogram/31866?src=cmemp
- Adherence rates to statin medications have been shown to decline to 50% by 5 years
  http://www.medscape.org/viewprogram/31866?src=cmemp

Committee on Cardiovascular and Metabolic Diseases

CCMD

CCMDweb.org

Atherogenic Cholesterol-Lowering Drug Therapy to Reduce ASCVD Risk

- Low or moderate risk: 3-month lifestyle trial before drug therapy
- Very-high risk: simultaneous drug and lifestyle therapy*

1. Initiate statin therapy*
2. If goal not achieved, intensify statin therapy
3. If goal not achieved, intensify statin therapy, add non-statin drug or refer to lipid specialist
4. Monitor response & adherence every 4-12 mos

- Moderate- or high-intensity statin is first-line therapy*
  - Moderate-intensity lowers LDL by 30% to <50%
  - High-intensity lowers LDL by ≥50%
- Non-statin therapies may be used for statin-intolerant subjects
- Very high TG (≥500 mg/dL): TG-lowering drug may be considered for first line to prevent pancreatitis
- Manage atherosclerotic CVD risk factors
- Goals should be achieved in ~6 months

ASCVD=atherosclerotic cardiovascular disease
*Unless contraindicated

Jacobson TA, et al. *J Clin Lipidol*. 2014;8:473-488.

Lipitor Package Insert

- **Benefits of LIPITOR**
- **LIPITOR Lowers Cholesterol**
- Along with diet and exercise, LIPITOR is proven to*:
- Lower LDL ("bad" cholesterol) by 39-60%
- Lower triglycerides (a type of fat found in the blood) by 19-37%
- Raise HDL ("good" cholesterol) by 5-9%
- *Average effects depending on dose.
- LIPITOR may start working within 2 weeks. At your next doctor's visit, your blood tests may show lower cholesterol numbers. When you begin to see these results, you'll feel more motivated. Motivation is key to making lifestyle changes. This should include exercising and eating healthier. All these changes put you on the path to better heart health.

www.lipitor.com

Crestor Package Insert

- **Indications:**
- CRESTOR is indicated as an adjunct to diet to reduce elevated Total-C, LDL-C, ApoB, non-HDL-C, and triglycerides, and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia and to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels
- CRESTOR is indicated to reduce the risk of myocardial infarction, stroke, and arterial revascularization procedures in patients without clinically evident coronary heart disease but with an increased risk of cardiovascular disease (CVD) based on age (men ≥50 and women ≥60), high-sensitivity C-reactive protein (hsCRP) ≥2 mg/L, and the presence of at least one additional CVD risk factor, such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease
- http://www.crestortouchpoints.com

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Vytorin Package Insert

- **HIGHLIGHTS OF PRESCRIBING INFORMATION**
- **These highlights do not include all the information needed to use**
- **VYTORIN safely and effectively. See full prescribing information**
- **for VYTORIN.**
- **VYTORIN (ezetimibe/simvastatin) Tablets**
- **Initial U.S. Approval: 2004**
- **----------RECENT MAJOR CHANGES ----------**
- Dosage and Administration
- Recommended Dosing (2.1) 06/2011
- Restricted Dosing for 10/80 mg (2.2) 06/2011
- Coadministration with Other Drugs (2.3) 06/2011
- Patients with Homozygous Familial Hypercholesterolemia (2.4)
- 06/2011
- Chinese Patients Taking Lipid-Modifying Doses (≥1 g/day Niacin) of
- Niacin-Containing Products (2.8) 06/2011
- Contraindications (4) 06/2011
- Warnings and Precautions
- Myopathy/Rhabdomyolysis (5.1) 06/2011
- Liver Enzymes (5.2) 06/2011
- **----------INDICATIONS AND USAGE----------**
- VYTORIN®, which contains a cholesterol absorption inhibitor and an
- HMG-CoA reductase inhibitor (statin), is ***indicated as adjunctive***
- ***therapy to diet*** to:
- • reduce elevated total C, LDL-C, Apo B, TG, and non-HDL-C, and to
- increase HDL-C in patients with primary (heterozygous familial and
- [illegible] dyslipidemia or mixed [illegible] (1.1)

Zocor/Simvastatin Package Insert

- **HIGHLIGHTS OF PRESCRIBING INFORMATION**
- **These highlights do not include all the information needed to use**
- **ZOCOR safely and effectively. See full prescribing information for**
- **ZOCOR.**
- **ZOCOR (simvastatin) Tablets**
- **Initial U.S. Approval: 1991**
- **----------RECENT MAJOR CHANGES ----------**
- Dosage and Administration
- Recommended Dosing (2.1) 06/2011
- Restricted Dosing for 80 mg (2.2) 06/2011
- Coadministration with Other Drugs (2.3) 06/2011
- Patients with Homozygous Familial
- Hypercholesterolemia (2.4) 06/2011
- Chinese Patients Taking Lipid-Modifying Doses
- (≥1 g/day Niacin) of Niacin-Containing Products (2.7) 06/2011
- Contraindications (4) 06/2011
- Warnings and Precautions
- Myopathy/Rhabdomyolysis (5.1) 06/2011
- Liver Dysfunction (5.2) 06/2011
- **----------INDICATIONS AND USAGE----------**
- ZOCOR® is an HMG-CoA reductase inhibitor (statin) *indicated as an adjunctive therapy to diet.*

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Hypertension

- 75 million people in U.S. have high blood pressure (http://thebloodpressurecenter.com/high-blood-pressure/)
- 1 in 3 adults in U.S. has high blood pressure http://www.americanheart.org/presenter.jhtml?identifier=4621
- 56% do not have HBP under control http://www.americanheart.org/presenter.jhtml?identifier=4621
- From 1996 to 2006 deaths from hypertension increased by 48% http://www.americanheart.org/presenter.jhtml?identifier=4621
- Is the current treatment strategy working?

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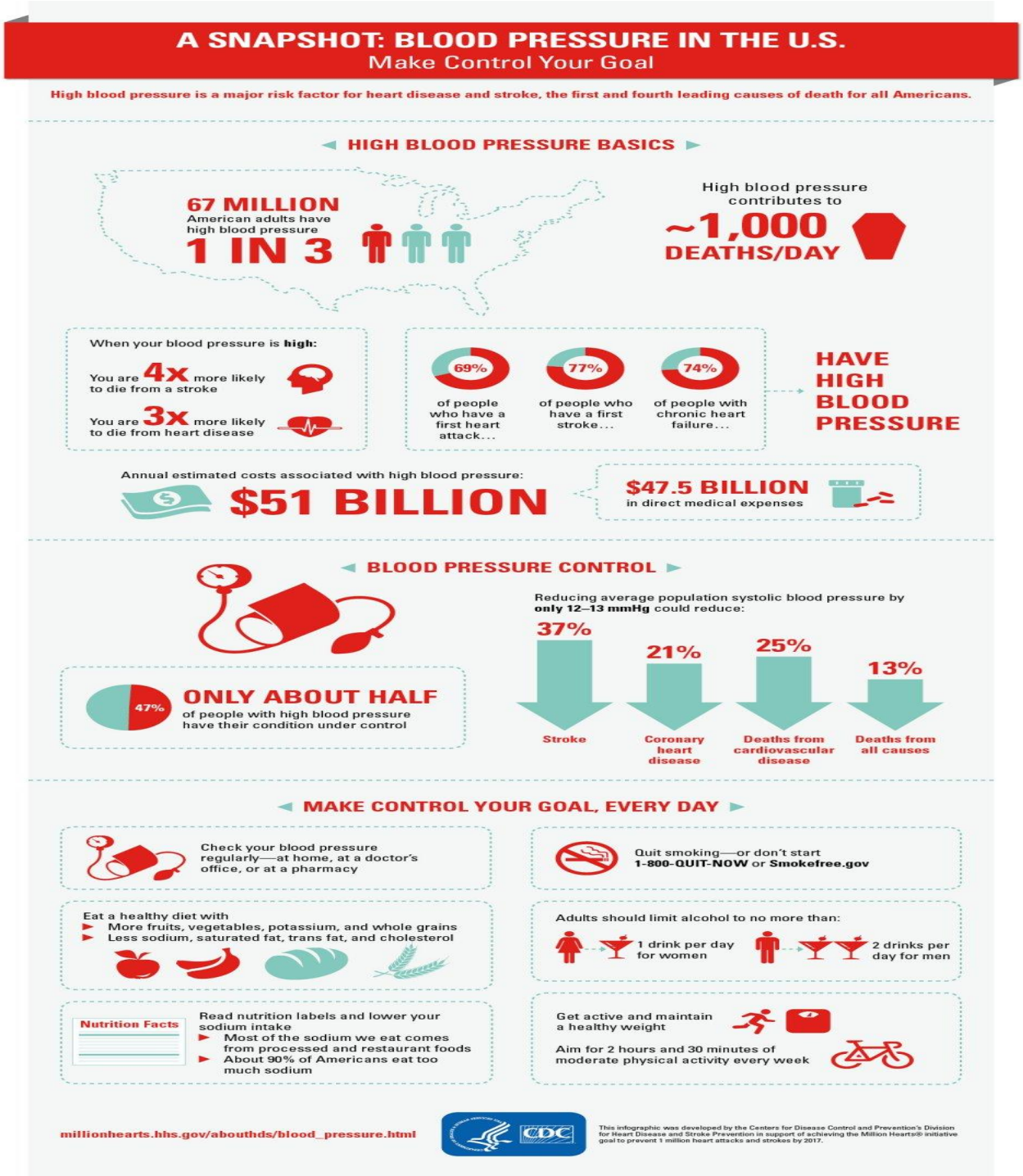

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Committee on Cardiovascular and Metabolic Diseases

CCMD

CCMDweb.org

Hypertension Management Algorithm: General Population—No Diabetes or CKD

Age ≥18 yrs—no diabetes or CKD

1

- Implement lifestyle interventions
- Continue throughout management

2

- Set BP goal
- Initiate BP-lowering therapy

Age ≥60	Age <60
BP goal <150/90	BP goal <140/90
Nonblack	Black

Therapy *choices—alone or in combo*
Thiazide-type diuretic
ACEI
ARB
CCB
Avoid ACEI-ARB combo

Therapy choices—*alone or in combo*
Thiazide-type diuretic
CCB

Select treatment titration strategy
Maximize Drug 1 before adding Drug 2
Add Drug 2 before reaching max dose of Drug 1
Start with 2 drugs (separate or fixed dose)

JNC 8=Eighth Joint National Committee
ACEI=angiotensin-converting enzyme inhibitor; ARB=angiotensin receptor blocker; BP=blood pressure; CCB=calcium channel blocker; CKD=chronic kidney disease

James PA, et al. *JAMA*. 2014;311(5):507-520.

STUDY: Reliance on Medication Will Not Lower Heart Risks

- Markers for predicting future CV distress (C-Reactive Protein and/or homocysteine) remained in place *"regardless of the medications being taken for high cholesterol, diabetes and high blood pressure."*
- *"Lifestyle changes and better food choices must be incorporated to make any real difference. The emphasis must be redirected to prevention, according to researchers."*

PHARMACY TIMES: JULY 2008; Page 18

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Where Can an Obese Patient Turn for Help?

What Kind of Counseling is Available in the Marketplace?

- Group
  - Hospitals via dieticians & CDEs
  - Endocrinologists
  - Support groups
  - Pharmacies
- Online
  - ADA
  - AADE
  - Drug companies
  - Diabetes groups
- One to one?????

Where is the Focus of Diabetes Counselors?

- Dieticians – Focus on Nutrition
- CDEs – Focus normally determined by area of specialty
- Nurses – Mechanical means of care
- Pharmacists – Medication management

* Just as in most situations the focus is on the area(s) in which the counselor has the most comfort or knowledge

New Opportunity – Health Coaching

- Why is this different?
  - Focus on the whole patient
  - Provides not only education but motivation
  - Provides accountability
  - Perfect liaison between patient and others on the healthcare team
- This role is ideal for pharmacists!

Why Pharmacists?

- Compared to competition in the weight loss industry pharmacists:
  - Are highly trained
  - Have access to information on patient's overall health condition
  - Have greater knowledge of how patient's current lifestyle choices are affecting their health
  - Easily communicate with other health care professionals to coordinate care
  - Have knowledge of co-morbid conditions associated with obesity
  - Are conveniently located in almost every town…large or small
  - Patients already see a pharmacist at least on a monthly basis

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Are Insurance Companies/3rd Party Payers Interested in Paying Pharmacists for Obesity Treatment or Prevention?

Why Insurers Don't Pay

- No health care professional involvement with any commercial program
- Commercial programs are only now connecting obesity with other medical conditions
- Physician "programs" focusing on medication or short term solutions
- Insurers know that the ONLY proven long term answer is a commitment to lifestyle modification by the patient
- No documentation of outcomes

CMS: Now Paying for Intensive Behavioral Therapy for Obesity

The Centers for Medicare and Medicaid Services (CMS) proposes the following:

"The evidence is adequate to conclude that intensive behavioral therapy for obesity is reasonable and necessary for the prevention or early detection of illness or disability…. under Part A or Part B"

CMS: Payment for Intensive Behavioral Therapy for Obesity

Screening for obesity in adults using measurement of BMI Dietary (nutritional) assessment; and intensive behavioral counseling and behavioral therapy to promote sustained weight loss through high intensity interventions on diet and exercise.

* 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 assistance/support and to adjust the treatment plan as needed, including referral to more intensive or specialized treatment.

CMS: Payment for Intensive Behavioral Therapy for Obesity

For Medicare beneficiaries with obesity, …whose counseling is furnished by a qualified primary care physician or other primary care practitioner and in a primary care setting, CMS proposes to cover:

*One face to face visit every week for the first month;

*One face to face visit every other week for months 2-6;

*One face to face visit every month for months 7-12.

***At the six month visit, a reassessment of obesity and a determination of the amount of weight loss should be performed. To be eligible for additional face to face visits occurring once a month for an additional six months, beneficiaries must have achieved a reduction in weight of at least 3kg (≈ 6.6lbs) over the course of the first six months of intensive therapy.

JAPhA Study Results 6/14

- Evaluation of a pharmacist led, 6 month weight loss program in obese patients
  - 5 A's
  - CMS recommendations followed
  - Only 12 patients
- Conclusions:
  - W/projected provider shortages pharmacists could be ideal providers of weight loss services!
  - Pharmacists are accessible HC providers who can effectively provide intense obesity counseling via CMS guidelines Journal of the American pharmacists Association Vol 54, #3 May/June 2014

CMS tells family physicians that pharmacist-provided services may be billed as incident-to service!!!

- Significant in that this is the first time CMS has allowed pharmacists to be considered a part of the "medical team."
- Could be a major first step in gaining independent provider status
- May enable billing for "intense obesity counseling" through physician partners

http://www.pharmacist.com/cms-tells-family-physicians-pharmacist-provided-services-may-be-billed-incident-4

Where Do Pharmacists Start?

- The time is NOW! Pharmacists must seize this opportunity to become a real part of the healthcare team
- Address an issue affecting almost ¾ of the U.S. population…obesity
- Education is the answer for our patients
- This may be “the final frontier” for our profession
- Both physicians & insurers are mandated to address obesity! Contact them!

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Where Do Pharmacists Start?

- Begin to educate yourselves
  - Understand the power that your recommendations have!
  - Everything that a health coach needs is found in the community pharmacist
  - Your patients trust in the knowledge that you share
  - Your patients NEED YOU!

What is the role of Nutrition in Obesity?

- Diets don't work!
- Whatever a patient does to lose weight they MUST continue for the results to last!
- Good food vs good nutrition
- Patient must be "on board" with nutritional choices
- Trial and error learning
- Do macronutrient ratios make a difference?

Macronutrient Ratios: Carbs

- Carbohydrates: The more complex the better
  - Whole grains, vegetables, legumes, nuts and seeds
  - Contain more complex chains of sugars and also usually contain some fiber, protein and/or healthy fats, as well as important vitamins and minerals
  - Utilize/burn almost as many calories to digest as they provide (watch as this is a generalization!)
  - Choose these foods for the nutrition they provide vs only the lower calories
  - Well balanced diet should contain 45-65%

Macronutrient Ratios: Proteins

- Proteins: Everyone can benefit from adding more plant based proteins to their diet
  - beans, peas, quinoa and lentils are also rich in other nutrients like fiber, vitamins and minerals
  - Low-fat dairy and eggs also contain protein
  - Meat eaters: choose lean cuts like pork and beef tenderloin (filet), chicken and fish (some also contain omega 3 fatty acids
  - Beware of serving size! 4-6oz
  - Well balanced diet should contain 15-25%

Macronutrient Ratios: Fats

- Yes! There are “good” fats!
- Healthy fats can actually improve our health, lower our risk for heart disease and improve the function and development our brains (omega 3s)
- Choose mostly plant based or fish based fats
- Avocados, nuts and seeds (Read labels on nuts)
- Cook with olive, grape seed, avocado, sunflower, almond or palm oils
- Well balanced diet should contain 15-25%

Exercise: Important for healthy lifestyle?

Exercise:

- Improves your body's use of insulin
- Improves muscle strength
- Increases bone density and strength
- Lowers blood pressure & blood sugar
- Helps to protect against heart and blood vessel disease by lowering 'bad' LDL cholesterol

American Diabetes Association

Exercise: Important for healthy lifestyle? (continued)

Exercise:

- Improves blood circulation and reducing risk of heart disease
- Increases energy level and enhances work capacity
- Reduces stress, promotes relaxation, and releases tension and anxiety
- Studies have shown A1C decrease similar to Metformin (American Diabetes Association)

What does a lifestyle modification program need?

- Organization
- Structure
- Accountability
- Educational Materials…Knowledge is Power!
- Follow up plan

Where do pharmacists turn for help?

- Determine: Can I do it myself?
- Local resources…All can use pharmacist input…All can offer things you can not
  - YMCA
  - Fitness Centers
  - Church groups
  - Senior groups

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Commercial Plans

- Weight Watchers
  - Offer space for meetings
  - Offer your time to speak
- Creative Pharmacist
  - Specific for diabetes & heart health
- Take Charge Pharmacist Lifestyle – Health – Nutrition System
  - Specific obesity treatment strategies for community pharmacists
  - Allows community pharmacists to work under a uniform, structured platform

Finally

- Get involved…don't be afraid of change
- Chart the future for community pharmacy
- Empower your patients
- Improve the health of your patients
- Show physicians that you are willing to partner with them
- Show insurers that you can help them address their #1 health issue

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Questions???

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