# Integrated Management of the Complexities of Cardiometabolic Diseases: A Patient-Centric Team Approach

Supported by an educational grant from Merck & Co., Inc.

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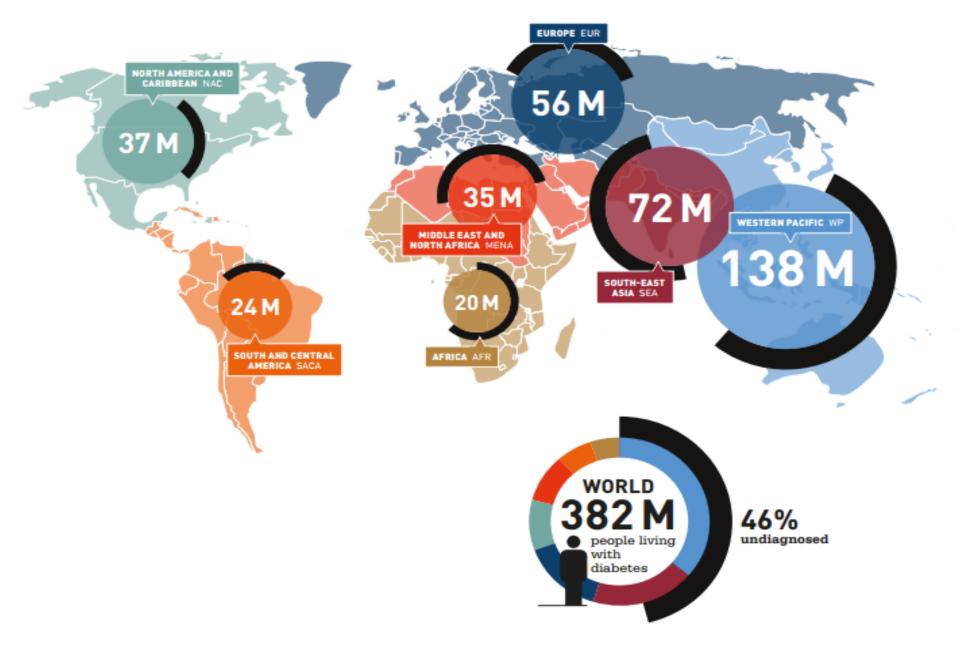
- The session is being videotaped. Please turn off all cell phones and pagers.
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### **Opening Remarks**

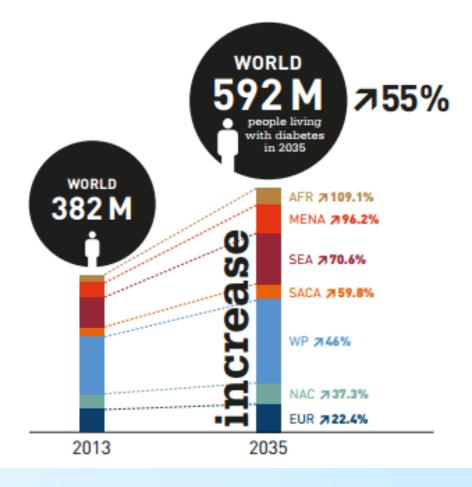
Lawrence Blonde, MD, FACP, FACE
Director, Ochsner Diabetes Clinical Research Unit
Department of Endocrinology
Ochsner Medical Center
New Orleans, Louisiana

## An Integrated Approach: Models for Comprehensive Diabetes Care

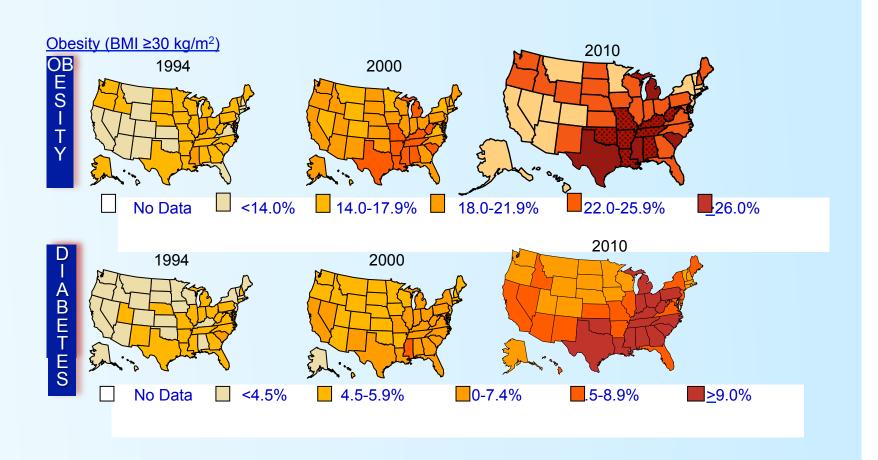
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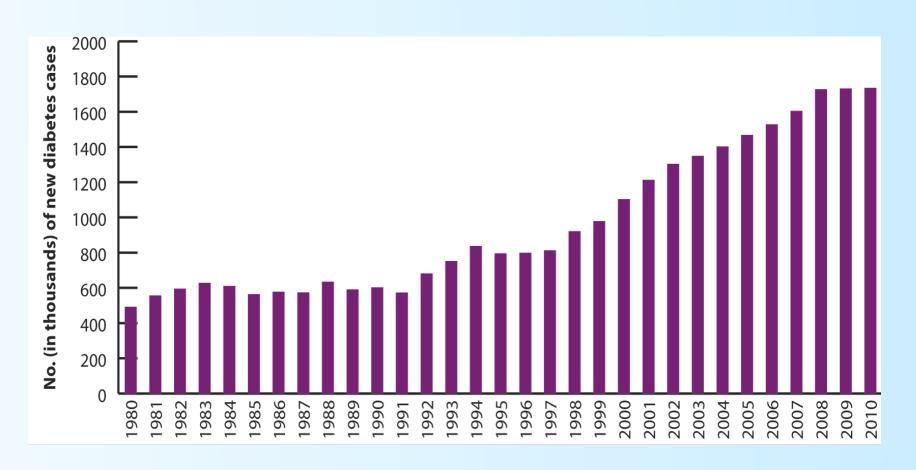
Diabetes is a huge and growing problem, and the costs to society are high and escalating.



## Geography Matters: Age-adjusted Percentage of U.S. Adults with Obesity or Diagnosed Diabetes

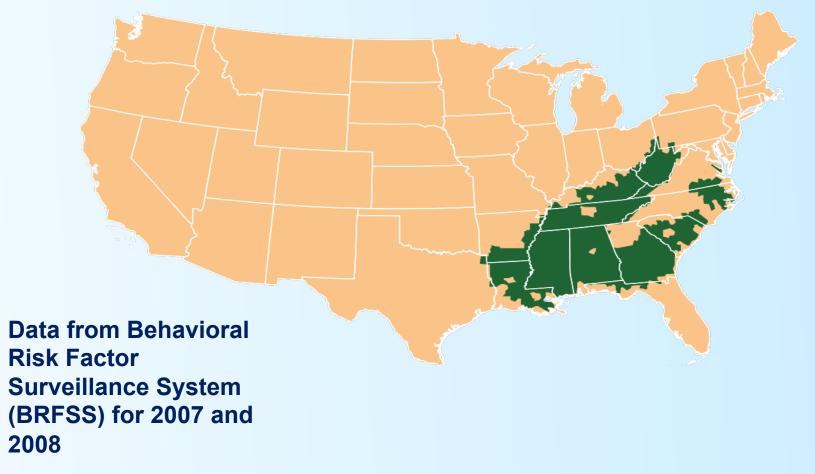


## The Diabetes Epidemic: Annual Number of New Cases of Diabetes Diagnosed Among US Adults, Aged 18-79; 1980-2010

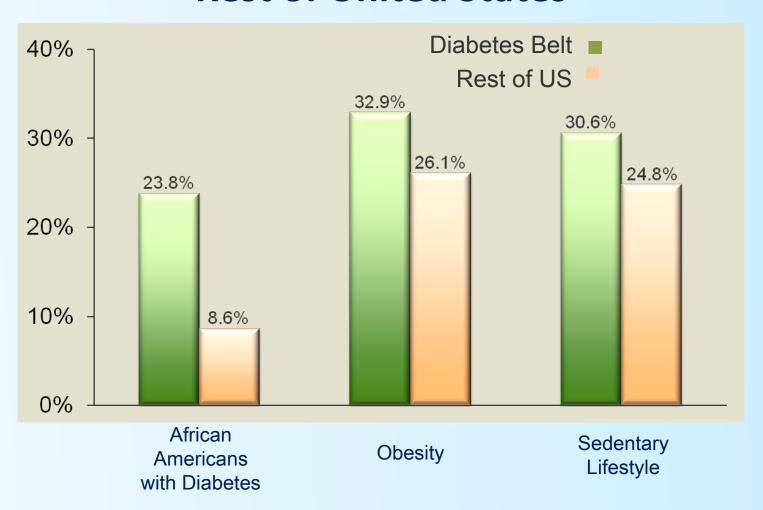


#### "Diabetes Belt" - United States

Prevalence of Population with Diagnosed Diabetes
Diabetes Belt = 11.7%
Rest of U.S. = 8.5%



#### Features of the Diabetes Belt vs Rest of United States



## AACE 2011/2013 and ADA 2014 Goals for Glycemic Control

Target Treatment Goals	AACE 2011/2013 <sup>1,2</sup>	ADA 2014 <sup>3</sup>						
A1C	≤6.5%	<7.0%*						
Fasting glucose	Fasting and premeal plasma glucose: <110 mg/dL	Preprandial capillary plasma glucose: 70-130 mg/dL*						
Postprandial glucose	2-hour postprandial glucose: <140 mg/dL	Peak postprandial capillary plasma glucose: <180 mg/dL†						
AACE=American Association of Clinical Endocrinologists ADA=American Diabetes Association								

<sup>\*</sup>Goals should be individualized based on: duration of diabetes, age/life expectancy, comorbid conditions, known CVD or advanced microvascular complications, hypoglycemia unawareness, and individual patient considerations. More or less stringent glycemic goals may be appropriate for individual patients.

<sup>†</sup>Postprandial glucose may be targeted if A1C goals are not met despite reaching preprandial glucose goals. Postprandial glucose measurements should be made 1-2 hours after the beginning of the meal, generally peak levels in patients with diabetes.

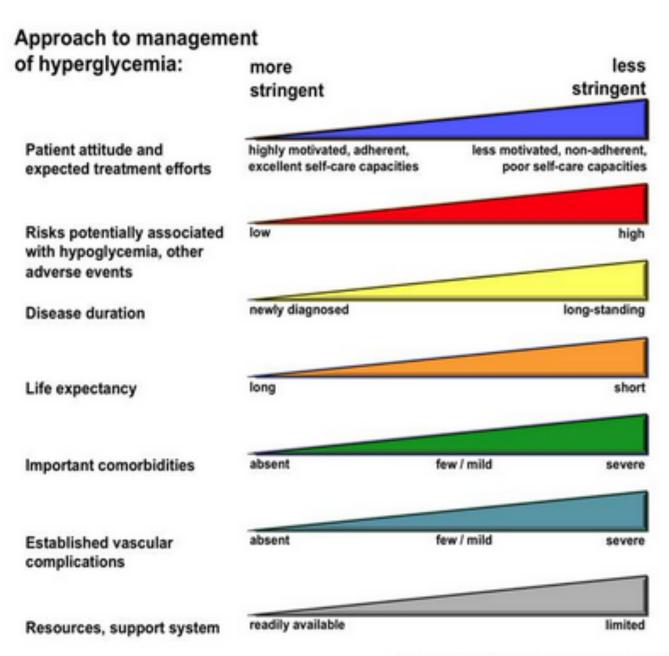


Figure 1

Diabetes Care, Diabetologia. 19 April 2012 [Epub ahead of print] (Adapted with permission from: Ismail-Beigi F, et al. Ann Intern Med 2011; 154:554)

## Reducing T2DM Complications Multidimensional Treatment Goals

### Comprehensive Diabetes Management

Lipidsa BMI BP A1c <25 mg/kg<sup>2</sup> <7.0% LDL-C: <100 mg/dL <140/80 (<70 mg/dL with CVD) mm Hg HDL-C: >40 mg/dL in men (<130/80 >50 mg/dL in women mm Hg for <150 mg/dL TG: some people)

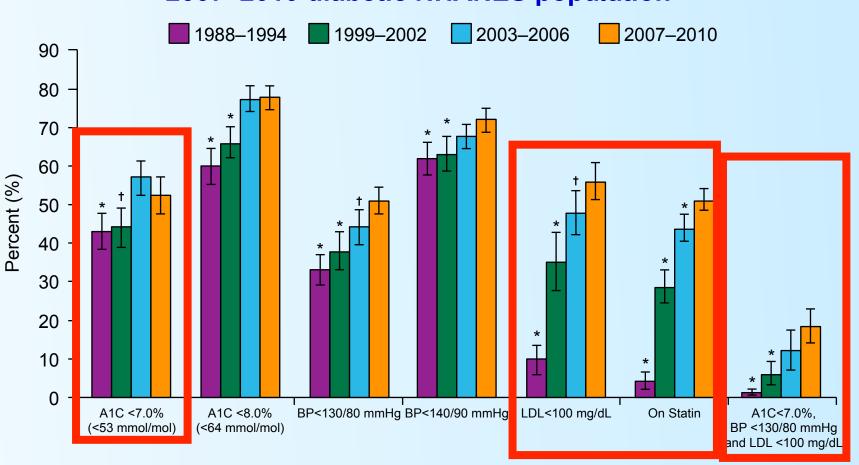
#### Lifestyle Modifications Healthy Diet; Exercise; Smoking Cessation

a2013 ACC/AHA guidelines on treatment of blood cholesterol: Based on 10-year ASCVD risk, use high-intensity (lower LDL-C by ≥50%) or moderate-intensity (lower LDL-C by 30% to <50%) statin therapy for patients aged 40-75 years with T2DM and initial LDL-C ≥70 mg/dL. A1c, glycated hemoglobin; ASCVD, atherosclerotic CVD; BMI, body mass index; BP, blood pressure; CVD, cardiovascular disease; HDL-C, low-density lipoprotein cholesterol; LDL-C, high-density lipoprotein cholesterol; TG, triglycerides.

ADA. Diabetes Care. 2014;37(suppl 1):S14-S80; Stone et al. Circulation. 2014;129(25 suppl 2):S1-S45.

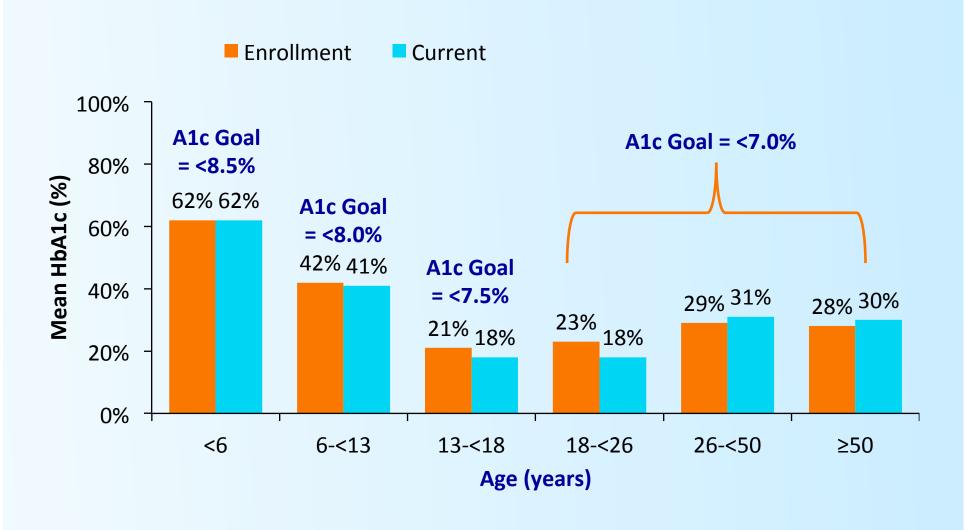
## Prevalence of Meeting ABC Goals Among Adults Aged ≥20 Years With Diagnosed Diabetes— NHANES 1988–2010

Estimates of age and sex standardized to the 2007–2010 diabetic NHANES population



Stark Casagrande S et al. Diabetes Care. 2013;36(8):2271-2279.

#### **Meeting ADA HbA1c Targets**



#### **End-Stage Renal Disease**

- Lower incidence of ESRD among those more recently diagnosed with T1D explained by improvements in glycemic and BP control over last several decades
- Intensive diabetes management, especially for glycemic control, remains important even in longstanding diabetes as it may delay the development of ESRD

#### ORIGINAL ARTICLE

#### Changes in Diabetes-Related Complications in the United States, 1990–2010

Edward W. Gregg, Ph.D., Yanfeng Li, M.D., Jing Wang, M.D., Nilka Rios Burrows, M.P.H., Mohammed K. Ali, M.B., Ch.B., Deborah Rolka, M.S., Desmond E. Williams, M.D., Ph.D., and Linda Geiss, M.A.

#### ABSTRACT

#### BACKGROUND

Preventive care for adults with diabetes has improved substantially in recent decades. We examined trends in the incidence of diabetes-related complications in the United States from 1990 through 2010.

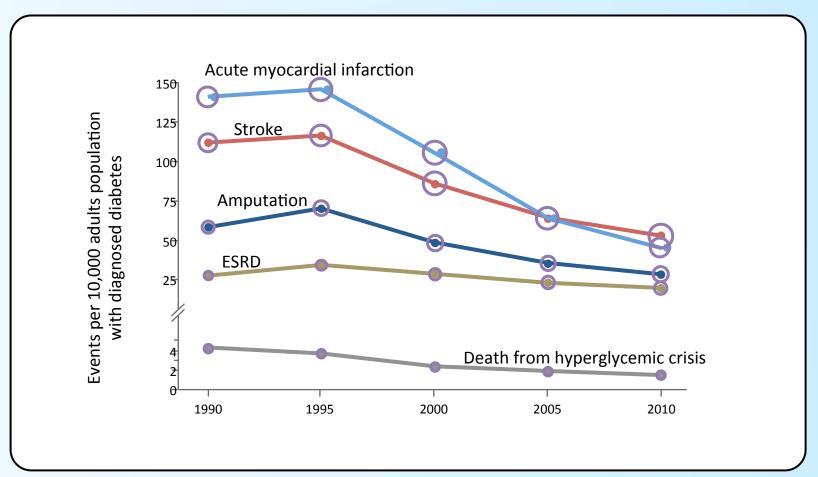
#### METHODS

We used data from the National Health Interview Survey, the National Hospital Discharge Survey, the U.S. Renal Data System, and the U.S. National Vital Statistics System to compare the incidences of lower-extremity amputation, end-stage renal disease, acute myocardial infarction, stroke, and death from hyperglycemic crisis between 1990 and 2010, with age standardized to the U.S. population in the year 2000.

#### RESULTS

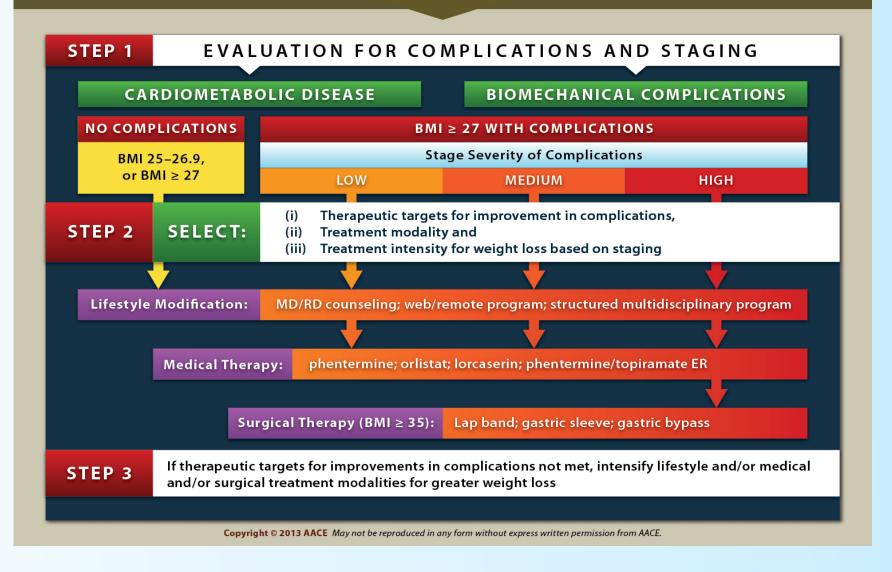
Rates of all five complications declined between 1990 and 2010, with the largest relative declines in acute myocardial infarction (-67.8%; 95% confidence interval [CI], -76.2 to -59.3) and death from hyperglycemic crisis (-64.4%; 95% CI, -68.0 to -60.9), followed by stroke and amputations, which each declined by approximately half (-52.7% and -51.4%, respectively); the smallest decline was in end-stage renal disease (-28.3%; 95% CI, -34.6 to -21.6). The greatest absolute decline was in the number of cases of acute myocardial infarction (95.6 fewer cases per 10,000 persons; 95% CI, 76.6 to 114.6), and the smallest absolute decline was in the number of deaths from hyperglycemic crisis (-2.7; 95% CI, -2.4 to -3.0). Rate reduc-

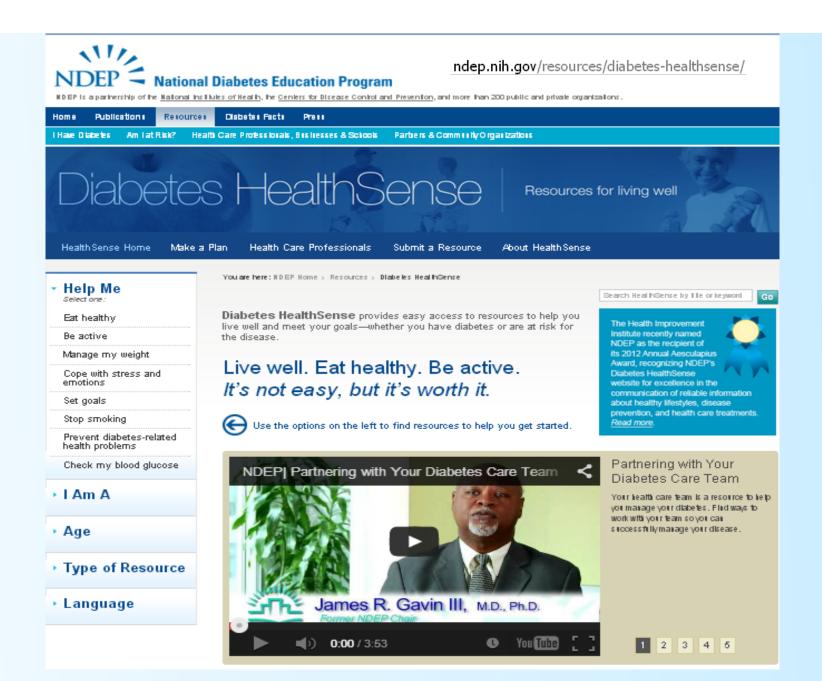
#### Trends in Age-standardized Rates of Diabetesrelated Complications among US Adults with and without Diagnosed Diabetes, 1990–2010





### COMPLICATIONS-CENTRIC MODEL FOR CARE OF THE OVERWEIGHT/OBESE PATIENT

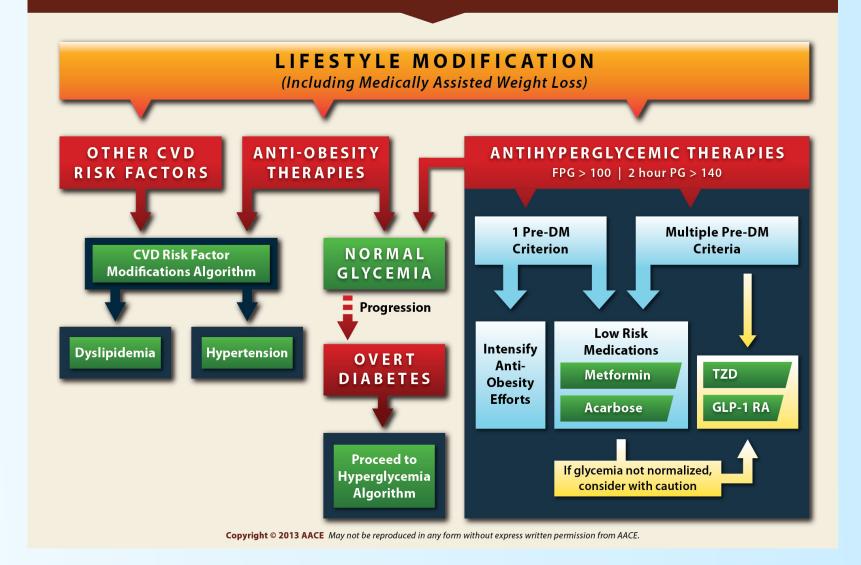


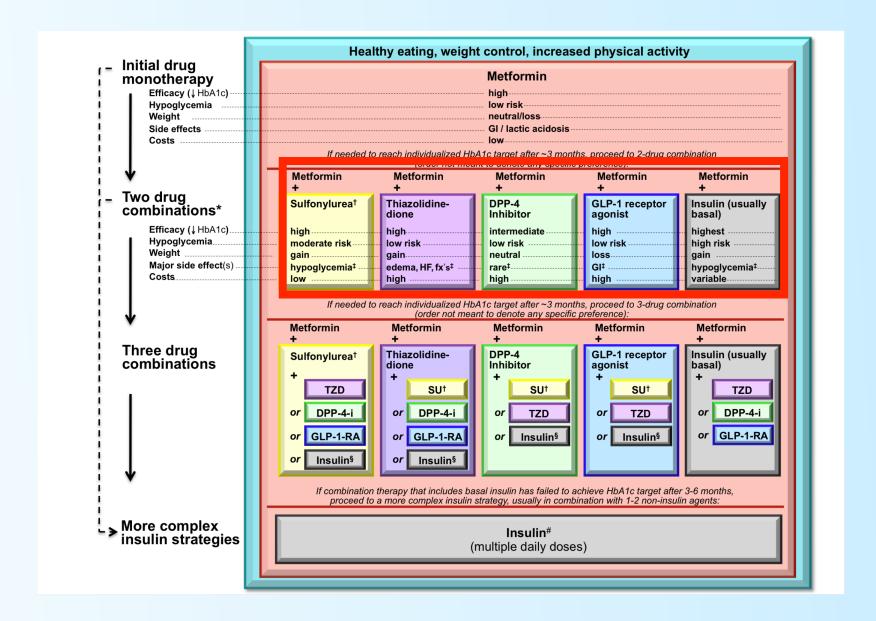




#### PREDIABETES ALGORITHM

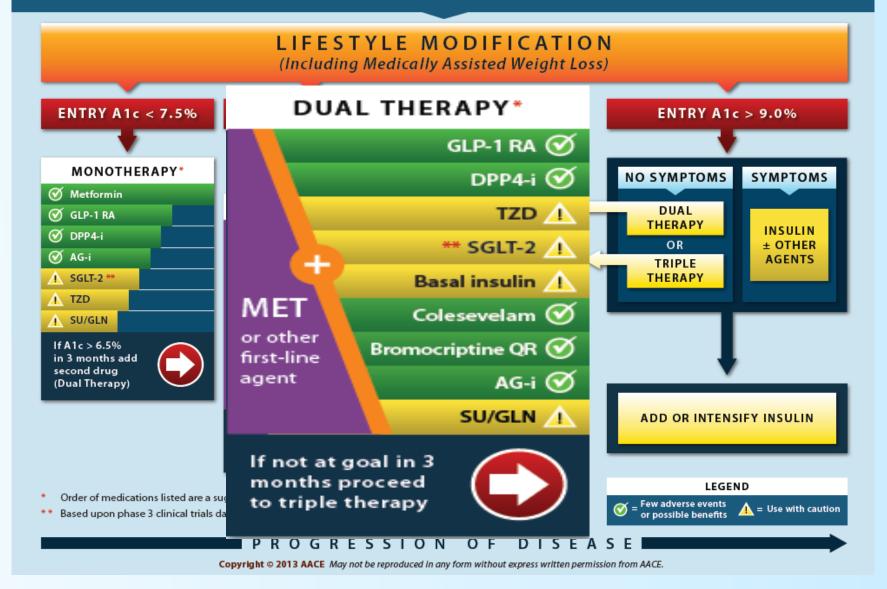
IFG (100-125) | IGT (140-199) | METABOLIC SYNDROME (NCEP 2005)







#### GLYCEMIC CONTROL ALGORITHM



AACE. Endocr Pract. 2013;19:329.







#### The Chronic Care Model

#### THE CHRONIC CARE MODEL

#### > MODEL ELEMENTS

Health System **Delivery System Design** Decision Support Clinical Information Systems Self-Management Support The Community Footnotes & Citations

- > THE MODEL TALKS
- > THE RAND EVALUATION
- > VERSIONS OF THE CCM
- > USING THE CCM IN YOUR WORK
- > 'TACKLING THE CHRONIC CARE CRISIS' CD
- > CCM GALLERY

CARE COORDINATION

PRACTICE CHANGE

PATIENT-CENTERED MEDICAL

GLOBAL WORK

EVIDENCE FOR BETTER CARE

#### > MODEL ELEMENTS

**Health System** Delivery System Design Decision Support Clinical Information Systems her in 1998 to test the Model nationally across varied Self-Management Support The Community

are system that encourage high-quality chronic disease ent support, delivery system design, decision support and ement, in combination, foster productive interactions rs with resources and expertise.

gs and target populations. The bottom line is healthier

Research Institute developed the CCM in the mid-1990s ess management, and organizing that literature in a new onth planning project supported by The Robert Wood al experts. It was then used to collect data and analyze ss Care".

es in the field of chronic care both from the research Model in their improvement efforts. We list more specific ve additional themes were incorporated into the CCM:

- Patient Safety (in Health System);
- Cultural competency (in Delivery System Design);
- Care coordination (in Health System and Clinical Information Systems) / to
- Community policies (in Community Resources and Policies); and
- Case management (in Delivery System Design).



NDEP is a partnership of the National Institutes of Health, the Centers for Disease Control and Prevention, and more than 200 public and private organizations.

Home	Public	ations	Resou	rces Diabetes Facts	Press		
I Have D	iabetes	Am I at R	Risk?	Health Care Professionals	, Businesses & Schools	Partners & Community Organizations	
Tengo dia	abetes	¿Corro rie	esgo?				
You are here: NDEP Home > Health Care Professionals, Businesses & Schools > Health Care Professionals > Practice Transformation for Physicians and Health Care Teams							

#### Practice Transformation

- Engage Leadership & Assess Practice
- Evidence-Based Care
- Information Systems
- Improve Practice Quality
- Clinical Decision Support
- Team-Based Care
- Patient-Centered Interactions
- Patient Care Coordination

Help Us Improve
The Practice Transformation
Website

Take the Survey



The Health Improvement Institute recently named NDEP as the recipient of its 2013 Annual Aesculapius Award, recognizing Practice Transformation for Physicians and Health Care Teams website for excellence in the communication of reliable information about healthy lifestyles, disease prevention, and health care treatments. Read more.

◀ Go Back

About the Practice Transformation Site

#### Practice Transformation for Physicians and Health Care Teams

The National Diabetes Education Program's (NDEP) free resource Practice Transformation for Physicians and Health Care Teams is based on the patient-centered medical home model and provides health care professionals with online tools to help them change their practices and improve care for people with diabetes.



Engage Leadership and Assess Your Practice



Provide Evidence-Based Care



Use Information Systems



Improve Practice Quality



Use Clinical Decision Support



Practice Team-Based Care



Enhance Patient-Centered Interactions



Improve Patient Care Coordination

#### **Building an Effective Diabetes Care Team**

No one can effectively manage diabetes alone, whether you have the disease or you're a physician caring for someone with it. "It's been known for years that diabetes requires a multidisciplinary team approach because there are so many components to its management," says Martin Abrahamson, M.D., Medical Director and Senior Vice President at Joslin Diabetes Center.

At Joslin, your team includes:

- Diabetes physicians
- Certified Diabetes Educators
- Nurses
- Dietitians
- Exercise Physiologists
- Nurse Practitioners
- Mental Health Counselors

#### **Ochsner Diabetes LifePlan**











Diagnosis

**Protocols** 

Diabetes BootCamp Diabetes Empowerment Diabetes Long-Term Management

## Care Coordination Is a Priority in Healthcare Quality Improvement<sup>1</sup>

- Care coordination activities associated with greater improvements in diabetes care include<sup>2</sup>
  - Incorporation of patient-centered care manager duties
  - Better use of EMR for messaging and patient tracking
  - Stronger integration of the care manager into the care team
- The PCMH is a care coordination model that is anticipated to provide benefits in<sup>3,4</sup>
  - Access to routine primary care
  - Delivery of preventive services
  - ED and hospital utilization
  - Chronic disease management
- PCMH may provide greater benefit to certain subsets of patients, such as those with more complex disease and/or higher resource utilization<sup>4</sup>

<sup>1.</sup> Hussey et al. JAMA Intern Med. 2014;174:742-48.

<sup>2.</sup> Taliani et al. Am J Manag Care. 2013;19:957-64.

<sup>3.</sup> Improving Chronic Illness Care. Care Coordination Model. http://www.improvingchroniccare.org/index.php?p=Care\_Coordination\_Model&s=353.

## Patient-Centered Medical Home as a Care Coordination Model

#### PATIENT-CENTERED MEDICAL HOME

- Accountability
- Patient support

Relationships and Agreements
Connectivity

Community agencies

Hospitals and emergency departments

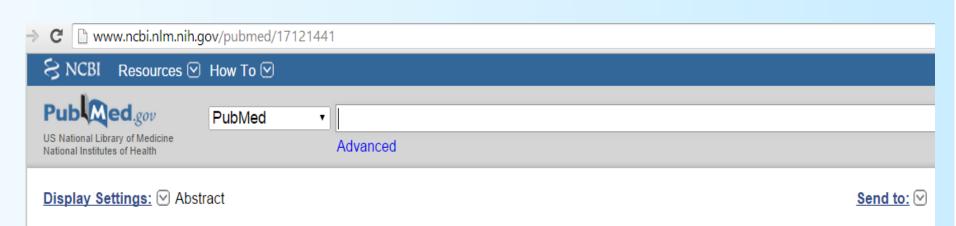
Medical specialists

Involved HCPs receive the information they need when they need it

Practice knows the status of all referrals/ transitions involving its panel

Patients report receiving help in coordinating care

High- quality referrals and transitions for providers and patients



J Sch Nurs. 2006 Dec;22(6):310-8.

#### The healthy learner model for student chronic condition management--part I.

Erickson CD<sup>1</sup>, Splett PL, Mullett SS, Heiman MB.

Author information

#### Abstract

A significant number of children have chronic health conditions that interfere with normal activities, including school attendance and active participation in the learning process. Management of students' chronic conditions is complex and requires an integrated system. Models to improve chronic disease management have been developed for the medical system and public health. Programs that address specific chronic disease management or coordinate school health services have been implemented in schools. Lacking is a comprehensive, integrated model that links schools, students, parents, health care, and other community providers. The Healthy Learner Model for chronic condition management identifies seven elements for creating, implementing, and sustaining an efficient and effective, comprehensive community-based system for improving the management of chronic conditions for school children. It has provided the framework for successful chronic condition management in an urban school district and is proposed for replication in other districts and communities.

PMID: 17121441 [PubMed - indexed for MEDLINE]







#### **Resources for Improving Care Coordination**

- National Committee for Quality Assurance (NCQA): http:// www.ncqa.org/PublicationsProducts/RecognitionProducts/ DRPProducts.aspx
- National Diabetes Education Program: http://ndep.nih.gov/hcpbusinesses-and-schools/practice-transformation/
- American Association of Diabetes Educators products and programs for improving individual practice: https://www.diabeteseducator.org/ ProfessionalResources/products/
- Improving Chronic Illness Care:http://www.improvingchroniccare.org/
- Improving Performance in Practice: http://www.ipipprogram.org/
- American Academy of Family Physicians: http://www.aafp.org/ practice-management/pcmh/overview.html
- National Center for Medical Home Implementation:
  - NY: http://www.medicalhomeinfo.org/state\_pages/new\_york.aspx
  - PA: http://www.medicalhomeinfo.org/state\_pages/pennsylvania.aspx
  - VT: http://www.medicalhomeinfo.org/state\_pages/vermont.aspx

#### **Quality Initiatives for Diabetes Care**

- National Healthcare Quality Report 2013 diabetes trends<sup>1</sup>
  - Improvements in adult hospital admissions for uncontrolled diabetes
  - Worsening rates of foot exams
  - Worsening rates of adult hospital admissions with short-term complications with worsening disparities between racial/ethnic subgroups
- National Quality Strategy (NQS)<sup>1,2</sup>
  - Part of the Affordable Care Act<sup>2</sup>
  - Emphasizes patient-centered, reliable, accessible, safe care<sup>2</sup>
- Physician Quality Reporting System (PQRS)
  - Many standards pertain to diabetes processes of care<sup>3</sup>
    - Example Diabetes Composite: Optimal Diabetes Care
    - Includes reaching A1C, LDL, BP targets; tobacco non-user; daily aspirin, as appropriate
  - Medicare payment reduction for failure to report data begins in 2015<sup>4</sup>

1. AHRQ. National Healthcare Quality Report 2013. http://www.ahrq.gov/research/findings/nhqrdr/index.html; 2. AHRQ. http://www.ahrq.gov/workingforquality/#; 3. CMS. 2014 PQRS measures list. http://www.apapracticecentral.org/update/2014/01-16/measures-list.pdf; 4. CMS. http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/pqrs/index.html.

AHRQ, Agency for Healthcare Research and Quality; CMS, Centers for Medicare and Medicaid Services.

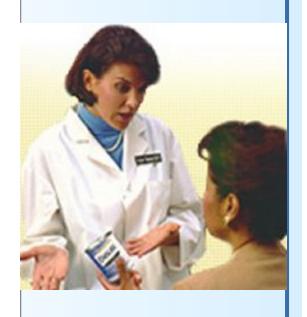
## An Integrated Approach: Models for Comprehensive Diabetes Care

- Type 2 Diabetes is epidemic in western societies; both T2DM and its complications have great personal and societal costs.
- Although lifestyle interventions are the cornerstone of therapy, most patients will also need pharmacologic treatments.
- Algorithms from ADA/EASD and AACE can help clinicians select among the some 15 classes of antihyperglycemic therapies.
  - --Both algorithms stress individualization of therapy
- Applying elements of the chronic care model including the medical home, may help clinicians to transform their practice and enhance care.
- Many resources, including the NDEP's Practice Transformation can assist clinicians and practices in these efforts.

# Overcoming Clinician/Patient Barriers to Treatment and Lifestyle Changes

Martha M. Funnell, MS, RN, CDE
Associate Research Scientist
Department of Learning Health Sciences
University of Michigan Medical School
Ann Arbor, Michigan

#### Ms. S



- 42 years old, type 2 diabetes and hypertension
- A1C is 9.4%; BP- 152/86
- BMI is 29
- On metformin 2000 mg, insulin glargine 25u
   qd, losartan, and atorvastatin
- Misses medicines "sometimes" and checks blood glucose levels "when she can"
- Frequently does not keep appointments
- Always promises to do better

# Why is she so frustrating?



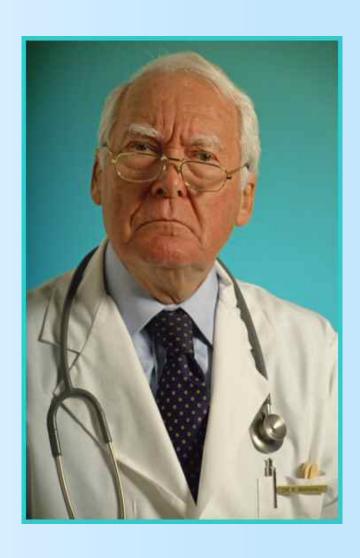
- Waste of time
- Her health is not important to her
- If she doesn't care, why should you?
- Makes us feel like a failure



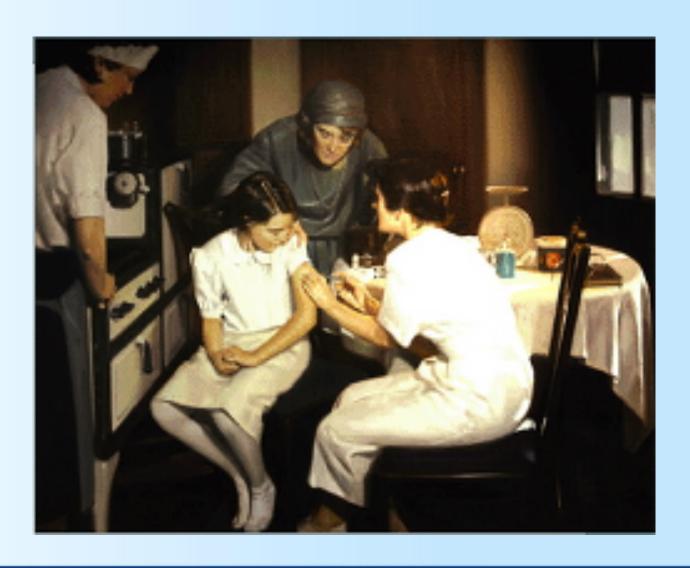
### Abracadabra

- 1. Better Communication Skills
- 2. Better Communication Skills
- 3. Better Communication Skills

# Communication Strategy: You Should



## Communication Strategy: I Know Best



# How's That Working?



### Patient Engagement: DAWN

(n=8,596; 17 countries)

 "Most people with diabetes are not actively engaged by their healthcare professionals to take control of their condition; education and psychosocial care are often unavailable."

## Medications



# How Are We Doing?

- Medication adherence rates range from 60% to 90% in diabetes
- Statin medications: 60.3% at 1 year; 48.8% at 5 years.
  - Rates were similar for beta-blockers and ACE inhibitors.

### What Can We Do?

- Physician communication is significantly positively correlated with patient medication-taking behaviors: risk 19% higher
- Communication training improves medication-taking by 1.62 times compared with physicians who did not receive training
- Strategies include patient-centered communication to increase patient understanding, improve the quality of decision-making, and increase self-efficacy and empowerment

#### Assessment

- How often?
  - About how often do you miss your...
  - During a typical month, what percent of the time do you miss your...
  - It's easy to forget to take your medicines. About how often does that happen to you?
- Why?
  - Is paying for your medicines a problem for you?
  - Are there times when you decide not to take your medicines? If so, why?
  - What gets in the way of taking your...
  - What would help you to be more faithful in taking your...

Gonzalez et al. Diabetes Care 2013;36:831-37.

- Risks and benefits
  - Have you ever heard of/read about this medicine?
  - What worries you most about this medicine?
  - How do you think this medicine will help you?
  - What do you think will happen if things stay the same?

#### Risks and benefits

- Have you ever heard of/read about this medicine?
- What worries you most about this medicine?
- How do you think this medicine will help you?
- What do you think will happen if things stay the same?
- What we know from the most recent studies is...
- Here is what is proven to work best...
- This is what the data show....
- Here is what my other patients have told me...
- Costs and coverage

- Ease of use:
  - Injection vs oral
  - Scheduling
  - Strategies for greatest benefit (eg, same time each day vs. bedtime)

#### Ease of use:

- Injection vs oral
- Scheduling
- Strategies for greatest benefit
- How will this fit into your schedule?
- What might get in your way of taking this medicine?
- Is there anything that would help you to be more faithful in taking this medicine?

# Talking About the "I" Word: It's Not About the Needle

- Setting the stage:
  - What have you heard about insulin?
  - What are your thoughts about taking insulin?
  - What do you think will be hardest for you?
  - What is your biggest worry?
  - What do you need to know to consider insulin?
  - Would you be willing to try it for 10 days?

# Talking About the "I" Word: It's Not About the Needle

- Setting the stage:
  - What have you heard about insulin?
  - What are your thoughts about taking insulin?
  - What do you think will be hardest for you?
  - What do you need to know to consider insulin?
  - Would you be willing to try it for 10 days?
- Closing the Deal:
  - You are not a failure
  - Insulin most effective/natural
  - Not your grandmother's insulin
  - Strategies to address fears
  - Would you be willing to try it for 10 days?
  - Manage expectations

# Self Monitoring of Blood Glucose



# Self Monitoring of Blood Glucose (SMBG)

- Increasing the Efficacy:
  - Tell me about your numbers
  - How to use the information
  - What to do when to call
  - Paired testing
    - Pre and 2 hours post food
    - Pre and post exercise
  - Structured testing<sup>1</sup>
    - 7 point testing for 3 days prior to appointment
    - Record results, meal size as SML, rate energy level and learning
    - Physicians were trained in reviewing for problem-solving/not blame (e.g., What did you learn?)

<sup>1</sup>Polonsky et al. Diabetes Care 2011;34:262-67.

# Lifestyle



#### DSME/S

- Diabetes self-management education is effective for improving clinical and quality of life outcomes, at least in the short-term.
- Diabetes self-management education is cost-effective.
- In DAWN2, 64% PWD and 35% family members had received formal diabetes education; 78/70% found it helpful.

Brown 1999; Norris 2001, 2002; Duncan 2009, 2011; Nicolucci t al. Diabet Med. 2013;30:767-77

# **DSME** Key Messages

- All types of diabetes need to be taken seriously
- Diabetes can be managed (not controlled)
- Effective self-management essential for positive outcomes
- Treatment will change over time and involves trial and error
- A collaborative partnership between patient, patient's family, and healthcare team essential for successful care
- Active and continued support and engagement is essential

Funnell M. Role of Diabetes Education in Patient Management. Therapy for Diabetes Mellitus and Related Disorders

# DSME: During a Clinical Visit

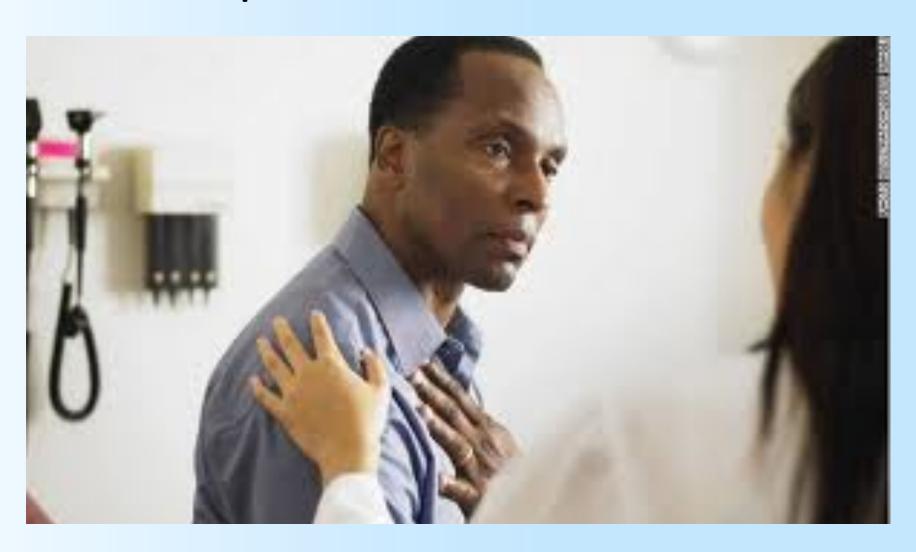
- At each visit, assess patient's concerns and questions
- Take advantage of teachable moments using open-ended questions and active listening
- Revise the plan as needed if it doesn't work in the patient's life, it doesn't work
- Provide information about therapeutic and behavioral options
- Refer for DSME/S

# Low Health Literacy

- "Chunk" information and set the stage at the beginning
- Teach-back and close the loop
  - Physicians assess patient recall and comprehension during 1 in 5 clinical encounters, but this "patient-centered communication" is associated with improved A1C
  - 83.5% retained information vs 60.8%
- Universal precautions

Osborn et al. Clinical Diabetes. 2010;20:171-75. Schillinger et al. Arch Intern Med. 2003;163: 83-90. Krapalini et al. IRB. 2008;30:13-19.

# **Depression and Distress**



# Diabetes and Depression

- People with diabetes have a 2-fold increased risk for depression, affecting approximately 1 in every 5 patients
- Depressed patients with diabetes are more likely to have poor self-management, increased healthcare utilization and cost, an increased risk of diabetes complications, and greater mortality

Ali et al. Diabet Med. 2006;23:1165-73. Lin et al. Diabetes Care. 2004;27:2154-60. Egede et al. Diabetes Care. 2002;25:464-70. Park et al. General Hospital Psychiatry. 2013;35:217-25.

# **Managing Depression**

- Medications work
- Cognitive behavioral therapy works
- Combination works best

### Diabetes-Related Distress

- Self-management problems are due in large part to psychosocial problems that are common but rarely treated
- 85% reported severe distress at diagnosis; 43% continued to experience these feelings (mean=15 years)
- Access to team care and communication between patients and professionals is associated with better outcomes
- Initiatives to address psychosocial needs must have a high priority in order to improve outcomes

### Diabetes-Related Distress

- Other studies show prevalence of 18% to 35% and an 18-month incidence of 38% to 48%
- Diabetes-related distress reported by 44.6%, but only 23.7% reported that their healthcare team asked them how diabetes impacted their life
- Different "conditions;" over 70% of type 2 adults with high distress are <u>NOT</u> clinically depressed; distress is more prevalent and persistent

Fisher et al. Diabetes Care. 2012;35:259-64. Nicolucci et al. Diabetic Medicine. 2013;30:767-777.

### What Is It?

- Fearful
- Frustrated
- Overwhelmed
- Anxious
- Guilty
- Angry
- Powerless
- Discouraged

### Does It Matter?

- Diabetes-related distress significantly linked to:
  - -A1C
  - Diabetes self-efficacy
  - Diet
  - Physical activity

### Diabetes Distress Scale: Short Form

- On a scale of 1 to 6, to what degree do the following cause distress:
  - Feeling overwhelmed by the demands of living with diabetes
  - Feeling that I am often failing with my diabetes regimen

Fisher L, et al. Annals of Family Medicine. 2008;6:246-252.

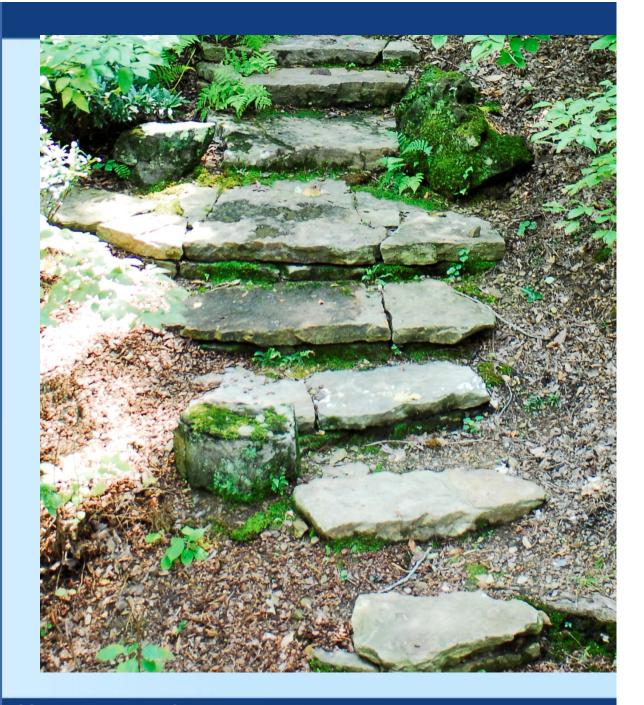
### PAID Scale: Short Form

- On a scale of 1 to 6, to what degree do the following cause distress:
  - Feeling that I will end up with serious longterm complications, no matter what I do

# **REDEEM Study**

- Diabetes-related distress is responsive to intervention
- Focused attention, self-management education interventions, and distress-specific interventions significantly reduce diabetes-related distress over time
- For those with high initial distress, best outcomes result from an intervention that addresses distress directly: one that targets patient feelings, beliefs, expectations around disease management

Step by Step to Behavior Change



### Before the Visit

- 1. What is hardest or causing you the most concern about caring for your diabetes at this time?
- 2. What do you find difficult or frustrating about it?
- 3. Describe your thoughts or feelings about this issue.
- 4. What would you like us to do during your visit to help address your concern?

Anderson et al. Clinical Diabetes. 2007;25:141-43. University of Michigan Health System. Diabetes Concerns Assessment Form. www.med.umich.edu/mdrtc/profs/documents/emh/ ConcernsAssessment.pdf. Accessed August 22, 2013.

## Empowerment and Patient-Centered Communication Strategies

- Behaviors are symptoms, not problems
- Self-management occurs in the context of daily life
- Recommendations must accommodate the patient's goals, priorities, values, and barriers
- Patients are in control of decisions and responsible for consequences
- Focus is on informed decisions and choices and consequences, not on adherence/compliance
- What decision did you make? What happened as a result?

Funnell et al. Clinical Diabetes. 2004;22:123-127.

## What's the Take Home?



#### What's the Take Home?

- "Here's what you should do" never effective and rarely helpful
- Ask, don't tell
- Psychosocial issues are the main barriers to selfmanagement
- Assess and address literacy, depression, distress, and collaboratively set goals
- Use open-ended questions to assist the patient to think creatively about how to achieve those goals
- Collaborate with patients to create a specific plan to change behaviors and achieve goals
- Create I-SMART behavioral experiments

## Diabetes HealthSense

Resources for living well

HealthSense Home

Make a Plan

Health Care Professionals

Submit a Resource

About HealthSense

#### I Am A

Select one:

Person with diabetes

Person with pre-diabetes

Person at risk for diabetes

Family member, friend, or caregiver

Health care professional

Teacher or school health professional

Pre-school

K-8th grade

High school

Community health worker

Community organization

- Help Me
- Age
- Type of Resource
- Language

You are here: NDEP Home > Resources > Diabetes HealthSense

Live well. Eat healthy. Be active. *It's not easy*. but it's worth it.

Use the options on the left to find resources to help you get started.

Search HealthSense by title or keyword

Go

#### Resource Offerings

#### Small Steps. Big Rewards. Your GAME PLAN to Prevent Type 2 Diabetes: Information for Patients

This three-booklet package from the National Diabetes Education Program (NDEP) helps you assess your risk for developing diabetes and implement a program to prevent or delay the onset of the disease. Use the activity tracker and fat and calorie counter to help track your progress. VIEW RESOURCE >

#### Get Fit on Route 66

Get Fit on Route 66 from AARP will take you on a virtual fitness journey down the legendary Route 66 highway. To help inspire you to be more active, you'll travel from Chicago to Santa Monica by recording your exercise minutes. VIEW RESOURCE >

#### Make a Plan

Change begins with just one step. Start here for a healthier you.

Eat healthy 3 Be active > Lose weight Cope with diabetes >



#### Health Care **Professionals**

Find research articles and resources for facilitating behavior change in your practice.

Research articles > Professional education > Patient resources



#### Follow NDEP

Facebook Market

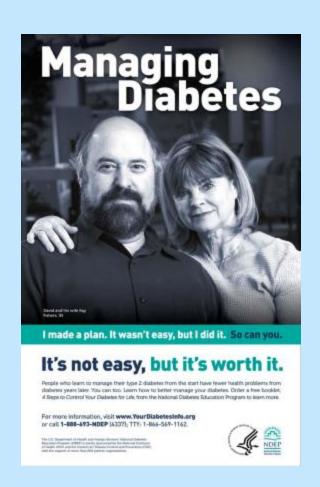


MOVE!

## NDEP Campaign

Managing Diabetes
It's not easy, but
it's worth it.
I made a plan.
It wasn't easy, but I
did it.

So can you.



# Performance in Practice: A Case-Based Approach to Providing Integrated Care to Patients with Multiple Risk Factors

Honey E. East, MD, FACP

**Premier Medical Group of Mississippi** 

#### Daniel M. Riche, PharmD, BCPS, CDE

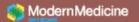
Associate Professor of Pharmacy Practice
The University of Mississippi School of Pharmacy
Associate Professor of Medicine
The University of Mississippi Medical Center
Clinic Coordinator, Cardiometabolic Clinic
Jackson, Mississippi

## **Objectives**

- Implementing best practices for integrated management of a cardiometabolic clinic
- Team composition according to patient needs, patient load, organizational constraints, resources, clinical setting, geographic location, and professional skills
- Case Learning: Preventing and managing hypoglycemia in high-risk patients with diabetes (i.e., elderly with renal dysfunction)
- Case Learning: Preventing progression of complications with early, aggressive management of co-morbid risk factors



#### Action for Outcomes Series CardioMetabolic Disorders & Weight



"The Cardiometabolic Clinic provides one-stop shopping for patients and eases the burden on primary care physicians, particularly those in rural areas where obesity and CVD are chronic problems." "Medical Economics Magazine

#### University of Mississippi Medical Center

JACKSON, MISSISSIPPI



Aungst. Medical Economics. 2009;86:40.

#### Making the Case to Hospital Administration

- More complicated patients
- Higher educational needs
- Higher level patient diversity
- Detailed medication training, including adherence
- Improved opportunity for culturally competent relationships
- Clinic not dependent on a single provider
  - Resource consideration

#### Cardiometabolic Clinic Model

- Referral based
  - Patient keeps PCP
- Patients scheduled to MD/PharmD
- Attending physician
  - 1 primary MD and 1 back-up provider
  - 6 MD, 3 NP have attended for at least 1 clinic
    - Over a 7-year span
- 4-5 ½ day clinics weekly
  - > 7-12 appointments per ½ day per PharmD
- 100% medical insurance (no Medicaid)

University of Mississippi by the numbers:

2007: Year founded

8: Faculty

- 2,500-3,000: Annual patient visits
- 8: Research protocols annually
- 6: Annual faculty publications
- 75 percent: Patients reaching target LDL levels
- 50 percent: Patients reaching all target lipid levels
- 1.5 percent: Average HbA<sub>ic</sub> reduction
- 90 percent: Achievement of quality assurance treatment markers such as annual monofilament foot examinations, aspirin therapy, and vaccinations

Aungst. Medical Economics. 2009;86:40.

## **Clinic Composition**

#### **Location/Setting**

## 



#### Resources/Professional Skills

Pharmacist <sup>1,2</sup>

Nurse Educator <sup>1,3</sup>

**Phone Nurse** 

Part-Time Admin
Asst

**Scheduler** 

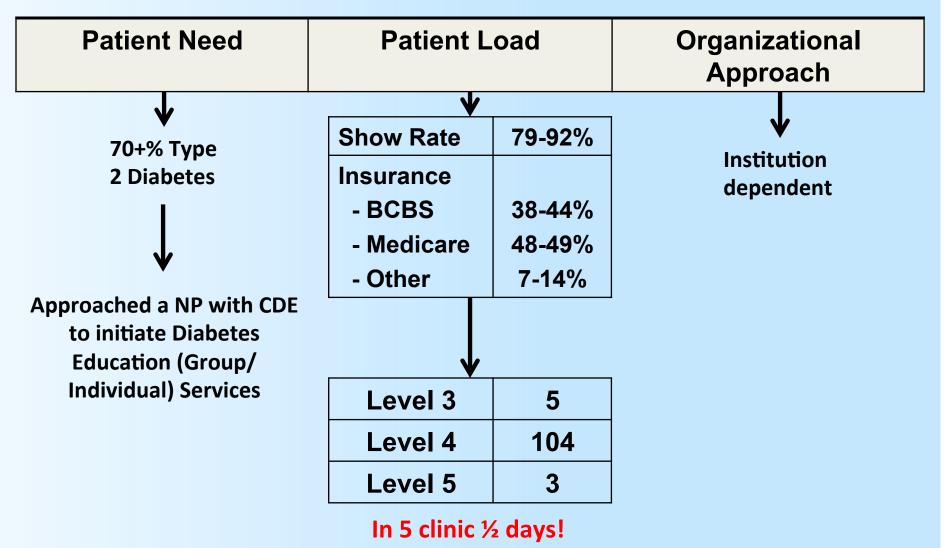
#### Referral Base:

- Physician Specialties
- Ophthalmology
- Physical Therapy
- Dietician
- Psych

- Standard Clinic Personnel
- 2 exam rooms per PharmD
- Appointment time dependent on MD
- Be sure to select a coordinator

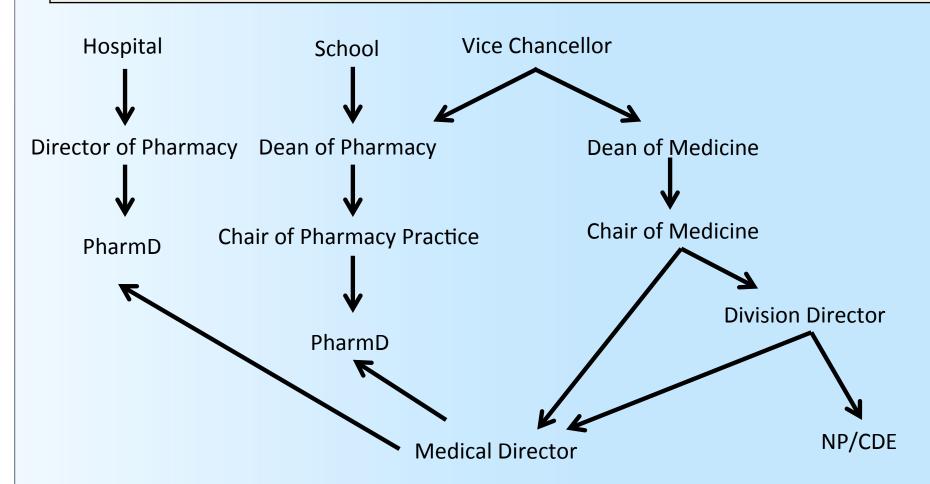
- <sup>1</sup> One or both should be CDE
- <sup>2</sup> Must be proficient in EMR
- <sup>3</sup> Could also be a RD

## **Clinic Composition**



## **Clinic Composition**

#### Organizational Approach (Academic Medical Center)



## **Hardest Thing to Avoid**

## **BECOMING THE PCP**

#### Cases

A Spoonful of Sugar

There's Something About Mary

The Pressure Cooker

Hiding in Plain Sight

## A Spoonful of Sugar

- Mr. Van Dyke is a 55-year-old WM here for new patient evaluation
  - History of medication-controlled HTN, migraines, dyslipidemia
- Social History
  - Without complaints
  - No exercise (other than the occasional chimney sweep)



## **Laboratory Data**

- Na=140, Cl=99, BUN=24
- K=3.9, CO2=29, SCr=1.0
- AST=25, ALT=33
- Glucose=97
- TSH=2.1
- Uric acid 8.9
- TC=392, TG=1,508 (increased from 299),
   HDL=43, LDL=N/C

## A Spoonful of Sugar

Chief Complaint: "Hey Doc, what's this rash?"





## Question 1 What do you think is the cause of Mr. Van Dyke's rash?



- Contact Dermatitis (Poison Ivy/Oak, etc...)
- B Infection (shingles, scabies, etc...)
- Hives
- D High Triglycerides

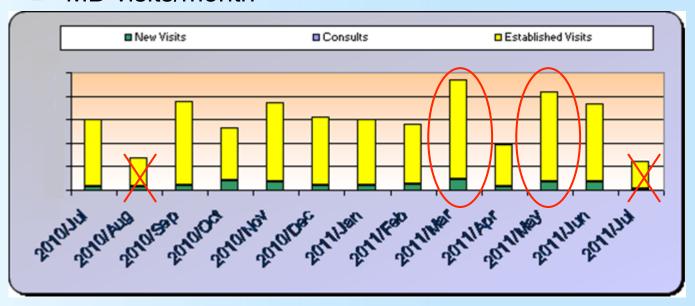
#### A Spoonful of Sugar...

- Should be avoided!
- Started on fenofibrate and fish oil despite patient resistance, patient was counseled intensively on lifestyle intervention
  - Directed education provided by pharmacist and nurse educator
  - Lifestyle changes were significant over an 18month period
- After 18 months, medications were stopped and TG=92 within 3 months

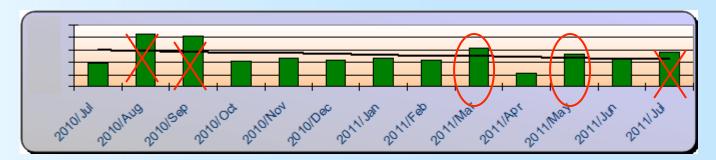
## OUTCOMES

#### **MD** Dashboard

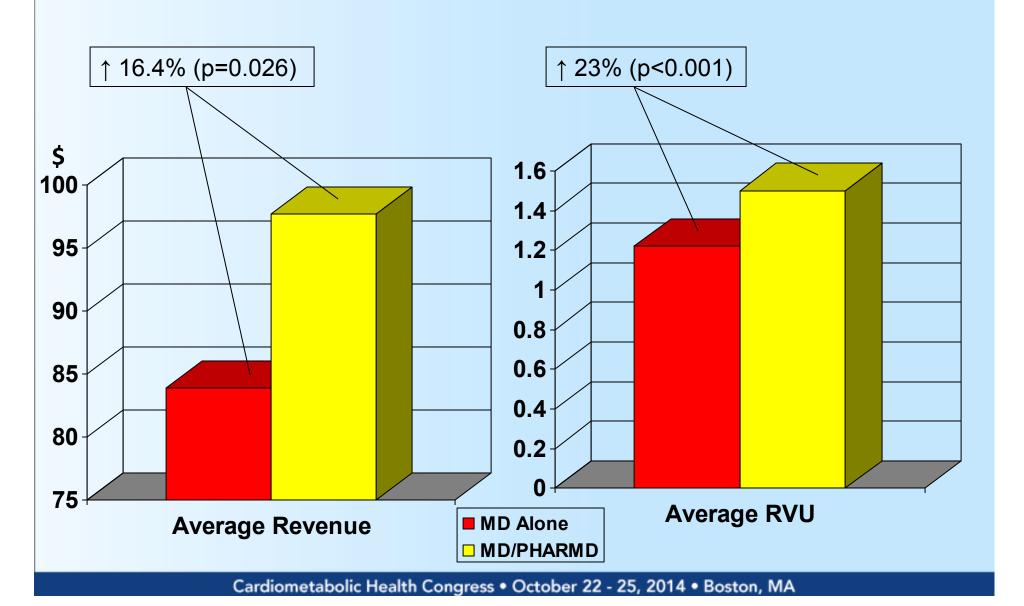
MD visits/month



MD RVU/month



## **Anticipated Revenue and RVU**



#### **Telemedicine**

- Level of service current procedural terminology codes (LOS CPT)
- Relative value units (RVUs)
  - Rank the resources used to provide a service
  - No UMMC RVUs for telemedicine services

LOS CPT Code	RVU
99441/98966 ≤ 10 minutes	0.38
99442/98967 11–20 minutes	0.74
99443/98968 > 20 minutes	1.08

#### Cases

A Spoonful of Sugar

There's Something About Mary

The Pressure Cooker

Hiding in Plain Sight

## There's Something About Mary

- 68 year-old WF here for new patient evaluation
  - $-BMI=40.6 \text{ kg/m}^2$
- Chief Complaint
  - Consistently uncontrolled DM
- Review of Systems
  - Without additional complaints



#### **Past Medical History**

- T2DM with Neuropathic Complications
  - Insulin glargine 100 units at noon
  - NPH insulin 150 units QAM/140 units QPM
  - Regular insulin U-500 = 0.17 mL (85 units) BID [TDD=560 units]
  - Pregabalin 150 mg one capsule TID (painful DPN)
  - Dexlansoprazole 60 mg one capsule daily (gastroparesis with pacemaker)
- Hypertension
  - Lisinopril 10 mg one tablet daily
  - Furosemide 40 mg one tablet daily
- Dyslipidemia
  - Fenofibrate 145 mg one tablet daily
  - Pravastatin 80 mg one tablet QHS
  - Ezetimibe 10 mg one tablet daily
- CAD Stent in left anterior descending coronary artery (LAD) (2002)
  - Nitroglycerin 0.4 mg PRN (none used recently)

#### **Past Medical History**

- Depression
  - Citalopram 40 mg one tablet daily
  - Aripiprazole 2 mg ½ tablet daily (recently added)
- Gout (untreated)
- Hypothyroidism
  - Levothyroxine sodium 175 mcg one tablet daily
- DVT
  - Warfarin 5mg two tablets daily
- Osteoporosis
  - Zoledronic acid infused yearly
- Obstructive Sleep Apnea (OSA)
  - CPAP used nightly +/- zolpidem
- Chronic Back Pain (multiple surgeries and pain medications)
- Chronic UTI (no prophylaxis)

#### **Laboratory Data**

- Today
  - Na=139, Cl=98, BUN=26
  - K=3.9, CO2=27, SCr=1.38
  - AST=52, ALT=45
  - Glucose=262
- 1 month ago
  - A1C=10.2% (worsened from 7.7% despite adding U-500)
- 3 months ago
  - TC=229, TG=380, HDL=29, LDL=124

#### **T2DM Pertinent Information**

- Insulin Pump
  - Could not afford and did not qualify for NIH gastroparesis study
- Cannot tolerate metformin
  - Dose as low as 250 mg causes severe GI upset with vomiting due to gastroparesis
- Not picking up medications consistently
- Number of injections daily = 7
- Aripiprazole added recently

## Question 2 How would you begin your visit with Mary?



- Tell her that her A1C is too high
- Ask to see her blood glucose log
- Ask her if she is taking her medication
- Ask her what she is struggling with

#### **Insulin Intervention**

- D/C Current Insulin Regimen
  - NPH 150 units QAM/140 units QPM
  - Glargine 100 units daily at noon
  - U-500 0.17 mL (85 units) BID
- Change to U-500 0.38 mL (190 units) TID 30 minutes before meals

Basal and prandial activity
Onset of activity 30 minutes
Peak at 1.75 to 4 hours
Duration of activity 7-10 hours (up to 24 hours)

#### **Our U-500 Dosage Protocol**

Total Daily Insulin Dose	Route and Frequency	U-500 Dosage
150-300	Twice daily	50%/50% or 60%/40% before
		breakfast and supper
150-300	Three times daily	33%/33%/33% before meals
300-600	Three times daily	33%/33%/33% before meals
300-600	Four times daily	Split 30%/30%/30%/10%
		at mealtimes and bedtime
> 600	Four times daily	Split 30%/30%/30%/10%
		at mealtimes and bedtime

#### Dose transition

- If A1C ≤ 8%: Reduce U-500 dose by 10-20%
- If A1C 8-10%: 1-to-1 TTD of U-500
- If A1C ≥ 10%: Increase U-500 dose by 10-20%

Cochran et al. Insulin. 2008;3:211-8.

## Minimizing U-500 Errors/Hypoglycemia

- Communication between healthcare professionals is key
  - Maintain continuity of care
  - Complete medication reconciliation
- Clarity on all U-500 prescriptions
  - Dose should be in actual units and volume
- Store separately from other insulin
- Administer via tuberculin syringe
  - Caution for dead space in syringes
- Diligence with SMBG and dose adjustment



#### **SMBG**

Date	Time	SMBG
10/28/2011	6:13 AM	149
10/28/2011	8:35 AM	349
10/28/2011	12:07 PM	220
10/28/2011	4:18 PM	123
10/29/2011	9:57 AM	274
10/29/2011	4:56 PM	346
10/30/2011	10:30 AM	121
10/30/2011	11:02 AM	198
10/30/2011	8:14 PM	168
10/31/2011	10:43 AM	139

- 10/29 Patient missed lunchtime injection
- 10/28 and 10/31 Patient complains of hypoglycemic symptoms when BG < 150</li>

#### Managing Hypoglycemia

American Diabetes Association
Recommendations for Patients Addressing
Hypoglycemia—The Rule of 15

- If you feel low, check your blood glucose.
- If blood glucose level is low, follow the rule of 15
  - Eat or drink something with 15 grams of carbs (fast-acting carb like glucose gel or juice).
  - Wait 15 minutes, then check your blood glucose.
  - If your blood glucose is still too low, eat another 15 grams of carbs and check your blood glucose again after 15 minutes. Once your blood glucose level starts to get back in your target range, you should start to feel better.
- Lots of people overtreat themselves when they feel low because they treat the symptoms and not the glucose level. You may not feel better instantly after eating your 15 grams of carbs, but remember the rule of 15.
- You may want to keep eating until you feel better but that might make your blood glucose shoot way up. Be patient with your body and give it the full 15 minutes!
- If you feel low, but cannot check your blood glucose, go ahead and treat it. When in doubt, it is always safer to get some food. If you go too low, you can faint, have a seizure, or go into a coma.

Riche, et al. US Pharmacist. 2013;(suppl): 21-9.

### **Telemedicine Course of Therapy**

- Adjustments made over the next 6 months
  - Dinner dose lowered due to nocturnal hypoglycemia to 0.32 mL (160 units)
  - Lunch dose increased due to late afternoon hyperglycemia to 0.40 mL (200 units)
  - At 4-5 weeks, A1C had decreased to 8.7%
  - Morning dose was increased to 0.42 mL (210 units)
  - Lunch dose was decreased to 0.35 mL (175 units)
  - At 6 months, A1C=7.0% (lowest ever on TDD=545)
    - Previous low=7.4% in 2006

# Question 3 Mary's weight and A1C (now 7.5%) increase over the next 6 months with 2-hr PP=213 mg/dL. What might you consider doing?



- Increase TID U-500 dose TID
- Add glyburide ER 10 mg PO daily
- Add sitagliptin 50 mg PO daily
- Add dapagliflozin 5 mg PO daily

#### Cases

A Spoonful of Sugar

There's Something About Mary

The Pressure Cooker

#### **Pressure Cooker**

- History of Present Illness
  - 68-year-old female with resistant hypertension
  - Referred by Endocrinology
    - Started spironolactone and reduced HCTZ dose
- Past Medical History
  - HTN (Dx in 30s)
  - Stroke (2012)
  - T2DM
  - Osteoporosis



#### **Pressure Cooker**

#### Pertinent History

- Denies EtOH, tobacco, and illicit drug use
- Does not speak English
- Daughter is patient's caretaker
- Confirmed compliance

#### Vitals

- Height = 5'3"
- Weight = 177 lbs
- BP = 151/73 (clonidine 30 minutes before)
- Pulse = 68
- Temp =  $98^{\circ}F$

#### Laboratory Tests

- BMP:
  - Glucose = 197
  - Sodium = 129
  - Potassium = 3.6
  - Chloride = 90
  - SCr = 0.71
- Aldosterone = 33

#### **Blood Pressure Medications**

Medication	Instructions	Total Daily Dose
Amlodipine 5 mg tablet	1 tab PO daily	5 mg
Clonidine 0.1 mg tablet	6:30 AM: 0.1 mg	0.8 mg
	12 N: 0.2 mg	
	6 PM: 0.1 mg	WOW!
	10 PM: 0.2 mg	
	1:30 AM: 0.2 mg	
<b>Hydralazine</b> 100 mg tablet	1 tab PO three times daily	300 mg
<b>Hydrochlorothiazide</b> 25 tablet	½ tab PO daily	12.5 mg
<b>Isosorbide dinitrate</b> 30 mg tablet	1 tab PO four times daily	120 mg
Metoprolol succinate 50 mg XL tablet	1 tab PO three times daily	150 mg
<b>Spironolactone</b> 50 mg tablet	1 tab PO daily	50 mg

#### **Average SMBP**

Varies 160-200s/90s mmHg About 1/3 of SMBPs are >200/100 mmHg

## Question 4 Which of these is the most appropriate initial intervention?



- Add ACE-I/ARB
- Reduce metoprolol dose frequency
- Taper PO clonidine
- All of the above

- 1st Phone Call Plan
  - Start 0.1 mg clonidine patch immediately
  - Decrease all 5 doses of PO clonidine to 0.1 mg in
     48 hours to allow for delay in patch efficacy
    - Max dose of 0.6 mg clonidine
  - SMBP before each clonidine PO dose
  - Follow-up phone call within 1 week

- 2<sup>nd</sup> Phone Call (1 week of telemedicine)
  - Systolic BP range = 160-180 mmHg
    - High of 190 (no 200's)
    - As low as 140 on occasion
  - Diastolic BP range = 80-110 mmHg
    - Previously never < 90</p>
  - Increase patch dose to 0.2 mg/day
  - D/c clonidine 1 AM dose
  - Switch hydralazine 1 AM dose to QHS
  - Switch metoprolol succinate XL to #1 in the AM and #2 at HS
  - Switch amlodipine from 1 AM dose to 6:30 AM

- 3<sup>rd</sup> Phone Call (3 weeks of telemedicine)
  - Systolic BP consistently 160s mmHg
    - Only 1 reading at 180 (none > 180)
    - As low as 120 during PO clonidine duration period
  - Diastolic BP is 80s mmHg during clonidine duration
    - 90s prior to next clonidine dose
    - Only 1 reading > 100
  - Increase patch dose to 0.4 mg/day (two 0.2 mg patches)
  - Change PO clonidine 0.1 mg TID
  - Decrease metoprolol succinate XL to once daily (#2 at HS)
  - Start olmesartan medoxomil HCT 40/25 ½ tablet daily

- 3 days later
  - Contacted by caregiver who held PO clonidine x 1
  - Average SMBP:
    - BP following was 158/74
  - Stop clonidine PO tablets
  - Double spironolactone to 2 tabs daily (check BMP)

4<sup>th</sup> Phone Call (4 weeks of telemedicine)

Medication	Instructions	Total Daily Dose
Amlodipine 5 mg tablet	1 tab PO daily	5 mg
Benicar HCT 40/25 mg tablet	½ tab PO daily	20/12.5 mg
Clonidine 0.2 mg/24hr patch	2 patches once weekly	0.4 mg
<b>Hydralazine</b> 100 mg tablet	1 tab PO three times daily	300 mg
Isosorbide dinitrate 30 mg tablet	1 tab PO four times daily	120 mg
Metoprolol succinate 50 mg tablet	2 tabs PO qHS	100 mg
<b>Spironolactone</b> 50 mg tablet	2 tabs PO daily	100 mg

#### Average SMBP:

Day #1: 158/92 (average of 9 readings)
Day #2: 162/89 (average of 7 readings)

## Question 5 What would you do next?



- A Increase dose of ARB/Diuretic
- Increase clonidine patches to 0.3 mg #2 daily
- Taper Isosorbide dinitrate
- D Taper hydralazine

• 5th Phone Call (5 weeks of telemedicine)

Medication	Instructions	Total Daily Dose
Amlodipine 5 mg tablet	1 tab PO daily	5 mg
Olmesartan medoxomil HCT 40/25 mg tablet	½ tab PO daily	20/12.5 mg
Clonidine 0.2 mg/24hr patch	1 patch once weekly	0.2 mg
Hydralazine 100 mg tablet	1 tab PO three times daily	300 mg
Isosorbide dinitrate 30 mg tablet	1 tab twice daily	60 mg
Metoprolol succinate 50 mg tablet	2 tabs PO qHS	100 mg
Spironolactone 50 mg tablet	2 tabs PO daily	100 mg

#### Average SMBP:

Day #1: 153/86 (average of 3 readings); Day #2: 161/94 (average of 3 readings)

Day #3: 143/86 (average of 3 readings); Day #4: 160/88 (average of 4 readings)

Cardiometabolic Health Congress • October 22 - 25, 2014 • Boston, MA

## Question 6 What would you do next?



- A Increase dose of ARB/Diuretic
- Increase clonidine patches to 0.3 mg #2 daily
- Increase dose of amlodipine
- Refer for renal denervation

6<sup>th</sup> Phone Call (6 weeks of telemedicine)

Medication	Instructions	Total Daily Dose
Amlodipine 5 mg tablet	1 tab PO daily	5 mg
Olmesartan medoxomil HCT 40/25 mg tablet	1 tab PO daily	40/25 mg
Clonidine 0.2 mg/24hr patch	1 patch once weekly	0.2 mg
<b>Hydralazine</b> 100 mg tablet	1 tab PO three times daily	300 mg
Metoprolol succinate 50 mg tablet	2 tabs PO QHS	100 mg
Spironolactone 50 mg tablet	2 tabs PO daily	100 mg

#### Average SMBP:

SBP consistently 130-150s

Only 3 readings > 160 (high = 172)

Caregiver reports meds not given on schedule these days DBP consistently 80-90s

#### Cases

A Spoonful of Sugar

There's Something About Mary

The Pressure Cooker

- 47-year-old WM referred for lipid management with nonalcoholic fatty liver disease (NAFLD)
- Past Medical History
  - HTN
  - Obesity
  - Type 2 diabetes
  - Dyslipidemia
  - Obstructive sleep apnea

- Family History
  - Both parents deceased from lung cancer
  - History of CHD, stroke, DM, dyslipidemia
- Social History
  - Denies tobacco and illicit drug use
  - EtOH very minimal only 5 beers/year
  - College professor

- Patient reports unable to tolerate several statins due to elevated liver enzymes (atorvastatin, lovastatin, pravastatin)
- Current Medications:
  - Insulin glargine 75 units QHS
  - Metformin 1000 mg BID
  - Olmesartan medoxomil HCT 40/25 mg one daily
  - Aspirin 81 mg daily
  - Bioperine (B-vitamin) one daily
  - Fish Oil (OTC) 1000 mg 5 capsules daily
  - Multivitamin Infusion one daily

#### Vitals and Labs

- Height: 76"; Weight: 305 pounds
- BP=139/81 mmHg; Pulse=72, Temp=98.1°F
- Laboratory Tests (blood drawn 2 months earlier)
- Basic Metabolic Panel ok (SCr=0.9 mg/dL)
- AST=62 units/L; ALT=98 units/L
- Complete Blood Count ok
- HbA1c=7.0%
- TC=259 mg/dL; LDL=190 mg/dL; TG=141 mg/dL; HDL=40 mg/dL
- Framingham Score: 10% (ASCVD score >7.5%)

Riche et al. Annals of Pharmacotherapy. 2014;48:137-41.

## Question 7 Which of the following is an important metabolic risk factor for this patient?



- A A1C
- B LDL
- Body weight
- All of the above

## Nonalcoholic Fatty Liver Disease (NAFLD)

#### What is NAFLD?

- Intracellular fatty infiltrates in liver due to excess fatty acid synthesis and storage
- Severity progresses from steatosis → NASH → cirrhosis
- Most common cause of elevated liver enzymes in adults
- Recent evidence suggests that NAFLD is independently associated with an increased risk of CVD

#### Epidemiology

- Approximately 20% of the general public
  - More common in men
- Hispanics > Caucasians > African Americans

#### Risk Factors

- Obesity (2/3 of patients with BMI >30 kg/m² have steatosis)
- Insulin resistance and/or diabetes
- Hypertriglyceridemia

Malinowski et al. Pharmacotherapy. 2013;33:223-42.

#### Statins and the Liver

- Can generally induce aminotransferase increases
  - Anecdotally, most common action=discontinuation
- Decrease fat peripherally and viscerally (in the liver)
- Fat removal from the liver may induce elevated transferases
  - Transient and eventually leads to biochemical improvement
- Timeframe
  - 2 (early improvement) to 8 months (maximum evidencebased)
- Statin properties
  - LDL lowering potential > lipophilicity

## Greek Atorvastatin and Coronary Heart Disease Evaluation (GREACE) study

- Prospective, open-label, randomized, survival study
  - -n=1,600
- CHD <75 years old with elevated LDL for 3 years</li>
- Atorvastatin 10-80 mg/day or usual care
- Abnormal baseline ALT/AST/GGT (n=437)
  - Statin (n=227) improved ALT/AST/GGT
  - No statin (n=210) worsened ALT/AST/GGT
- Normal baseline ALT/AST/GGT (n=1,163)
  - 56% received statin

Athyros et al. Lancet 2010;376:1916-22.

#### **GREACE**

- Control-compared relative cardiovascular event risk reduction (post-hoc analysis)
  - Abnormal baseline ALT/AST/GGT
    - Statin vs. Non-Statin=68%
  - Normal baseline ALT/AST/GGT
    - Statin vs. Non-Statin=39%
- "Statins global benefit in NAFLD patients may outweigh the current lack of specific histological improvement"

## Question 8 A liver ultrasound and GI referral are made; what would you do for this patient today?



- Start rosuvastatin 20 mg/day
- B Start simvastatin 20 mg/day
- Change metformin to pioglitazone 30 mg/day
- Change fish oil to fenofibrate 145 mg/day

### **Treatment Options: Statins**

- Most assessments are pilot studies
  - Pilot study (n=23) using rosuvastatin 10 mg for 8 months in NAFLD
  - No assessment of histology
  - ALT/AST started to normalize at 2 months
  - 100% normalized AST/ALT
  - 100% reached LDL goal
- 1-year placebo-controlled trial (n=16) with NASH
  - Simvastatin 40 mg/day
  - No significant differences in aminotransferase levels or hepatocellular structure

### **Therapy Timeline**

- Now what happened?
  - 08/09: Changed to rosuvastatin
    - Continued fish oil
  - 11/09: Diagnosed with severe NAFLD on U/S
  - 01/10: Rosuvastatin held due to rising AST/ALT (65/111)
  - 05/10: LFT still elevated off rosuvastatin for 4 months
    - Vitamin E recommended
  - AST/ALT persistently elevated for the next year

Riche et al. Annals of Pharmacotherapy. 2014;48:137-41.

## **In Clinic Today**

- A1c=9.2%
- AST=88 units/L, ALT=146 units/L
- TC=282, TG=173, HDL=30, LDL=217
- Chemistries ok except glucose
- Vital Signs:
  - 306#, 97°, 106/74, 74, BMI=37.2

Riche et al. Annals of Pharmacotherapy. 2014;48:137-41.

## Question 9 Now, what would you do for this patient?



- Start rosuvastatin 20 mg/day
- Start simvastatin 20 mg/day
- Start pioglitazone 15 mg/day
- Start orlistat 120 mg TID with meals

#### 2-Week Lab Check

- AST=39 units/L (-56%)
- ALT=63 units/L (-57%)
- No complaints or ADR

### 3-Month Follow-Up Visit

	4/8/11	8/4/11
A1c	9.2%	7.0%
AST	88 units/L	46 units/L
ALT	146 units/L	59 units/L
Total Cholesterol	282 mg/dL	147 mg/dL (-48%)
Triglycerides	173 mg/dL	95 mg/dL
HDL	30 mg/dL	37 mg/dL
LDL	217 mg/dL	91 mg/dL (-58%)

- Vitals: 309 lbs, 98°, 128/77, 83
- Ultrasound demonstrated improvement in steatosis and reduced size
- Weight slightly increased (no edema)

Riche et al. Annals of Pharmacotherapy. 2014;48:137-41.

### **Summary**

- Discussed the implementation of a best practice for integrated management of a cardiometabolic clinic
- Reviewed team composition according to patient needs, patient load, organizational constraints, resources, clinical setting, geographic location, and professional skills
- Case Learning: Preventing and managing hypoglycemia in high-risk patients with diabetes (i.e., elderly with renal dysfunction) [There's Something About Mary]
- Case Learning: Preventing progression of complications with early, aggressive management of co-morbid risk factors [Pressure Cooker & Hiding in Plain Sight]