The National Diabetes Education Program: Guiding Principles for the Care of People With or at Risk for Diabetes

Sunday, June 7, 2015
Introductions

Linda M. Siminerio, RN, PhD, CDE
Chair, NDEP Executive Committee
Professor of Medicine
University of Pittsburgh
• **Development and Use of “Guiding Principles”**
  Judy Fradkin, MD

• **Using “Guiding Principles”: Preventing Cardiovascular Disease**
  John Buse, MD, PhD

• **Using “Guiding Principles”: Optimizing Self-Management Education and Support**
  Marti Funnell, MS, RN, CDE

• **Using “Guiding Principles”: Moving toward Patient-Centered Diabetes Care**
  Linda Siminerio, RN, PhD, CDE

• **Using “Guiding Principles”: Preventing Type 2 Diabetes – Progress on Implementation of the National Diabetes Prevention Program**
  Ann Albright, PhD, RD

• **Moving Forward: Future Directions for the NDEP**
  Joanne Gallivan, MS, RD
  Judith McDivitt, PhD
Development and Use of “Guiding Principles”

Judith Fradkin, MD
Member, NDEP Executive Committee
Director, Division of Diabetes, Endocrinology, and Metabolic Diseases
National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health
No Disclosures
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Should the Target A1C Level Be Less Than 7 Percent?

No: The Case for Modest Glycemic Control in Patients with Type 2 Diabetes
HENRY C. BARRY, MD, MS, Michigan State University College of Human Medicine, East Lansing, Michigan

Between firmly held beliefs in tight glycemic control and the available empiric data lies a wide chasm. In a review of 13 randomized controlled trials (RCTs) comparing tight control versus usual care in patients with type 2 diabetes mellitus, overall, tight control did not improve all-cause mortality, cardiovascular mortality, or total myocardial infarctions.1 There was a decrease in the study.3 They found a linear relationship between A1C levels and the rate of aggregate clinical events. 

Yes: This Should Be the Target for Most Patients
KEVIN PETERSON, MD, MPH, FRCS, FAAFP, University of Minnesota Medical School, Minneapolis, Minnesota

In 1993, the DCCT (Diabetes Control and Complications Trial) demonstrated that better glycemic control reduces microvascular disease in patients with type 1 diabetes mellitus.1 Ten years later, the EDIC (Epidemiology of Diabetes Interventions and Complications) trial established that microvascular disease was also reduced by the DCCT.2 In 1998, the UKPDS (United Kingdom Prospective Diabetes Study) demonstrated that intensive glycemic control also reduces microvascular disease in patients with type 2 diabetes, but that macrovascular disease reduction is only a statistical trend.3 (Veterans Affairs Diabetes Trial), did not show increases in mortality from intensive control, they also did not show a reduction in cardiovascular disease outcomes from low A1C levels.7,8 Although we all agree that these trials demonstrate that not everyone should target a normal A1C level, we should also recognize that these clinical trial populations are different from the general population. A closer examination of the evidence shows why family physicians should still recommend an A1C target of less than 7 percent...
## ACCORD: Primary & Secondary Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Intensive N (%)</th>
<th>Standard N (%)</th>
<th>HR (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>352 (6.86)</td>
<td>371 (7.23)</td>
<td>0.90 (0.78-1.04)</td>
<td>0.16</td>
</tr>
<tr>
<td><strong>Secondary</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mortality</td>
<td>257 (5.01)</td>
<td>203 (3.96)</td>
<td>1.22 (1.01-1.46)</td>
<td>0.04</td>
</tr>
<tr>
<td>Nonfatal MI</td>
<td>186 (3.63)</td>
<td>235 (4.59)</td>
<td>0.76 (0.62-0.92)</td>
<td>0.004</td>
</tr>
<tr>
<td>Nonfatal Stroke</td>
<td>67 (1.31)</td>
<td>61 (1.19)</td>
<td>1.06 (0.75-1.50)</td>
<td>0.74</td>
</tr>
<tr>
<td>CVD Death</td>
<td>135 (2.63)</td>
<td>94 (1.83)</td>
<td>1.35 (1.04-1.76)</td>
<td>0.02</td>
</tr>
<tr>
<td>CHF</td>
<td>152 (2.96)</td>
<td>124 (2.42)</td>
<td>1.18 (0.93-1.49)</td>
<td>0.17</td>
</tr>
</tbody>
</table>
UKPDS: Legacy Effect of Earlier Glucose Control

*After median 8.5 years post-trial follow-up*

<table>
<thead>
<tr>
<th>Aggregate Endpoint</th>
<th>1997</th>
<th>2007</th>
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<tbody>
<tr>
<td>Any diabetes related endpoint</td>
<td>12%</td>
<td>9%</td>
</tr>
<tr>
<td></td>
<td>0.029</td>
<td>0.040</td>
</tr>
<tr>
<td>Microvascular disease</td>
<td>25%</td>
<td>24%</td>
</tr>
<tr>
<td></td>
<td>0.0099</td>
<td>0.001</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>16%</td>
<td>15%</td>
</tr>
<tr>
<td></td>
<td>0.052</td>
<td>0.014</td>
</tr>
<tr>
<td>All-cause mortality</td>
<td>6%</td>
<td>13%</td>
</tr>
<tr>
<td></td>
<td>0.44</td>
<td>0.007</td>
</tr>
</tbody>
</table>

*RRR = Relative Risk Reduction, P = Log Rank*
Prevalence of meeting A1C goals among adults aged ≥ 20 years with diagnosed diabetes

Glycemic Control Among Older US Adults With Diabetes Mellitus Across 3 Health Status Categories

Treatment of Older US Adults With Diabetes Mellitus
With an HbA$_{1c}$ <7% Across Health Status Categories

Prevalence of meeting BP goals among adults aged ≥ 20 years with diagnosed diabetes

Prevalence of meeting lipid management goals among adults aged $\geq 20$ years with diagnosed diabetes

Smoking Status Among US Adults with Diabetes, 1999-2010

"Guiding Principles for the Care of People With or at Risk for Diabetes"

www.nidc.nih.gov/guidingprinciples
# Collaborative Approach

## Matrix for blood glucose management

<table>
<thead>
<tr>
<th>Org</th>
<th>Treatment goals</th>
<th>Patient safety</th>
<th>Initiating pharmacologic therapy for type 2*</th>
<th>MNT</th>
<th>Physical activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>AACE</td>
<td>In general ≤5.5% for most FPG &lt;110 2-h PPG &lt;140</td>
<td>Individualize—consider age, comorbidities, duration of disease, closer to normal for healthy; less stringent for “less healthy”</td>
<td>The choice of therapeutic agents should be based on their differing metabolic actions and adverse effect profiles as described in the 2009 AACE/AACE Diabetes Algorithm for Glycemic Control (Goal B; REL. 6)**. Consider insulin for patients with T2DM when oral monotherapy fails to achieve target glycemic control (Goal A; REL. 1).</td>
<td>Individualized MNT: insulin dosage adjustments to match CHO intake, increase-containing or high glycemic index food limitations, adequate protein intake, &amp; “heart healthy” diet use; weight mgmt. - calorie reduction to reduce weight by at least 5 to 10%; avoid weight gain.</td>
<td>At least 150 minutes/week of moderate-intensity PA. Incorporate flexibility and strength training exercises. Evaluate patients initially for contraindications and/or limitations to PA, then develop an exercise prescription. Patient goals &amp; exercise limitations.</td>
</tr>
<tr>
<td>AAFP</td>
<td>A1C &lt;7% for most people</td>
<td>The goal is to maintain BG levels as close to normal as possible without risking significant hypoglycemia. A1C &gt; 7.0% may be appropriate for patients with a history of severe hypoglycemia, limited life expectancy, advanced microvascular or macrovascular complications, or extensive comorbidities.</td>
<td>Metformin is a first-line consideration. Although insulin is typically introduced when glucose control is no longer possible with oral agents, it can also be used when contraindications to oral medications exist. Newly diagnosed patients also can benefit from an insulin use.</td>
<td>Weight loss with an initial goal of 7% of baseline weight, and a low-fat, reduced-calorie diet.</td>
<td>Intensive lifestyle intervention that includes at least 150 minutes per week of physical activity and angiotensin-converting enzyme inhibitors, and normalization of blood glucose levels.</td>
</tr>
<tr>
<td>AHA</td>
<td>Normal FPG (&lt;110 mg/dL) and near normal HbA1c (&lt;7%)</td>
<td>Second-step therapy is usually oral hypoglycemic drugs: sulfonylureas and/or metformin with ancillary use of acarbose and thiazolidinediones. Third-step therapy is insulin.</td>
<td>First step is diet and exercise.</td>
<td>First step is diet and exercise.</td>
<td>First step is diet and exercise.</td>
</tr>
<tr>
<td>ACP</td>
<td>A1C &lt;7% for many but not all patients</td>
<td>The goal for A1C should be based on individual assessment of risk for complications from diabetes, comorbidity, life expectancy, and patient preferences, &amp; a discussion of the benefits &amp; harms of specific levels of glycemic control with the patient</td>
<td>Add oral agent when lifestyle modifications have failed to adequately improve hyperglycemia (Grade: strong recommendation; high-quality evidence). Prescribe metformin initially for most patients (Grade: strong recommendation; high-quality evidence). Add 2nd agent to metformin for persistent hyperglycemia when lifestyle &amp; metformin fail to control hyperglycemia (Grade: strong recommendation; high-quality evidence). Begin insulin in patients who do not achieve adequate glycemic control with oral agents, whether alone or in combination.</td>
<td>Lifestyle modifications, including diet and weight loss.</td>
<td>Lifestyle modifications, including exercise. Caution patients receiving drug therapy about hypoglycemia during and after exercise.</td>
</tr>
<tr>
<td>ADA</td>
<td>A1C &lt;7.0% for many people Pre-RPG 70–130 Post-RPG &lt;180 Post-RPG may be targeted if A1C goals are not met despite reaching pre-RPG goals</td>
<td>Individualize goals based on: duration of diabetes; age/life expectancy; comorbid conditions; known CVD or advanced microvascular complications; hypoglycemia unawareness; individual patient considerations. More-less stringent glycemic goals may be appropriate for individual PWD.</td>
<td>At diagnosis, initiate metformin along with lifestyle therapy unless metformin is contraindicated. (A). 2) In newly diagnosed patients with markedly symptomatic and/or elevated HbA1c or A1C, consider insulin therapy, with or without additional agents, from the outset. (E). If noninsulin monotherapy at minimal tolerated dose does not achieve or maintain the A1C target over 3–6 months, add a 3rd oral agent, a GLP-1 receptor agonist, or insulin. (E) Refer to reference: ** for algorithm.</td>
<td>1) The mix of CHO, protein, &amp; fat may be adjusted to meet the metabolic goals &amp; individual preferences (C). 2) Monitoring CHO intake by CHO, choices, or experience-based estimation, is a key for achieving glycemic control. (B). 2) Saturated fat intake should be &lt;7% of total calories. (B) 3) Reduced intake of trans fat lowers LDL-C &amp; increases HDLC. (A) Minimize intake of trans fat (E).</td>
<td>1) 150 min/week of moderate-intensity aerobic PA (50–70% of maximum heart rate), spread over at least 3 days/week with no more than 2 consecutive days without exercise. (A) 2) In the absence of contraindications, perform resistance training at least twice per week. (A)</td>
</tr>
</tbody>
</table>
Writing Group

- Stephen J. Spann, MD, MBA, American Academy of Family Physicians
- Farhad Zangeneh, MD, FACP, FACE, American Associations of Clinical Endocrinologists
- Apostolos P. Dallas, MD, FACP, American College of Physicians
- Sue Kirkman, MD, American Diabetes Association
- Rose Marie Robertson, MD, FAHA, FACC, American Heart Association
- Carol Mangione, MD, MSPH, The American Geriatrics Society
- Robert A. Vigersky, MD, The Endocrine Society
- NDEP Executive Committee Members:
  - John Buse, MD, PhD, Immediate Past NDEP Chair
  - Ann Albright, PhD, RD
  - Judith Fradkin, MD
  - Martha Funnell, MS, RN, CDE
Supporting Organizations

- Academy of Nutrition and Dietetics
- Agency for Healthcare Research and Quality
- American Academy of Ophthalmology
- American Academy of Physician Assistants
- American Association of Clinical Endocrinologists
- American Association of Diabetes Educators
- American Association of Nurse Practitioners
- American College of Obstetricians and Gynecologists
- American Diabetes Association
- American Heart Association
- American Optometric Association
- American Podiatric Medical Association
- Department of Defense
- Endocrine Society
- Health Resources and Services Administration
- Indian Health Service
- National Council of Asian Pacific Islander Physicians and AANPHI Diabetes Coalition
- Office of Minority Health
- The American Geriatrics Society
Individualized Approach to A1C Treatment Goals

- Consider A1C targets as close to non-diabetic levels (< 6.5 percent) as possible without significant hypoglycemia in people with short duration of diabetes, little comorbidity, and long life expectancy.

- Consider less stringent A1C targets (e.g., 8 percent) for people with a history of severe hypoglycemia, limited life expectancy, extensive comorbid conditions, advanced complications, major impairments to self-management (e.g., visual, cognitive, social), or long-standing diabetes where the A1C goal is difficult to attain despite optimal efforts.

- Reassess A1C targets and change (lower or higher) as appropriate.
Shared Decision Making in Blood Glucose Management

- Agreed upon goals for glycemic control

- Information about advantages and disadvantages of the available medication classes can help guide joint therapy selection when metformin is contraindicated or insufficient to achieve goals
Diabetes Education Among US Adults with Diabetes, 1999-2010

GUIDING PRINCIPLES
FOR THE CARE OF PEOPLE WITH OR AT RISK FOR DIABETES

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Using “Guiding Principles”: Preventing Cardiovascular Disease

John B. Buse, MD, PhD
Verne S. Caviness Distinguished Professor
Director, Diabetes Care Center
Chief, Division of Endocrinology
Executive Associate Dean, Clinical Research
University of North Carolina School of Medicine
Chapel Hill, NC U.S.A.

jbuse@med.unc.edu
Presenter Disclosure

John Buse


Consultant: PhaseBio Pharmaceuticals Inc

Employee: None


Speaker’s Bureau: None

Stock/Shareholder: PhaseBio Pharmaceuticals, Inc

Other: None
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Principle 7:
Provide Blood Pressure and Cholesterol Screening and Control, Smoking Cessation, and Other Therapies to Reduce Cardiovascular Disease Risk

- Blood pressure
- Lipids
- Multiple risk factor management
- Antiplatelet therapy
- Cardiovascular risk assessment
- Smoking cessation
UKPDS Blood Pressure Study
Tight (<150/85 mmHg) vs. less tight control group (<180/105 mmHg)
On treatment averages: 144/82 vs. 154/87 mmHg

- Any diabetes related endpoint: 24% reduction (p=0.005; 95% CI 0.62–0.92)
  - 32% reduction in diabetes deaths (p=0.02)
  - 44% reduction in stroke (p=0.01)
  - 37% reduction in microvascular complications (p=0.009)

BMJ. 1998 Sep 12;317(7160):703-13
HOT Trial: Effect of Diastolic Target on Cardiovascular Events - 4 Years

Lancet 351: 1755-1762, 1998

Diabetic Patients
n=1,501, P=0.016

Non-Diabetic Patients
n=18,790, P=NS
# ACCORD Blood Pressure

**<120 mmHg vs 130-140 mmHg**

<table>
<thead>
<tr>
<th>Event Category</th>
<th>Intensive Events (%/yr)</th>
<th>Standard Events (%/yr)</th>
<th>HR (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary</strong></td>
<td>208 (1.87)</td>
<td>237 (2.09)</td>
<td>0.88 (0.73-1.06)</td>
<td>0.20</td>
</tr>
<tr>
<td><strong>Total Mortality</strong></td>
<td>150 (1.28)</td>
<td>144 (1.19)</td>
<td>1.07 (0.85-1.35)</td>
<td>0.55</td>
</tr>
<tr>
<td><strong>Cardiovascular Deaths</strong></td>
<td>60 (0.52)</td>
<td>58 (0.49)</td>
<td>1.06 (0.74-1.52)</td>
<td>0.74</td>
</tr>
<tr>
<td><strong>Nonfatal MI</strong></td>
<td>126 (1.13)</td>
<td>146 (1.28)</td>
<td>0.87 (0.68-1.10)</td>
<td>0.25</td>
</tr>
<tr>
<td><strong>Nonfatal Stroke</strong></td>
<td>34 (0.30)</td>
<td>55 (0.47)</td>
<td>0.63 (0.41-0.96)</td>
<td>0.03</td>
</tr>
<tr>
<td><strong>Total Stroke</strong></td>
<td>36 (0.32)</td>
<td>62 (0.53)</td>
<td>0.59 (0.39-0.89)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

N = 4773
Mean follow-up 4.7yrs

*References*

Blood pressure: General considerations

• Measure at every routine medical visit.
• Consider home blood pressure monitoring when office/clinic measurements are borderline or elevated.
• Non-pharmacologic therapy can be very effective:
  • Reduce sodium intake
  • Reduce excess body weight
  • Avoid excessive alcohol consumption
  • Follow the DASH Eating Plan
  • Engage in 40 minutes of aerobic physical activity at a moderate to vigorous intensity, at least 3 days a week.
• Referral to a registered dietitian can also be helpful
Blood pressure: Therapy considerations

- Blood pressure of 130-139 mmHg systolic or 80-89 diastolic may initially be treated with lifestyle therapy alone.
- The primary goal of therapy: less than 140/90 mmHg.
- Lower blood pressure targets can be individualized based on shared decision making:
  - level of CVD risk,
  - presence of kidney disease, and
  - burden of therapy.
- Consider initial therapy with a thiazide, calcium channel blocker, ACE inhibitor, or an ARB.
- Two or more agents at maximal doses is usually required to maintain blood pressure targets.
- ACE inhibitors and ARB’s are contraindicated in pregnancy.
Blood pressure: Controversy

• How low should we really go in people with diabetes? Should there be different targets for the advanced elderly? For those under 40?
• In African Americans with diabetes, should the initial therapy be a thiazide diuretic or calcium channel blocker as opposed to ACEi/ARB?
• What did ACCORD really tell us about blood pressure management? Targets?
  • In the ACCORD BP trial, compared with combined standard treatment, intensive BP (SBP < 120 mmHg) or intensive glycemia treatment (A1C <6%) improved major CVD outcomes, without additional benefit from combining the two.
  • The comparison was <120 vs 130-140 mmHg.
Principle 7: Provide Blood Pressure and Cholesterol Screening and Control, Smoking Cessation, and Other Therapies to Reduce Cardiovascular Disease Risk

- Blood pressure
- Lipids
- Multiple risk factor management
- Antiplatelet therapy
- Cardiovascular risk assessment
- Smoking cessation
4S: Statins reduce coronary events

**Diabetic Patients**

- Placebo: 45 patients with major coronary event (%)
- Simvastatin: 23 patients with major coronary event (%)
- 55% Risk Reduction

**Nondiabetic Patients**

- Placebo: 27 patients with major coronary event (%)
- Simvastatin: 19 patients with major coronary event (%)
- 32% Risk Reduction

*CHD death or nonfatal MI

Pyörälä et al. *Diabetes Care*. 1997;20:614
Statins: Targets?

• Studies using the HMG-CoA reductase inhibitors (statins) have clearly shown that moderate to intensive statin therapy can reduce CVD events in people with diabetes.
  • Rather than targeting specific levels of LDL cholesterol, these studies have generally achieved 30 to 40 percent reductions from baseline LDL cholesterol levels.
• In people with diabetes over age 40 and with other CVD risk factors, moderate-to high-intensity statin therapy reduces CVD risk regardless of the baseline LDL cholesterol level.
Cholesterol Management

• Lifestyle modification to optimize lipids is indicated for everyone.
• Statin therapy for everyone with diabetes who have overt CVD.
• Statin therapy should be considered in individuals with diabetes who are without overt CVD but are at substantial risk of developing CVD (e.g., over age 40).
• Risk of CVD is increased more in type 1 diabetes compared with type 2 diabetes, but it is not known if routine use of statins in people with type 1 diabetes under age 40 is useful for primary prevention of CVD.
• The strongest evidence for statin use is in people with diabetes who are 45 to 75 years old.
• Additional lipid-lowering medications have not been shown to reduce CVD risk in people with type 2 diabetes on statin therapy.
• Statins are contraindicated for women who are pregnant or considering pregnancy.
Cholesterol Management: Controversies

• How early should statin therapy start?
• How potent a statin and how high a dose?
• Should there be a target?
• Does LDL (or non-HDL cholesterol) need to be followed?
• Is there a role for advanced lipid testing?
• What to do for the statin intolerant? Lower dose, alternative statin, intermittent therapy, addition of other classes, novel agents.
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**Principle 7: Steno-2: Multiple Risk Factor Management**

- **N=160**
- Intensive vs. conventional therapy for glucose, BP, lipids
- 7.8 y treatment, 13.3 y follow-up

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Post Interv.</th>
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<tbody>
<tr>
<td></td>
<td>INT</td>
<td>CONV</td>
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<tr>
<td>BP—Systolic</td>
<td></td>
<td></td>
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<tr>
<td>Diastolic</td>
<td>146</td>
<td>149</td>
</tr>
<tr>
<td></td>
<td>85</td>
<td>86</td>
</tr>
<tr>
<td>A1C, %</td>
<td>8.4</td>
<td>8.8</td>
</tr>
<tr>
<td>Lipids (mg/dL)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TC</td>
<td>210</td>
<td>233</td>
</tr>
<tr>
<td>LDL-C</td>
<td>133</td>
<td>137</td>
</tr>
<tr>
<td>HDL-C</td>
<td>40</td>
<td>39</td>
</tr>
<tr>
<td>TGs</td>
<td>159</td>
<td>205</td>
</tr>
</tbody>
</table>

Deaths in 13.3 y follow-up:
- 24 vs. 40 deaths
- Absolute Risk Reduction=20%, \( p=0.02 \)
- Relative Risk Reduction=46%, \( p=0.02; 95\% CI: 0.32-0.89 \)

Principle 7: Provide Blood Pressure and Cholesterol Screening and Control, Smoking Cessation, and Other Therapies to Reduce Cardiovascular Disease Risk

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- Smoking cessation
Antiplatelet therapy

• Use low-dose aspirin in adults with diabetes and a history of atherosclerotic CVD.

• In men over 50 and women over 60 with diabetes and other major atherosclerotic CVD risk factors, low-dose aspirin may be considered as a prevention strategy for cardiovascular events.

• For primary prevention of atherosclerotic CVD for people with diabetes, consider aspirin therapy in those who have a 10-year CHD risk of more than 10 percent.
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Risk Calculators

http://www.dtu.ox.ac.uk/riskengine/
### ARIC Coronary Heart Disease Risk Calculator

This risk assessment tool uses information from the ARIC Study. It is designed for adults, 45-65 years old, who do not have heart disease to predict a person’s chance of having a heart attack in the next 10 years. To find your risk score, enter your information in the calculator below then click the 'Calculate Risk' button.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Female □</th>
<th>Male □</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race</td>
<td>Black □</td>
<td>White □</td>
</tr>
<tr>
<td>Are you a cigarette smoker?</td>
<td>Yes □</td>
<td>No □</td>
</tr>
<tr>
<td>Age</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>Total Cholesterol mg/dL</td>
<td>150</td>
<td></td>
</tr>
<tr>
<td>HDL (Good Cholesterol) mg/dL</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Systolic Blood Pressure mm Hg</td>
<td>70</td>
<td></td>
</tr>
<tr>
<td>Are you currently taking any medication to treat high blood pressure?</td>
<td>Yes □</td>
<td>No □</td>
</tr>
<tr>
<td>Do you have Diabetes?</td>
<td>Yes □</td>
<td>No □</td>
</tr>
</tbody>
</table>

Calculate your 10-year risk of heart disease or stroke using the algorithm published in 2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk.

This calculator assumes that you have not had a prior heart attack or stroke.

UPDATE (5/26/14) -- The calculator now also incorporates guidelines from JNC-8 for blood pressure management.

An excel spreadsheet is also available for download.
Principle 7: Provide Blood Pressure and Cholesterol Screening and Control, Smoking Cessation, and Other Therapies to Reduce Cardiovascular Disease Risk

- Blood pressure
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- Multiple risk factor management
- Antiplatelet therapy
- Cardiovascular risk assessment
- Smoking cessation
Tobacco use cessation

• Smoking more than doubles the risk for CVD in people with diabetes.
• While smokeless tobacco poses a lesser risk for CVD than cigarette smoking, all forms of tobacco should be discouraged.
• People who stop using tobacco greatly reduce their risk of premature death.
• Medications, counseling, telephone help lines, and smoking cessation programs increase a person’s chances of success at stopping tobacco use.
• Additional effective therapies include nicotine replacement products (e.g., gum, inhaler, and patch).
Note

• Failure to take medication regularly as directed should be considered in people who do not meet blood pressure targets or show evidence of cholesterol lowering.

• Using strategies to help people with diabetes take their medicines as directed can improve adherence and affect their clinical outcomes, productivity, and quality of life.
Numbers of trial participants are added at the time of publication for historical trials (solid line) and at the estimated time of reporting for ongoing trials (dotted line). The red circle indicates when the new US Food and Drug Administration guidance for industry was issued.

Guiding Principles: Optimizing Self-management Education and Support

Martha Funnell, MS, RN, CDE
Chair, Diabetes HealthSense Task Group
Associate Research Scientist, Department of Learning Health Sciences, University of Michigan Medical School
Disclosures

• Advisory Boards: Eli Lilly, Bristol-Myers Squibb/AstraZeneca Diabetes, Novo Nordisk, Omada Health, Sanofi US
GUIDING PRINCIPLES
FOR THE CARE OF PEOPLE WITH OR AT RISK FOR DIABETES

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- Principle 1: Identify Undiagnosed Diabetes and Prediabetes
- Principle 2: Manage Prediabetes
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- Principle 7: Reduce Cardiovascular Disease Risk
- Principle 8: Detect and Monitor Microvascular Complications
- Principle 9: Consider Special Populations
- Principle 10: Provide Patient-Centered Care
Guiding Principles: Optimizing Self-management Education and Support

• “Effective DSME and on-going DSMS are essential to enable people with or at risk for diabetes to make informed decisions and to assume responsibility for the day-to-day management of their disease or risk factors.”
Why is Diabetes Self-management Education and Support a Guiding Principle?
Why is DSME/S a Guiding Principle?

- 99% of diabetes management is self-management
- Self-management and patient decision-making greatly impact outcomes
- Self-management is primarily affected by psychosocial issues and diabetes-related distress
- Effective education addresses all of these so that patients can take charge
Why is DSME/S a Guiding Principle?

• “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.”
  – 48.8% of participants in the DAWN2 study had received formal diabetes education; 81.1% found it helpful.

Why is DSME/S a Guiding Principle?

• Among newly diagnosed persons with diabetes in the US between 2009-2012, about 6.8% of privately insured, newly diagnosed adults (ages 18-64) participated in DSME during the first year after diagnosis.

Why is DSME/S a Guiding Principle?

• To clarify old, unquestioned assumptions about diabetes self-management education
  – It doesn’t work
  – It is not practical
  – There is nothing really new
Does DSME Work?
Evidence for DSME/S

- Effective for improving clinical and quality of life outcomes, at least in the short-term.\(^1\)\(^-\)\(^3\)
- Cost-effective.\(^4\)
- Repeated contacts over-time result in a dose-responsive effect on outcomes.\(^5\)

Evidence for DSME/S

- There is no single best educational program or approach.\(^1\)-\(^2\)
- However, programs that incorporate behavioral and psychosocial strategies have improved outcomes.\(^3\)-\(^4\)
- Group education is at least as effective as individual education.\(^5\)-\(^6\)
- Age and culturally appropriate programs improve outcomes.\(^3\)

Evidence for DSME/S

- Traditional knowledge-based diabetes DSME is essential but not sufficient for sustained behavior change.
- On-going diabetes self-management support (DSMS) is critical in order to sustain participants’ progress resulting from diabetes self-management education.

Practical Approaches to DSME/S
Practical Approaches to DSME/S

Interventions are more effective when:

• Tailored to patients’ preferences
• Tailored to patients’ social/cultural environment
• Actively engage patients in goal-setting
• Incorporate coping skills
• Provide follow-up support
Practical Approaches: Starting the Visit

• What is your biggest worry about diabetes?
• What is hardest for you or your biggest struggle about managing your diabetes?
• How has diabetes affected your daily life and that of your family?
• What questions do you have? What would you like to know when you leave here today?
• Do you have any cultural or religious practices that affect how you care for your diabetes?
• What one thing would you like to be different in terms of your daily life with diabetes?
Practical Approaches: Ending the Visit

Teach-back

• If you were to tell someone what we talked about here today, what would you say?
• What is one key thing you learned today?

Closing the Loop

• What is one thing you will do to better manage your diabetes?
Culture and Ethnicity
Building Cultural Awareness

- Ask your patients about their health beliefs and practices
- “Do you have any cultural/religious practices that influence how you care for your diabetes?”
- Ask your patients about their medications (including ones other than you prescribed)
- Ask about traditional and natural remedies
- Assess the role of family members and friends in making healthcare decisions
- Offer to include family members in discussions
What’s New in DSME/S?
What’s New?

• Evolved from primarily didactic interventions into more theoretically-based empowerment models.
• Initially focused on knowledge and “compliance/adherence” as the major outcome.
• More recently focused on behavior change and strategies to facilitate behavior change.
• Most recently have recognized need to address knowledge, behavior and psychosocial aspects (i.e., diabetes-related distress), along with providing on-going support.
What’s New: Patient-centered

• No lectures
• Respond to questions based on patient concerns
• Integrate clinical, behavioral and psychosocial
• Patient experiences serve as the curriculum
• Effective

What’s New: Technology

• Data are mixed in terms of DSME outcomes
• Useful for DSMS, prevention, reinforcement, tracking behaviors, communication
• Use will increase
Goals of New Beginnings

Help African Americans with diabetes:

- Manage the emotional impact of diabetes
- Build positive, supportive family relationships
- Develop behavioral skills:
  - Goal setting
  - Problem solving
  - Improved self-efficacy
  - Health literacy
New Beginnings Discussion Guide

- Use in small groups
- People with diabetes
- Family members
- Support coping and behavior change

www.cdc.gov/diabetes/ndep/new-beginnings.htm
In Summary:

• Ensure that the patient receives adequate self-management education and support.
• Set collaborative goals based on the patient’s personal goals, culture, values and environment.
• Review lab and other data at each visit.
• Share decision-making and be open-minded to the patient’s choices.
• Revisit and revise goals at each visit.
• Encourage participation in community programs.
• Recognize that the behaviors involved in managing and preventing diabetes are dynamic and multidimensional.

Using “Guiding Principles”: Moving toward Patient-Centered Diabetes Care

Linda M. Siminerio, RN, PhD, CDE
Chair NDEP
Professor of Medicine
University of Pittsburgh
Presenter Disclosure

Research Support: Becton-Dickinson
GUIDING PRINCIPLES
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- Principle 9: Consider Special Populations
- Principle 10: Provide Patient-Centered Care
Elements of Patient-Centered Care

1. Respecting values, preferences, and expressed needs
2. Communicating effectively
3. Development of individualized care plans
4. Assessing social, financial, clinical, & emotional needs
5. Proactive approach
6. Care coordination
7. Collaborative multidisciplinary team care
8. Incorporating access to community resources
Good Communication and Practice Transformation
Are we empathetic?

• Study aimed to describe relationship between patient BMI and physician communication behaviors.
• PCPs demonstrated less emotional rapport with overweight and obese patients than for normal weight patients.
• Findings raise concern that low levels of emotional rapport may weaken relationship, diminish adherence and effectiveness of counseling.

Empathy and diabetes

Patients of physicians with high empathy scores as compared to those with low empathy were:

• more likely to have good control of A1c ($p < .001$).
• proportion of patients with good LDL control ($p < .001$).
• lower rate of acute complications
• physicians’ understanding of their patients’ beliefs associated with better self-care among patients (e.g., improved diet, SMBG).

Patient Satisfaction

• 52% in ratings of care satisfaction was accounted for by physicians’ levels of warmth and respect.
• Dietitians’ empathic engagement predictive of patient satisfaction and successful consultations.
• Empathy was the most important quality for being considered a “good physician”.
• Patients who don’t have decision support more often blame their practitioner for bad outcomes.

Are decisions really shared?
Traditional Decision Model: Paternalism at Its Peak

“When we want your opinion, we’ll give it to you”
Consider approaches like: Shared Decision Making

Collaborative process that allows patients and their providers to make health care decisions together, taking into account the best scientific evidence available, as well as the patient’s values and preferences.
Consider that:

- Decisions may conflict with evidence-based guidelines.
- Discussion of options requires time & effort.
- Key to patient satisfaction and good outcomes.
- Better experience with providers associated with medication & treatment plan adherence.
Do they understand us?:
Health Literacy and Numeracy

• Health literacy includes ability to:
  – Make critical health decisions.
• 1 in 3 Americans has low health literacy.
• Older people, non-whites, immigrants, & those with low incomes are more likely to have trouble reading and understanding health information.
• Limited health literacy is associated with poorer outcomes and higher costs.
Health Literacy

Among diabetes patients, those with low literacy:

– Have greater difficulty understanding their condition
– Are less confident managing their diabetes
– Are less likely to engage in self-management
– Have worse glycemic control
– And have poorer communication with providers

Health Literacy

• Use plain language in written and spoken materials (no jargon)
  – Less than 2 syllables
• Explain medical terms
• Avoid phrases with two interpretations (eg, positive test results; negative test results)
• Open-ended questions (‘What questions do you have?’ not ‘Do you have questions?’)
• Highlight key recommendations
• Universal Precautions

Good Communication and Practice Transformation
Gap between what people want and what they get regarding engagement in health care:

- 8 in 10 people want their health care provider to listen to them, but just 6 in 10 say it actually happens.
- Less than half of people say their provider asks about their goals and concerns for their health.
- 9 in 10 people want their providers to work together as a team, but just 4 in 10 say it actually happens.

Real-Life & Practice Realities

525,600 minutes/year versus 45 minutes/3-4 visits/year

- 10-17 minutes with PCP every 3-6 months
- Follow-up visit provider addresses approximately 17 topics; writes 2 prescriptions; and discusses nutrition & medication changes within 17 minutes

Addressing Comorbidities and Screening

- Dental
- Eye care
- Depression/Distress

Activities of Daily Living

Micro- & Macro-Vascular Disease

Cancer

Tobacco
Patient Centered Medical Home
### Team Care: Differences in A1C

**Shojania KG, et al. JAMA. 2006;296:427-440.**

<table>
<thead>
<tr>
<th>Quality Improvement Strategy</th>
<th>No. of Trials</th>
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<td><strong>Team changes</strong></td>
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<td>Audit and feedback</td>
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<th>Difference in Post-Intervention A1C (%)</th>
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<td>Favors Intervention</td>
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<td>Favors Control</td>
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Bar chart showing the difference in post-intervention A1C (%) for various interventions.
Effective Teams:
Shared “Party-line” And Common Goals
Patient-Centered Medical Neighborhood: The Community
Our communities
What does NDEP have to offer?
NDEP and Health Literacy

Review of NDEP’s most popular publications for health literacy/plain language principles, including:

- Content
- Literacy Demand
- Health Numeracy
- Graphics and Visuals/ Layout and Design
- Learning Stimulation, Interaction and Motivation
- Cultural Appropriateness
NDEP Tools to Support Health Care Professional/Patient Communication

Redesigning the Health Care Team
Diabetes Prevention and Lifelong Management

Helping the Student with Diabetes Succeed
A Guide for School Personnel
Updated Edition 2010

Working Together to Manage Diabetes:
A GUIDE FOR PHARMACY, OPTOMETRY, AND DENTISTRY

NEW BEGINNINGS
A Discussion Guide for Living Well With Diabetes

LIVING A BALANCED LIFE WITH DIABETES
Engaging Health Organization Partners

- Pharmacy, Podiatry, Optometry and Dentistry Partnership Activities (PPOD)
  - "traditional" health care providers and PPOD professionals
- Range of providers collaborated on Guide
  - Access to expertise
  - Access to audiences
  - Consistent messages
  - Better final product

www.cdc.gov/diabetes/ndep/ppod.htm
Using “Guiding Principles”: Preventing Type 2 Diabetes – Progress since the Diabetes Prevention Program

Ann Albright, PhD, RD
Director, Division of Diabetes Translation
Centers for Disease Control and Prevention

National Diabetes Education Program
A program of the National Institutes of Health and the Centers for Disease Control and Prevention
Disclosures

• Nothing to disclose
# GUARDING PRINCIPLES
FOR THE CARE OF PEOPLE WITH OR AT RISK FOR DIABETES

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Evidence for National Diabetes Prevention Program

- The NIH DPP research study showed that structured lifestyle change program achieved modest weight loss of 5-7 percent and 150 min PA/wk reduced type 2 diabetes by 58% (71% in those over age 60) in those at high risk for type 2 diabetes
  - True for all participating ethnic groups and for both men and women
  - Blood pressure and lipids improved
  - 10-year f/u shows continued reduction in new cases of type 2 diabetes

- Translational studies demonstrate trained lay health workers and health professionals are effective in delivering the lifestyle change program

- Community Guide shows that longer duration programs are more effective

- National DPP is 1/3 of the cost of DPP research study and demonstrates similar lifestyle change results
National Diabetes Prevention Program - largest national effort to bring diabetes prevention lifestyle programs to communities

REDUCING THE IMPACT OF DIABETES

Congress authorized CDC to establish the NATIONAL DIABETES PREVENTION PROGRAM (National DPP) —a public-private initiative to offer evidence-based, cost effective interventions in communities across the United States to prevent type 2 diabetes to achieve a greater combined impact on reducing type 2 diabetes

Research shows structured lifestyle interventions can cut the risk of type 2 diabetes in half
National Diabetes Prevention Program

COMPONENTS

Training: Increase Workforce
Train the workforce that can implement the program cost effectively.

Recognition Program: Assure Quality
Implement a recognition program that will:
- Assure quality.
- Lead to reimbursement.
- Allow CDC to develop a program registry.

Intervention Sites: Deliver Program
Develop intervention sites that will build infrastructure and provide the program.

Health Marketing: Support Program Uptake
Increase referrals to and use of the prevention program.

Summary of Status of National DPP

- 624 CDC-recognized organizations delivering the program
- Program delivery sites in all 50 states, D.C. and Guam
- Programs being delivered in-person and through virtual technology
  - Recognition of organizations offering program via technology began with revised program standards in 2/15
- All CDC-recognized sites can be found at www.cdc.gov/diabetes/prevention/recognition
Source: Diabetes Prevention Recognition Program Registry (CDC/National Diabetes Prevention Program 4/14/2015)

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Summary of Status of National DPP

• About 30,000 participants served by organizations in CDC recognition program (does not yet include virtual program participants)

• Average weight loss is 4.6% by participants who have attended at least 4 sessions

• More than 20 health plans providing some amount of coverage

• 6,843 coaches trained

• More national partners coming on board
NDEP contributions to National DPP

- Helping to build organizational capacity
- Supplementing National DPP resources
Building Organizational Capacity

• Demonstration project using the *Road to Health Toolkit*
  – 3 community-based organizations serving Hispanic/Latino populations
  – Training and technical assistance
  – Monitoring behavioral change
  – Measuring capacity before, during, and after
Building Organizational Capacity

- Recruit an adequate number of participants
- Retain participants during the program and follow-up period
- Collect, track, report, and manage data
- Implement group sessions and 2 follow-up sessions
- Cover the contents with fidelity
- Participate in project’s evaluation activities

CBOs with CHWs
Recruit an adequate number of participants
Retain participants during the program and follow-up period
Collect, track, report, and manage data
Implement group sessions and 2 follow-up sessions
Cover the contents with fidelity
Participate in project’s evaluation activities

CBOs with CHWs
Supplementing Program Resources

- **CDC/AMA toolkit**
  - Refers people to NDEP’s Small Steps, Big Rewards GAMEPLAN
  - Source of additional resources

- **Lifestyle change programs**
  - NDEP resources for ethnic minorities supplement handouts from curriculum
Prevent Diabetes STAT
Screen, Test, Act –Today™

- The AMA and CDC have launched a multi-year initiative as part of the National DPP to reach more Americans with prediabetes, utilizing their collective muscle to offer the tools, resources and training needed to bridge the gap between the clinical setting and communities to achieve a healthier nation.

- The AMA and CDC are urging stakeholders to join them in this critical effort to Prevent Diabetes STAT.
Goals of Prevent Diabetes STAT

- Raise awareness about prediabetes
- Communicate a sense of urgency
- Increase screening, testing and referrals to CDC-recognized diabetes prevention programs
- Rally front-line healthcare providers, community organizations, public health professionals, health systems, employers, insurers, the public and more to ACT today
Prevent Diabetes STAT

- Dedicated Web site for key stakeholders
- www.preventdiabetesstat.org
Moving Forward: Future Directions for the NDEP

Joanne Gallivan, MS, RD
Director, NIH-NDEP
Disclosures

• Nothing to disclose
Goal: NDEP’s goal is to reduce the burden of diabetes and prediabetes by facilitating the adoption of proven approaches to prevent or delay the onset of diabetes and its complications.

Strategy 1: Behavior Change
Share model programs and resources to develop and sustain a healthy lifestyle with a focus on prevention and/or management.

Strategy 2: Clinical Setting
Share tools, resources and programs that help improve effectiveness in diabetes management and prevention interventions.

Strategy 3: Community Setting
Share tools and resources to improve health outcomes for people with diabetes and people at risk.

Diabetes HealthSense Resources for living well

Practice Transformation for Physicians and Health Care Teams
This site is dedicated to supporting health care professionals and health care administrators as they work to change the system of health care delivery around diabetes. NDEP shares best practice strategies to provide the focus of diabetes care connected to the Patient-Centered Medical Home (PCMH) model to physicians and other health care providers. The PCMH incorporates dimensions of care centered care presented by the Institute of Medicine and Chronic Care Model. This site is organized according to these dimensions.
Diabetes HealthSense

http://www.ndep.nih.gov/HealthSense

Diabetes HealthSense provides easy access to resources to help you live well and meet your goals—whether you have diabetes or are at risk for the disease.

Live well. Eat healthy. Be active. It’s not easy, but it’s worth it.
Medication Adherence

www.ndep.nih.gov/MedicationAdherence
Practice Transformation

www.ndep.nih.gov/PracticeTransformation
Resources for Health Care Professionals

www.ndep.nih.gov/GAMEPLAN

www.ndep.nih.gov/Webinars
NDEP Publications Reviewed for Plain Language Principles

www.ndep.nih.gov/Publications
Working with Partners to Support Systems Change: ACP

- The American College of Physicians incorporated the Practice Transformation website into a training module for their ACP Quality Champions in Diabetes.
- The goal of the training was to advance understanding of key practice transformation and quality improvement strategies.

www.ndep.nih.gov/PracticeTransformation

www.acponline.org
Working with Partners to Provide Better Diabetes Care for Students: ADA

- ADA Partnership Activities
  - Provides organizational expertise and input in the development of (and updates to) NDEP’s *School Guide*
  - Incorporates the *School Guide* as part of its "Safe at School" initiative
  - Cross-promotion

www.diabetes.org/safeatschool
www.YourDiabetesInfo.org/SchoolGuide
Working with Partners to Provide Support and Behavior Change: AADE and Diabetes HealthSense

- Input on evaluation plans and instruments
- Access to AADE’s membership
- Recruitment of evaluation sites and participants
- Contributions to final reports and/or evaluation manuscripts

www.diabeteseducator.org

Support for Clinical Trials

- D2d Vitamin D and Type 2 Diabetes Ancillary Study
- GRADE Study
- RAPID Study
- All use NDEP patient education materials as part of intervention

www.d2dstudy.org
https://portal.bsc.gwu.edu/web/grade
NDEP National Diabetes Survey (NNDS)

- Provides specific and timely data about the population's diabetes KAP’s
- 2011 results showed continued lack of awareness of diabetes and CVD link

  - NDEP Campaign:

Be Smart About Your Heart
Control the ABCs of Diabetes

- 2014 focus: self-management, self-care, perceived risk
Ways You Can Get Involved

- Stakeholder Groups
- Task Groups
- Pretesting
- Technical Reviewers
- News & Notes
- Webinars
- Social Media

http://ndep.nih.gov/partners-community-organization
Moving Forward: Future Directions for the NDEP

Judith A. McDivitt, PhD
Director, National Diabetes Education Program
Centers for Disease Control and Prevention
Presenter Disclosure

No conflict of interest
**Goal:** NDEP’s goal is to reduce the burden of diabetes and prediabetes by facilitating the adoption of proven approaches to prevent or delay the onset of diabetes and its complications.

**Strategy 1: Behavior Change**
Promote model programs to develop and sustain a healthy lifestyle with a focus on prevention and/or management.

**Strategy 2: Clinical Setting**
Promote models and strategies for team care.

**Strategy 3: Community Engagement**
Increase adoption of tools and resources to improve health outcomes for people with diabetes and people at risk.
Working with States and Cities

Build support for healthy lifestyles
- Partner networks
- Tailored communications

Health system interventions
- Team-based care
- Systems to identify & refer people with prediabetes

Community-clinical linkages
- Diabetes Self-management Education access
- Lifestyle change programs
Working in Communities

- Community-based organizations
- Community Health Workers
- Business and worksite community
Supporting Community-based Organizations and Individuals

- Build capacity
  - Toolkits
  - Training
  - Technical assistance

- Link partners

- Provide access to culturally-appropriate resources
Supporting Community Health Workers

• Build relationships
• Increase capacity related to diabetes
• Facilitate inclusion of diabetes in certification requirements
• Develop key guidance documents
Supporting Businesses and Worksites

www.DiabetesAtWork.org
Empowering Partners

- Provide easy access to science-based relevant resources
  - Website
  - Collections of resources
  - Webinars
  - Training and technical assistance

www.CDC.gov/diabetes/NDEP
Collections of Resources

- African American/African Ancestry
- American Indian/Alaska Native
- Asian American/Native Hawaiian/Pacific Islander
- Hispanic/Latino
- Pharmacy, Podiatry, Optometry and Dentistry (PPOD)
- Community Health Workers
Webinars

What Can PPOD Providers Do?
- PPOD providers can:
  - Embrace a team approach to diabetes care.
  - Recognize signs of diabetes and systemic concerns across all PPOD areas.
  - Reinforce the importance of annual screenings and healthy habits.
  - Educate patients about diabetes.
  - Encourage self-management.
  - Provide treatment.

Living a Balanced Life With Diabetes: An Introductory Webinar

Shondra McCage, M.P.H., CHES
Michelle Owens-Gary, Ph.D.
On behalf of NDEP’s American Indian/Alaska Native Stakeholder Group

Webinars

Community Health Workers: Their Role in Preventing and Controlling Chronic Conditions

Whole Population Health Management

Population Health Management… Improving health where we live, work and play
Partner Activities

- Identify needs
- Collaborate on strategies
- Ensure relevance
- Incorporate, adopt, and adapt
- Extend reach
Alone we can do so little; together we can do so much.

Helen Keller
Join Us!

www.ndep.nih.gov
Joanne.Gallivan@nih.gov

www.cdc.gov/diabetes/ndep
JMcDivitt@cdc.gov