2013 NDEP Symposium: New Science – Implications for Diabetes Care

Sunday, June 23, 2013
Introduction and Highlights

Ann Albright, PhD, RD
Director, Division of Diabetes Translation
Centers for Disease Control and Prevention
• **New Science about Weight Management in Diabetes**
  John Buse, MD, PhD

• **Systems of Care: Implications for Diabetes Management**
  Carol Mangione, MD, MSPH

• **Health Care Professional/Patient Communication: Effect on Diabetes Outcomes**
  Linda Siminerio, RN, PhD, CDE

• **How New Science is Shaping NDEP’s Messages and Materials**
  Judy Fradkin, MD
Introduction to NDEP

• Starting its 16th year
• Collaboration between CDC and NIH, with over 200 partners
• Science-based education tools, strategies, and messages
  – Prevention of diabetes and its complications
  – Range of audiences – public to professional
  – Culturally and linguistically appropriate
Current Major Activities

• Strategic planning for 2014-2019
• Updating and revising
  – New science
  – Health literacy
• Evaluating
Strategic Plan for 2014-2019

• Task group of partner volunteers is assisting
• Environmental scan and input from partners
• Empower partners to
  – Support people with/at risk for diabetes make and sustain lifestyle changes
  – Conduct effective clinical and community-based interventions that improve health outcomes
Updating and Revising

• Web sites
  – www.DiabetesAtWork.org

• Team care resource – guide and toolkit for pharmacy, podiatry, optometry, dentistry (PPOD)

• New Beginnings Guide
Evaluation

• Evaluation of reach and use of 5 major NDEP resources
  – Evaluation task group helping to design
  – Quantitative and qualitative data collection
  – Results to be presented and feed into program improvement

• Continued monitoring of NDEP and partner activities
New Science – Implications for Diabetes Care

• New science about weight management and diabetes
• Implications of systems of care
• Health care professional/patient communication
• New science and NDEP resources
New Science about Weight Management in Diabetes

John Buse, MD, PhD
Chair, National Diabetes Education Program
Verne S Caviness Distinguished Professor of Medicine, University of North Carolina School of Medicine
Presenter Disclosure

• I am an investigator or consultant under contract with my employer for:

• These provide no direct financial benefit to me.
Diabetes HealthSense
www.YourDiabetesInfo.org/HealthSense
Look AHEAD
(Action for Health In Diabetes)
Current Status of Look AHEAD

• In September 2012, NIH, based on the recommendation of the DSMB, terminated the intervention for futility--no difference in primary outcome between the two groups after up to 10 years of follow-up.

• Look AHEAD results will be presented on Monday at 4:30-6p.

• Follow-up of participants will continue
Intensive Lifestyle Intervention in Look-AHEAD Provided Benefits

- BMI, CVD risk factors and A1C, despite less medication\(^1\)
- Increased rates of partial diabetes remission\(^2\)
- Urinary incontinence in women\(^3\)
- Sleep apnea\(^4\)
- Depression symptoms\(^5\)
- Quality of life\(^6\)
- Physical function\(^7\)
- Mobility\(^8\)
- Reduced NAFLD\(^9\)
- Biomarkers\(^10\)
- Sexual dysfunction in women\(^11\)

Figure 1. Model of Four States of Clinical Disability.

In state 1 (good mobility), participants had some difficulty in performing vigorous physical activities. In state 2 (mild mobility-related disability), participants had problems in bending and long-distance walking. In state 3 (moderate mobility-related disability), participants had deficits in many tasks and some deterioration in the ability to climb stairs and engage in moderately demanding activities. In state 4 (severe limitations), participants had difficulty in nearly all tasks. In each category, the longer the horizontal bar, the higher the probability that participants could perform that task without difficulty.
Look AHEAD: Mobility & Disability

Figure 2. Prevalence of the Four States of Clinical Disability during the 4-Year Study.

The numbers in each color block are the percentages of participants at each state of mobility-related disability among those receiving diabetes support and education and those receiving an intensive lifestyle intervention. Values at follow-up visits for years 1 to 4 have been adjusted for baseline values.
Look AHEAD: Sexual Dysfunction in Women

ORIGINAL ARTICLE

FTO predicts weight regain in the Look AHEAD clinical trial

JM McCaffery1, GD Papandonatos2, GS Huggins3, I Peter4, SE Kahn5, WC Knowler6, GE Hudnall7, EW Lipkin8, AE Kitabchi5,
LE Wagenknecht9 and RR Wing1, The Genetic Subgroup of Look AHEAD, and The Look AHEAD Research Group10

BACKGROUND: Genome-wide association studies have provided new insights into the genetic factors that contribute to the development of obesity. We hypothesized that these genetic markers would also predict magnitude of weight loss and weight regain after initial weight loss.

METHODS: Established obesity risk alleles available on the Illumina Care iSelect (IBC) chip were characterized in 3899 overweight or obese participants with type 2 diabetes from the Look AHEAD (Action for Health in Diabetes), a randomized trial to determine the effects of intensive lifestyle intervention (ILI) and diabetes support and education (DSE) on cardiovascular morbidity and mortality. Primary analyses examined the interaction between 13 obesity risk polymorphisms in eight genes and randomized treatment arm in predicting weight change at year 1, and weight regain at year 4 among individuals who lost 3% or more of their baseline weight by year 1.

RESULTS: No single-nucleotide polymorphisms (SNPs) were significantly associated with magnitude of weight loss or interacted with treatment arm at year 1. However, fat mass and obesity associated gene (FTO) rs3751812 predicted weight regain within DSE (1.56 kg per risk allele, P = 0.005), but not ILI (P = 0.761), resulting in SNP × treatment arm interaction (P = 0.009). In a partial replication of prior research, the obesity risk (G) allele at BDNF rs6265 was associated with greater weight regain across treatment arms (0.773 kg per risk allele), although results were of borderline statistical significance (P = 0.051).

CONCLUSIONS: Variations in the FTO and BDNF loci may contribute risk of weight regain after weight loss.

International Journal of Obesity advance online publication, 30 April 2013; doi:10.1038/ijo.2013.54

Keywords: type 2 diabetes; weight loss; diet; genetics
Intensive Lifestyle Intervention in Look-AHEAD Provided Benefits

- BMI, CVD risk factors and A1C, despite less medication\(^1\)
- Increased rates of partial diabetes remission\(^2\)
- Urinary incontinence in women\(^3\)
- Sleep apnea\(^4\)
- Depression symptoms\(^5\)
- Quality of life\(^6\)
- Physical function\(^7\)
- Mobility\(^8\)
- Reduced NAFLD\(^9\)
- Biomarkers\(^10\)
- Sexual dysfunction in women\(^11\)

Translating the DPP Lifestyle Intervention for Weight Loss Into Primary Care

Estimated mean ± SE weight change over a 15-month period in the intention-to-treat population.

Primary Prevention of Cardiovascular Disease with a Mediterranean Diet

Ramón Estruch, M.D., Ph.D., Emilio Ros, M.D., Ph.D., Jordi Salas-Salvadó, M.D., Ph.D., Maria-Isabel Covas, D.Pharm., Ph.D., Dolores Corella, D.Pharm., Ph.D., Fernando Arós, M.D., Ph.D., Enrique Gómez-Gracia, M.D., Ph.D., Valentina Ruiz-Gutiérrez, Ph.D., Miquel Fiol, M.D., Ph.D., José Lapetra, M.D., Ph.D., Rosa Maria Lamuela-Raventos, D.Pharm., Ph.D., Lluís Serra-Majem, M.D., Ph.D., Xavier Pintó, M.D., Ph.D., Josep Basora, M.D., Ph.D., Miguel Angel Muñoz, M.D., Ph.D., José V. Sorlí, M.D., Ph.D., José Alfredo Martínez, D.Pharm, M.D., Ph.D., and Miguel Angel Martínez-González, M.D., Ph.D., for the PREDIMED Study Investigators*
• Parallel group multi-center randomized controlled trial
• Inclusion/exclusion criteria
  – Men: 55 to 80 years of age       Women: 60 to 80 years of age
  – No CVD, but at high risk for CVD
    • Type 2 diabetes OR
    • At least 3 of the following major risk factors: smoking, hypertension, elevated LDL, low HDL, overweight, family history of CHD
• From 10/2003 – 6/2009, 7441 participants randomized in 1:1:1 ratio to
  – Med diet plus extra virgin olive oil
  – Med diet plus nuts
  – Control diet (lower fat diet)

Mediterranean Diet . . . More of:

<table>
<thead>
<tr>
<th>Food</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Olive Oil (extra virgin olive oil) (1 tbsp = 14 gms)</td>
<td>≥ 4 tbsp/day</td>
</tr>
<tr>
<td>Tree nuts and peanuts (30g, 15g walnuts, 7.5g almonds, 7.5g hazelnuts)</td>
<td>≥ 3 servings/wk</td>
</tr>
<tr>
<td>Fresh fruits</td>
<td>≥ 3 servings/day</td>
</tr>
<tr>
<td>Vegetables</td>
<td>≥ 2 servings/day</td>
</tr>
<tr>
<td>Fish (especially fatty fish), seafood</td>
<td>≥ 3 servings/wk</td>
</tr>
<tr>
<td>Legumes</td>
<td>≥ 3 servings/wk</td>
</tr>
<tr>
<td>Sofrito (sauce made w/ tomatoes &amp; onions, often including garlic and herbs simmered slowly w olive oil)</td>
<td>≥ 2 servings/wk</td>
</tr>
<tr>
<td>White meat</td>
<td>Instead of red meat</td>
</tr>
<tr>
<td>Wine with meals (optional, only for habitual drinkers)</td>
<td>≥ 7 glasses/wk</td>
</tr>
</tbody>
</table>
## Mediterranean Diet . . . Less of:

<table>
<thead>
<tr>
<th>Food</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soda Drinks</td>
<td>&lt; 1 drink/day</td>
</tr>
<tr>
<td>Commercial bakery goods, sweets, and pastries</td>
<td>&lt; 3 servings/wk</td>
</tr>
<tr>
<td>Spread Fats</td>
<td>&lt; 1 servings/day</td>
</tr>
<tr>
<td>Red and processed meats</td>
<td>&lt; 1 servings/day</td>
</tr>
</tbody>
</table>

Control (lower fat) Diet . . . More of:

<table>
<thead>
<tr>
<th>Food</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-fat dairy products</td>
<td>≥ 3 servings/day</td>
</tr>
<tr>
<td>Bread, potatoes, pasta, rice</td>
<td>≥ 3 servings/day</td>
</tr>
<tr>
<td>Fresh fruits</td>
<td>≥ 3 servings/day</td>
</tr>
<tr>
<td>Vegetables</td>
<td>≥ 2 servings/day</td>
</tr>
<tr>
<td>Lean fish and seafood</td>
<td>≥ 3 servings/wk</td>
</tr>
</tbody>
</table>

## Control (lower fat) Diet . . . Less of:

<table>
<thead>
<tr>
<th>Food</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vegetable oils (including olive oil)</td>
<td>≤ 2 tbsp/day</td>
</tr>
<tr>
<td>Commercial bakery goods, sweets, pastries</td>
<td>≤ 1 serving/wk</td>
</tr>
<tr>
<td>Nuts and fried snacks</td>
<td>≤ 1 serving/wk</td>
</tr>
<tr>
<td>Red and processed fatty meats</td>
<td>≤ 1 serving/wk</td>
</tr>
<tr>
<td>Visible fats in meats and soups</td>
<td>Always remove</td>
</tr>
<tr>
<td>Fatty fish, seafood canned in oil</td>
<td>≤ 1 serving/wk</td>
</tr>
<tr>
<td>Spread fats</td>
<td>≤ 1 serving/wk</td>
</tr>
<tr>
<td>Sofrito</td>
<td>≤ 2 serving/wk</td>
</tr>
</tbody>
</table>

Diet Intervention--Format

• Dietitians ran individual and group sessions at baseline and quarterly thereafter
• 14 item dietary screener was used to assess adherence to the Med Diet

## Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Med Olive Oil N = 2543</th>
<th>Med Nuts N = 2454</th>
<th>Control N = 2450</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, %</td>
<td>59%</td>
<td>54%</td>
<td>60%</td>
</tr>
<tr>
<td>Age, years</td>
<td>67</td>
<td>67</td>
<td>67</td>
</tr>
<tr>
<td>White, from Europe, %</td>
<td>97%</td>
<td>97%</td>
<td>97%</td>
</tr>
<tr>
<td>Current smoker, %</td>
<td>14%</td>
<td>14%</td>
<td>14%</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>30</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td>Hypertension, %</td>
<td>82%</td>
<td>82%</td>
<td>84%</td>
</tr>
<tr>
<td>Type 2 diabetes, %</td>
<td>50%</td>
<td>47%</td>
<td>48%</td>
</tr>
<tr>
<td>Dyslipidemia, %</td>
<td>72%</td>
<td>73%</td>
<td>72%</td>
</tr>
<tr>
<td>Family history premature CHD, %</td>
<td>23%</td>
<td>22%</td>
<td>23%</td>
</tr>
<tr>
<td>Statins, %</td>
<td>41%</td>
<td>39%</td>
<td>40%</td>
</tr>
<tr>
<td>Score for adherence to Med diet</td>
<td>8.7</td>
<td>8.7</td>
<td>8.4</td>
</tr>
</tbody>
</table>

Follow-up
  - Median 4.8 years
  - As of 12/2010:
    • 523 (7%) lost to follow-up
    • Drop out higher in control (11%) then in Med groups (5%)

Compliance with diet
  - Similar diets at baseline per 14 item screener
  - During follow-up, significant differences for:
    • 12 of 14 items
    • Also changes in objective biomarkers (urine for hydroxytyrosol in olive oil and plasma alph-linolenic acids for nuts)

Primary Endpoint

Incidence of composite CVD Endpoint

## Adjusted Hazard Ratios Compared to Control Diet

<table>
<thead>
<tr>
<th>End Point</th>
<th>Med Olive Oil</th>
<th>Med Nuts</th>
<th>Med Both</th>
<th>P Olive</th>
<th>P Nuts</th>
<th>P Both</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary end point</strong></td>
<td>.70</td>
<td>.72</td>
<td>.71</td>
<td>.01</td>
<td>.03</td>
<td>.005</td>
</tr>
<tr>
<td><strong>Secondary end points</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>.67</td>
<td>.54</td>
<td>.61</td>
<td>.04</td>
<td>.006</td>
<td>.005</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>.80</td>
<td>.74</td>
<td>.77</td>
<td>.34</td>
<td>.22</td>
<td>.20</td>
</tr>
<tr>
<td>CVD death</td>
<td>.69</td>
<td>1.01</td>
<td>.83</td>
<td>.17</td>
<td>.98</td>
<td>.41</td>
</tr>
<tr>
<td>All death</td>
<td>.82</td>
<td>.97</td>
<td>.89</td>
<td>.15</td>
<td>.82</td>
<td>.32</td>
</tr>
</tbody>
</table>

• Discussion (authors):
  – Energy unrestricted Med Diet associated with a 30% decrease in risk for CVD events in high risk population (roughly equivalent to effect of statins)
  – Consistent with prior observational studies about diet and heart disease
  – Consistent with lower CVD risk in Mediterranean countries compared to US and northern Europe
  – The major between group difference involved the supplements – EVO and nuts
  – For most participants, baseline diet was similar to the Med Diets studied, suggesting a potentially greater benefit for Med Diet c/t Western diets

• Other Outcomes—Noted in Commentaries:
  – No weight gain among those on Med Diet
  – Effects additive to that of statins

Effects of Promoting Longer-term and Exclusive Breastfeeding on Adiposity and Insulin-like Growth Factor-I at Age 11.5 Years
A Randomized Trial
Effects of Promoting Longer-term and Exclusive Breastfeeding on Adiposity and Insulin-like Growth Factor-I at Age 11.5 Years
A Randomized Trial

**Importance**  Evidence that longer-term and exclusive breastfeeding reduces child obesity risk is based on observational studies that are prone to confounding.

**Objective**  To investigate effects of an intervention to promote increased duration and exclusivity of breastfeeding on child adiposity and circulating insulin-like growth factor (IGF)-I, which regulates growth.

**Design, Setting, and Participants**  Cluster-randomized controlled trial in 31 Belarusian maternity hospitals and their affiliated clinics, randomized into 1 of 2 groups: breastfeeding promotion intervention (n=16) or usual practices (n=15). Participants were 17,046 breastfeeding mother-infant pairs enrolled in 1996 and 1997, of whom 13,879 (81.4%) were followed up between January 2008 and December 2010 at a median age of 11.5 years.


**Main Outcome Measures**  Body mass index (BMI), fat and fat-free mass indices (FMI and FFM), percent body fat, waist circumference, triceps and subscapular skinfold thicknesses, overweight and obesity, and whole-blood IGF-I. Primary analysis was based on modified intention-to-treat (without imputation), accounting for clustering within hospitals and clinics.

**Results**  The experimental intervention substantially increased breastfeeding duration and exclusivity when compared with the control (43% vs 6% exclusively breastfed at 3 months and 7.9% vs 0.6% at 6 months). Cluster-adjusted mean differences in outcomes at 11.5 years of age between experimental vs control groups were: 0.19 (95% CI, 0.09 to 0.46) for BMI; 0.12 (0.03 to 0.26) for FMI; 0.04 (−0.11 to 0.18) for FFMI; 0.47% (−0.11% to 1.05%) for percent body fat; 0.30 cm (−1.41 to 2.01) for waist circumference; −0.07 mm (−1.71 to 1.57) for triceps and −0.02 mm (−0.79 to 0.75) for subscapular skinfold thicknesses; and −0.02 standard deviations (−0.12 to 0.08) for IGF-I. The cluster-adjusted odds ratio for overweight/obesity (BMI ≥85th vs <85th percentile) was 1.18 (95% CI, 1.01 to 1.39) and for obesity (BMI ≥95th vs <85th percentile) was 1.17 (95% CI, 0.97 to 1.41).

**Conclusions and Relevance**  Among healthy term infants in Belarus, an intervention that succeeded in improving the duration and exclusivity of breastfeeding did not prevent overweight or obesity, nor did it affect IGF-I levels at age 11.5 years. Breastfeeding has many advantages but population strategies to increase the duration and exclusivity of breastfeeding are unlikely to curb the obesity epidemic.

**Trial Registration**  isrctn.org: ISRCTN37687716; and clinicaltrials.gov: NCT01561612
Summary

• Look AHEAD: Lifestyle intervention aimed at weight loss provides broad benefits. Continuing follow-up will provide additional insights.

• DPP: Interventions are being successfully translated to provide meaningful weight loss. Cost-effectiveness and outcomes will require further follow-up.

• PREDIMED: Diet composition/quality does have important influences on health.

• In general, preconceived notions require careful study. NDEP’s HealthSense attempts to keep on top of this for providers and the public.
Systems of Care – Implications for Diabetes Management

Carol M. Mangione, MD, MSPH
Barbara A. Levey and Gerald S. Levey Professor of Medicine and Health Policy & Management
Outline

• The TRIAD Study and lessons learned about system level interventions
• Importance of benefit design/generosity – Results from the TRIAD Part D Study
• The Patient Protection and Affordable Care Act – What does it mean for people with diabetes?
• NEXT–D Study – A learning lab for system level interventions
• Conclusions
Translating Research Into Action for Diabetes

TRIAD

A Multi-Center Study of Diabetes Care in Managed Care Settings
TRIAD Sites and Sponsoring Agencies

- Pacific Health Research Institute
- Kaiser Permanente Northern California
- UCLA
- U Michigan
- Indiana U
- UMDNJ
- CDC
- NIDDK
- Veterans Health Administration / TRIAD Study Sites (2000-2004)
- National Institute of Digestive and Diabetes and Kidney Disorders - Sponsor

Translational Research Centers / TRIAD Study Sites
TRIAD Design and Structure

• **Multi-center study:** 10 managed care health plans.

• **Multi-level study:** diabetes outcomes study with assessment of 11,927 diabetic patients, linked to measurement of 68 provider groups, 10 health plans, and hundreds of communities that serve them.

• **Multi-design study:** Unified, multi-center cohort study with focused evaluations and natural experiments overlaid on broader structure.

• Diverse in age, gender, race/ethnicity, socioeconomic status, geography, and type of system.
TRIAD Focus

“System-level” analyses of managed care organizational characteristics and services:

• impact of diabetes interventions in everyday practice
• possibility that managed care creates barriers to care

“Patient-level” factors in this large and diverse cohort of diabetic patients:

• variation in quality of care across diverse populations
• role of socioeconomic position on health status, health behaviors, diabetes complications, comorbidities
TRIAD Conceptual Model for Relationships of System-Level Factors, Processes and Outcomes of Care

System Factors
- Health Systems Structure
- Disease Mgmt. Strategies
  - Performance Feedback
  - Physician Reminders
  - Patient Reminders
- Guideline Use
- Formal Case Management
- Patient Education resources
- Management of Referral Care
- Clinician payment, incentives
- Cost-containment strategies
- Data Systems

Processes of Care (Quality of Care)
- Periodic Hb A1c Testing
- Periodic Lipid Testing
- Retinal Examinations
- Periodic Microalbuminuria testing
- Periodic Foot Examinations
- Smoking Cessation Counseling
- Aspirin Prescription/Advice

Health Outcomes
- Glycemic Control
- Blood Pressure Control
- LDL-c Control
- Cardiovascular Disease
- Nephropathy/ESRD
- Retinopathy
- Mortality
- Health Status
- Symptoms
- Utilization and Costs
Original TRIAD Cohort Ethnicity

- White (Non-Hispanic) 39%
- African American (Non-Hispanic) 15%
- Hispanic/Latino 15%
- Asian & Pacific Islander 15%
- Other 8%
- Unknown or Missing 8%
Predictor: PG Physician Feedback

**Least Intense Quintile**  **Most Intense Quintile**

- HbA1c Check
- Lipid Check
- Proteinuria Check
- Eye Exam
- Foot Exam
- Flu Shot
- ASA Rec

* significant p<.05

Predictor: PG Diabetes Care Management

![Graph showing HbA1c, Lipid Check, Proteinuria Check, Eye Exam, Foot Exam, Flu Shot, ASA Rec, Least Intense Quintile, Most Intense Quintile, and significant p<.05.]

Mangione et al., Ann Intern Med, 2006

* significant p<.05
Association Between Disease Management Intensity and Levels of Risk Factor Control

## Adjusted Quality-of-Care Rates for Veterans Affairs and Commercial Managed Care Participants*

<table>
<thead>
<tr>
<th>Quality-of-Care Measure (Data Source)</th>
<th>VA Rate (95% CI) (n= 1273), %</th>
<th>CMC Rate (95% CI) (n= 6901), %</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Processes of Care</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annual eye exam</td>
<td>91 (87–93)</td>
<td>75 (69–80)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Annual hemoglobin A1c test</td>
<td>93 (89–96)</td>
<td>83 (76–87)</td>
<td>0.005</td>
</tr>
<tr>
<td>Annual lipid screening</td>
<td>79 (69–86)</td>
<td>63 (51–73)</td>
<td>0.02</td>
</tr>
<tr>
<td>Annual foot exam</td>
<td>98 (96–99)</td>
<td>84 (79–88)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Annual proteinuria screening</td>
<td>92 (89–95)</td>
<td>81 (75–86)</td>
<td>0.005</td>
</tr>
<tr>
<td>Aspirin use counseling</td>
<td>75 (69–79)</td>
<td>49 (44–53)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Influenza vaccination</td>
<td>72 (66–77)</td>
<td>64 (60–68)</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Intermediate Outcomes</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood pressure &lt; 140/90 mm Hg</td>
<td>53 (46–60)</td>
<td>52 (47–57)</td>
<td>&gt;0.2</td>
</tr>
<tr>
<td>Hemoglobin A1c value &lt;8.5%</td>
<td>83 (75–89)</td>
<td>65 (54–75)</td>
<td>0.009</td>
</tr>
<tr>
<td>LDL cholesterol level &lt;2.59 mmol/L (&lt;100 mg/dL)</td>
<td>52 (45–59)</td>
<td>36 (32–40)</td>
<td>0.003</td>
</tr>
</tbody>
</table>

* Higher rates represent higher quality. CMC = commercial managed care; LDL = low-density lipoprotein; VA = Veterans Affairs.
**Key Health System and Structural Factors**

**Findings:**


Health System and Structural Factor Findings:

- Processes of care at the provider group level are related to patient satisfaction and perceptions of quality, but not HbA1c or SBP – Ackermann et al., Diabetes Care, 2006.

- Only 20-23% of patients in poor control appeared to have poor medication adherence, whereas 30-47% of patients had good adherence but pharmacotherapy had not been intensified in response to the poor control – Schmittdiel et al., J Gen Intern Med, 2008.
**TRIAD Cost-Related Findings:**

- Greater out-of-pocket costs (through co-pays, non-coverage) are associated with lower rates of retinal exams, health education, and self-monitoring of blood glucose — Karter et al., *Diabetes Care*, 2003.

- Respondents reported using less medication than recommended because of costs — Tseng et al., *Diabetes Care*, 2008.
Medicare Part D, Cost Sharing, Medication Adherence, and Outcomes for Patients with Diabetes

Results from the UCLA TRIAD Part D Study (2006-2011)
Background on Medicare Part D

• The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) established an outpatient pharmacy benefit, known as Part D
• Went into effect on January 1, 2006
• Coverage provided through private plans but overseen by CMS
  – Stand-alone prescription drug plans (PDPs)
  – Medicare Advantage prescription drug plans (MA-PDs)
Figure 3.1
Prescription Drug Coverage Among Medicare Beneficiaries, 2010

- No Drug Coverage: 4.7 million (10%)
- Other Drug Coverage: 5.9 million (13%)
- Retiree Drug Coverage: 8.3 million (18%)
- Medicare Advantage Drug Plan: 9.9 million (21%)
- Stand-Alone Prescription Drug Plan (PDP): 17.7 million (38%)

Total in Part D Plans: 27.7 Million (60%)

Total Number of Medicare Beneficiaries = 46.5 Million
The Coverage Gap

- Most Part D plans have a coverage gap.
- An estimated 3.4 million Medicare beneficiaries (14% of all Part D enrollees) reached the coverage gap in 2007 and faced the full cost of their prescriptions.
- Of those who reached the gap, 20 percent stopped taking their medication, reduced their medication use, or switched medications.
Diabetes & the Part D Coverage Gap

- Diabetes treatment is associated with significant out-of-pocket medication costs

- Patients with diabetes may be at high risk of entering the coverage gap, leading to adverse consequences such as cost-related non-adherence

- Cost-related non-adherence leads to increased hospitalizations and mortality
Analysis

- Compares drug costs and adherence among beneficiaries with diabetes from MAPD plans with varying levels of gap coverage
- We examined the effect of reaching the coverage gap on:
  - Total drug costs
  - Patient out-of-pocket costs
  - Adherence to chronic medications

Key Findings

• 25 to 29% of persons with diabetes entered the gap
• Having a coverage gap was associated with 4 to 7% reduction in total drug costs
• Adherence was lower for those who entered the coverage gap
• Generic-only coverage during the gap was associated with only modest differences in out-of-pocket spending and adherence compared with having a complete gap in coverage

Patients want to discuss the cost of their meds, but are not always doing so.

Summary

- Overall, more patients wanted to discuss drug costs with their MDs than actually did.
- MDs are relatively more likely to:
  - switch patients to a cheaper medication
  - specifically discuss which medications not to skip
- MDs are relatively less likely to:
  - ask patients if they can afford medications
  - provide information on where to get less expensive medications
Expenditure Simulation

• Identify the drug classes contributing the most to total costs
• For these drug classes, identify whether a therapeutic substitute exists
• If so, substitute the weighted mean price of the therapeutic substitute within GPI code for original price

Key Findings

• Among Medicare beneficiaries 52% had at least one possible cost-saving therapeutic substitution

• Therapeutic substitution in 2007 would have saved an average annual saving of $393 per participant
TRIAD/Medicare Part D Study: Take-Home Points about costs

- More than 25% of persons with diabetes entered the coverage gap in 2006 and gap entry was associated with a modest reduction in total costs and adherence.
- Persons with diabetes who enter the gap report less adherence and going without necessities as compared to those with coverage in the gap.
- Many more patients report that they want to have conversations about costs of medications with their MD than are having them.
- Therapeutic substitution is a promising strategy to reduce overall medication costs and delay gap entry.
Changes in 2010

- The Affordable Care Act of 2010 provides a $250 rebate to Part D enrollees with any spending in the coverage gap in 2010.
- Between 2011 and 2020 coverage in the gap is gradually phased in.
- The standard benefit amounts increase annually by the rate of per capita Part D spending growth.
Patient Protection and Affordable Care Act (ACA)

• Federal Health Care Reform Legislation that became law in 2010
• June 2012 US Supreme Court declares that the ACA is constitutional
ACA Provisions that Impact Persons with Diabetes

• In 2014 insurance companies can no longer deny coverage because of pre-existing conditions such as diabetes
• Insurers are no longer allowed to limit or drop coverage to avoid paying diabetes related expenses
• People cannot be charged higher premiums because they have diabetes
ACA Provisions that Impact Persons with Diabetes

• Since 2010, children under 19 could not be excluded from coverage because they have diabetes
• Young adults up to age 26 can stay on their parents insurance
• In 2012, Medicare beneficiaries who reach the donut hole, had to pay 50% for branded and 86% of the cost of generics. By 2020 the ACA closes the donut hole in Part D.
NEXT-D  Natural Experiments in Translation for Diabetes

A Collaborative Network of Effectiveness Studies of Population-Targeted Polices for Diabetes Prevention and Control

Basic Barriers to Prioritizing Policies for Diabetes Prevention and Control

• Lack of research platforms for rigorous health policy research.

• Limitations of commonly employed study designs.

• Identifying control conditions to distinguish between secular trends and gauge true effectiveness.
5 Year Goals and Intended Impact

• Identify, prioritize, (and in some cases, reject) major population-targeted policies to prevent and control diabetes using rigorous longitudinal studies.

• Provide a new model for high impact policy research for diabetes prevention and control through use of innovate collaborative study designs.

• Enhance the capacity of our research groups, trainees, and collaborators to conduct influential diabetes policy research.
Attributes of Studies

• Population targeted policies and interventions from 3 sources:
  – Health Systems
  – Business and community organizations
  – Government agencies

• Ongoing or imminent interventions with cost of intervention underwritten by other sources.

• Aimed at prevention of diabetes and/or its complications.
Attributes of Studies

• Study designs:
  – With strong longitudinal designs and unbiased controls.
  – Group level exposure.
  – Diverse sources of data.

• Assess outcomes:
  – Across populations with intention-to-impact perspectives.
  – Range from care and behaviors to incidence and morbidity.
  – Assess implementation, costs, unintended consequences.
Natural Experiments and Effectiveness Studies of Population-Targeted Policies for Diabetes Prevention and Control

• The Diabetes Health Plan: A System-Level Intervention to Prevent and Treat Diabetes
  – University of California Los Angeles
  – Principal Investigator: Dr. Carol Mangione
• Effectiveness of a National Health Care Community Partnership to Prevent Diabetes
  – Northwestern University and Indiana University
  – Principal Investigator: Dr. Ron Ackermann
• The Impact of Emerging Health Insurance Designs on Diabetes Outcomes and Disparities
  – Harvard Pilgrim Health Care and Harvard University
  – Principal Investigator: Dr. Dennis Ross-Degnan
• Learnings in Diabetes Prevention from an Integrated Delivery System
  – Kaiser Foundation Research Institute
  – Principal Investigator: Dr. Julie Schmittdiel
• Management and Education for Diabetes in New York City
  – St. Luke’s-Roosevelt Institute for Health Sciences
  – Principal Investigator: Dr. Jeanine Albu
Conclusions

With the implementation of the ACA, rigorous studies that describe the impact of care delivery models, benefit design, and population based strategies to prevent and treat diabetes has never been more important.
Health Care Professional/Patient Communication: Effect on Diabetes Outcomes

Linda Siminerio, RN, PhD, CDE
Chair, NDEP Support for Behavior Change Task Group
Professor of Medicine
University of Pittsburgh
Presenter Disclosure

• I am an investigator under contract with my employer for:
  – Sanofi, Becton-Dickinson

• This provides no direct financial benefit to me.
What we hear in clinical practice – sound familiar?

• My patients are non-compliant
• Our patient population is different/unique
• Standardized approaches inhibit critical thinking and individualized care
• I know what is best for my patients based on my experience
What we know about patient-provider communication:

- Directive approach is not effective
- Improving knowledge does not translate to improved behavior
- Health literacy is a problem
- Health care providers do not always communicate with each other
Traditional Decision-Making Model: Paternalism at Its Peak

"When we want your opinion, we’ll give it to you"
A lot of patients I meet have problems with grazing.

Does she think I eat or look like a cow?

Do they understand us?
Your sugars have been high. After seeing your lab results – I am thinking that you may have a problem with Cushing’s …..

The patient’s perception of Cushing’s?

Cushions?
I do have problems sleeping. Umm....I wonder what pillows have to do with my blood sugars being high?
Traditional Healthcare Decision-Making: Unequal Partnership
Activated, engaged patients

Partnership
Sharing Information
Setting Expectations

Trained Healthcare Professionals

Patient-Centered Outcomes

Patient Engagement
What do studies tell us about patient/provider communication?
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 ($p \leq 0.001$).
• proportion of patients with good LDL control ($p \leq 0.001$).
• 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.

Institute of Medicine

*Communicating with patients on health care evidence.* Discussion Paper, Institute of Medicine, Washington, DC.

http://www.iom.edu/evidence.
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.

What can we do?
Strategies to Improve Care & Communications

1. **Shared decision-making**
2. Redesign practice
3. Adjust supply of healthcare
Shared decision making (SDM)

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.
Cochrane review of 86 clinical trials found that patient use of decision aids led to:

- improved knowledge of options
- more accurate expectations of possible benefits and harms
- greater participation in decision making
- higher satisfaction
- choices resulting in lower costs and better health outcomes

Barriers To Implementing Shared Decision and Practice Redesign
Responses to Shared Decision Making

We do it already!
My patients don’t want it
I don’t have the time!

Will it work?
Don’t have tools!

I don’t know how to do it!
It won’t work in my practice.
Medical Evidence

Informed Medical Decision

Clinician Expertise

Patient Goals & Concerns
Personalized: Name and Risk

1. What is your risk of having a heart attack in the next 10 years?

2. What benefit can you expect from taking statins compared to not taking statins?

3. What downsides can you expect from taking statins compared to not taking statins?

4. What do you want to do now?
A Demonstration Of Shared Decision Making In Primary Care Highlights Barriers To Adoption And Potential Remedies

Research Objective:
To better understand how delivery systems can implement shared decision making.

Methods:
Interviewed representatives of 8 primary care sites.

Results:
Barriers to shared decision making included:
• overworked physicians,
• insufficient training, and
• clinical information systems incapable of prompting or tracking patients through the decision-making process.
Conclusions:

Methods to improve shared decision making include using automatic triggers for the distribution of decision aids and engaging team members other than physicians in the process.
Strategies to Improve Care & Communications

1. Shared decision-making aids
2. Redesign practice
3. Adjust supply of healthcare
What do we know about practice redesign?
People with chronic disease want but do not receive coordinated care (n=409)
### Quality Improvement Strategy

<table>
<thead>
<tr>
<th>Strategy</th>
<th>No. of Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Team changes</td>
<td>26</td>
</tr>
<tr>
<td>Case management</td>
<td>26</td>
</tr>
<tr>
<td>Patient reminders</td>
<td>14</td>
</tr>
<tr>
<td>Patient education</td>
<td>38</td>
</tr>
<tr>
<td>Electronic patient registry</td>
<td>8</td>
</tr>
<tr>
<td>Clinician education</td>
<td>20</td>
</tr>
<tr>
<td>Facilitated relay of clinical information</td>
<td>15</td>
</tr>
<tr>
<td>Self-management</td>
<td>20</td>
</tr>
<tr>
<td>Audit and feedback</td>
<td>9</td>
</tr>
<tr>
<td>Clinician reminders</td>
<td>18</td>
</tr>
<tr>
<td>Continuous quality improvement</td>
<td>3</td>
</tr>
<tr>
<td><strong>All interventions</strong></td>
<td><strong>66</strong></td>
</tr>
</tbody>
</table>

Redesigning Practice
### Who best provides education & support in Primary Care

<table>
<thead>
<tr>
<th>Diabetes Education (0-6 weeks)</th>
<th>CMI, Inc.</th>
<th>FQHC</th>
<th>PSU</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c (%)</td>
<td>0.6 [.0001]*</td>
<td>1.1 [.0001]*</td>
<td>.35 [.0001]*</td>
</tr>
<tr>
<td>SBP (mm/Hg)</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>DBP (mm/Hg)</td>
<td>2.5 [.005]*</td>
<td>3.6 [.02]*</td>
<td>NS</td>
</tr>
<tr>
<td>HDL (mg/dL)</td>
<td>NS</td>
<td>NS</td>
<td>NS</td>
</tr>
<tr>
<td>LDL (mg/dL)</td>
<td>8.5 [.04]*</td>
<td>11 [.01]*</td>
<td>NS</td>
</tr>
<tr>
<td>tChol (mg/dL)</td>
<td>8.7 [.05]*</td>
<td>13.3 [.009]*</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS=No Significant Change * p<.05

Peg and Sharlene have done an outstanding job not only in educating our diabetic patients about diet, exercise and medication regimens but they have also been able to motivate our patients to finally take a proactive role in their disease. These are changes that even I as an internal medicine physician have been unable to convince my patients to do in my years of caring for them.

I have seen improvements in lipid profiles and hemoglobin A1C’s in patients that I never expected. Patients who previously refused insulin therapy have now been able to successfully start on insulin because of these diabetic education counseling sessions. Peg and Sharlene have spent considerable time winning the trust and confidence of these patients and this has translated into a better patient understanding of their disease state and what they need to do to successfully manage it.

I am hopeful that my letter of testimony will serve to have a positive effect in the evaluation of studies and programs that can be offered by the Diabetes Institute. It has
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
Diabetes HealthSense
www.YourDiabetesInfo.org/HealthSense
Xavier

• Wants to lose some weight
• Has a hard time “sticking with it”
• Really doesn’t like to exercise
Go4Life

“Be active every day with Go4Life!”
Try our sample exercises anytime, anywhere.
Health Care Professionals

When patients are successful at making changes in their behaviors, health outcomes improve.

Let Diabetes HealthSense help you help your patients identify their priorities, set goals, and think through the steps necessary to achieve those goals—putting them on the path to success.

Diabetes HealthSense provides easy access to resources that support people with diabetes and those at risk for the disease in making lifestyle changes and coping with stress and negative emotions. Diabetes HealthSense also includes resources to facilitate behavior change in your practice. Let Diabetes HealthSense help you help your patients live well—whether they have diabetes or are at risk for the disease.

Find Research Articles

Click here to find research articles on the science of behavior change and implementation.
NDEP Tools to Support Health Care Professional/Patient Communication
How New Science is Shaping NDEP’s Messages and Materials

Judy Fradkin, MD
Member, NDEP Executive Committee
Director, Division of Diabetes, Endocrinology, and Metabolic Diseases
NIDDK, National Institutes of Health
Presenter Disclosure

• Disclosed no conflict of interest.
NDEP Campaigns

Primary prevention
- DPP/DPPOS
  - small steps big rewards
  - Prevent type 2 Diabetes

Secondary prevention
- DCCT/EDIC UKPDS
  - Control your Diabetes. For Life.
  - Controle la Diabetes. Por su y de por Vida.
CONCLUSIONS

Although there were improvements in risk-factor control and adherence to preventive practices from 1999 to 2010, tobacco use remained high, and almost half of U.S. adults with diabetes did not meet the recommended goals for diabetes care.
Smoking Status Among US Adults with Diabetes, 1999-2010

Diabetes Education Among US Adults with Diabetes, 1999-2010

Annual Examinations Among US Adults with Diabetes, 2007-2010

% of survey participants

- Eye: 73.4
- Foot: 71.4
- Dental: 62.5
- Annual influenza: 60
- Eye, Foot, Influenza: 22.4

2007-2010

Working Together to Manage Diabetes: A Guide and Toolkit for Pharmacy, Podiatry, Optometry, and Dentistry (PPOD)
Prevalence of meeting ABC goals among adults aged ≥ 20 years with diagnosed diabetes

The prevalence of achieving A1C <8.0% among adult with previously diagnosed diabetes (2007-2010)

Type 2 Diabetes in Youth

Rate of new cases of type 1 and type 2 diabetes among youth ages younger than 20 years, by race/ethnicity, 2002–2005
Treatment Options for type 2 Diabetes in Adolescents & Youth

TODAY was a nationwide research study to find the best ways to treat young people with type 2 diabetes

Diabetes Care

June 2013
TODAY Study: Time-to-outcome analysis

Proportion not experiencing glycemic failure

- Failure Rates
  - M: 51.7%
  - M+R: 38.6%
  - M+L: 46.6%

- Pairwise Tests
  - M+L vs. M+R: p=0.15
  - M vs. M+R: p=0.006
  - M vs. M+L: p=0.17

Time from randomization in months

Number at Risk

- 699
- 542
- 425
- 297
- 187
- 92

TODAY: Risk Factor Control and Emerging Microvascular Disease

Worsening Outcomes in TODAY youth

Percentage (%)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Baseline</th>
<th>End of Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>11.6</td>
<td>33.8</td>
</tr>
<tr>
<td>Microalbuminuria</td>
<td>6.3</td>
<td>16.6</td>
</tr>
<tr>
<td>LDL&gt;130</td>
<td>4.5</td>
<td>10.7</td>
</tr>
<tr>
<td>Retinopathy</td>
<td>13.7</td>
<td></td>
</tr>
</tbody>
</table>

Currently Being Updated
Emerging Guiding Principles

- **Principle 1**: Identify People with Undiagnosed Diabetes and Prediabetes
- **Principle 2**: Manage Prediabetes to Prevent or Delay the Onset of Type 2 Diabetes
- **Principle 3**: Provide Ongoing Self-Management Education and Support for People With or at Risk for Diabetes
- **Principle 4**: Provide Individualized Nutrition Therapy for People With or at Risk for Diabetes
- **Principle 5**: Encourage Regular Physical Activity for People With or at Risk for Diabetes
Emerging Guiding Principles (cont’d)

- **Principle 6**: Control Blood Glucose to Prevent or Delay the Onset of Diabetes Complications and Avert Symptoms of Hyperglycemia
- **Principle 7**: Provide Blood Pressure and Cholesterol Control, Tobacco Cessation and Other Therapies to Reduce Cardiovascular Disease Risk
- **Principle 8**: Provide Regular Assessments to Detect and Monitor Diabetes Microvascular Complications and Treatment to Slow Their Progression
- **Principle 9**: Provide Patient Centered Care
- **Principle 10**: Consider the Needs of Special Populations — Children, Women of Childbearing Age, Older Adults, and High-Risk Racial and Ethnic Groups