Use of Real-World Data to Improve the Prevention and Care of Diabetes-Related Outcomes

Applications to Primary Care and Prevention of Diabetes

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Evidence Base: Type 2 Diabetes is Preventable
The Diabetes Prevention Program

- U.S. randomized efficacy trial
- 3,200 overweight / obese adults with elevated blood glucose
- Compared 3 preventive interventions
  - Brief Education (usual care)
  - Metformin 850 mg twice daily
  - Resource-Intensive Lifestyle Intervention Program
- Over 2.8 years and compared to brief education alone...
  - Metformin: 31% lower rate of diabetes development
  - Lifestyle intervention: 58% lower rate of diabetes development
- Every 1 kg of additional weight loss = 16% further reduction in T2D incidence

DPP Intensive Lifestyle Intervention

- Cognitive & behavioral intervention
- Goals for modest weight loss, dietary change, & physical activity
- Delivered as 1-hour face-to-face meetings
  - Individual meetings with skilled coach weekly for 16 weeks
  - Individual & group meetings every 4 weeks thereafter
- 30 contact hours with skilled educator in year 1 alone
- Intervention cost of ~$1500-$2000 per person

Lower-cost “DPP-like” Interventions

Small studies show that DPP-like interventions can be implemented in both healthcare and community settings.
Opportunity & Challenge for Routine DPP Delivery in Primary Care

- Opportunity
  - Health insurance may pay costs of preventive services
  - 83% of American adults visit a health professional each year
  - Health provider advice motivates some patients to set goals for change

- Challenges
  - Limited time: the average American spends only 18 min/year with a PCP
  - 85% of all primary care visits are problem focused (not for prevention)
  - Brief physician counseling interventions alone typically lack the intensity needed to achieve sustained behavioral change


How Does Evidence Inform Population T2D Prevention?

Evidence-Base (DPP; MTF) → ? → Population T2D Prevention
How Does Evidence Inform Population T2D Prevention?

Implementation in Real World

Delivery Channels (Adoption)  Engagement (Reach)

Evidence-Base (DPP; MTF)  Population T2D Prevention

Implementation Innovations

Delivery Channel Innovations (Adoption)  Engagement Innovations (Reach)

“Essential Components”

Evidence-Base (DPP; MTF)  Population T2D Prevention
Growth of Delivery Channels for DPP

Community DPP Interventions – there are now thousands of low cost and commercial intensive lifestyle programs in communities & via the web, BUT Less than 1% of all adults with prediabetes today have participated in DPP

Policies to Catalyze Population T2D Prevention

USPSTF – health systems should perform screening for abnormal glucose metabolism and should offer intensive lifestyle interventions to overweight or obese adults with prediabetes

ACA – health payers must pay for services recommended by the USPSTF

CMS – Medicare will pay the costs of a recognized DPP intervention program for beneficiaries with A1c elevated

Community DPP Interventions – there are now thousands of low cost and commercial intensive lifestyle programs in communities & via the web, but less than 1% of all adults with prediabetes today have participated
What is the Role of the Health System?

**USPSTF** – health systems should perform screening for abnormal glucose metabolism and should offer intensive lifestyle interventions to overweight or obese adults with prediabetes.

**ACA** – health payers must pay for services recommended by the USPSTF.

**CMS** – Medicare will pay the costs of a recognized DPP intervention program for beneficiaries with A1c elevated.

**Community DPP Interventions** – there are now thousands of low cost and commercial intensive lifestyle programs in communities & via the web, but less than 1% of all adults with prediabetes today have participated.

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**Health System Interventions to Expand DPP Reach**

**System Interventions** – Reorganize system roles / functions to leverage policies & catalyze reach leading to population diabetes prevention.

↑ Reach X Individually Effective Programs = Population Effectiveness
Questions of Interest to Primary Care

- Are there DPP programs where I can send my patients?
- What benefits will my patient experience if I refer him/her to a community DPP intervention?
- What will it cost them to participate? How much will it cost health insurers?
- What is the effect of community DPP participation on my patient’s healthcare expenditures?

- How are recent policies influencing prediabetes screening, diagnosis, and DPP participation for patients?
- What are major health systems doing in response to these policies?
- Which health system innovations are working best to increase prediabetes screening, diagnosis, and linkages to DPP?
Recent and Ongoing RWE Studies Linking Primary Care Systems Change with Community DPP Resources

Natural Experimental Opportunity
Commercial Health Payer (UHG) & YMCA Partnership to Scale YDPP Nationally: 2010 - 2016

UHG: United Health Group
YUSA: YMCA of the USA
Natural Experimental Questions

- What is the overall yield of UHG-led efforts to increase employer-based prediabetes screening?
  - Numbers of employers
  - Numbers of adults identified/referred to YDPP?
- What percent of employees identified through screening will take part in YDPP?
- Do employees who enroll continue to participate at high levels?
- Do participants lose meaningful weight?
- What are the costs to health payers to reimburse YMCAs for DPP delivery?
- Are there differences in employee healthcare expenditures after participating?

Non-Randomized DPP Exposure

1. Risk for T2D
2. Progression of Dysglycemia
3. Completion of Screening for Dysglycemia (A1c or FPG)
4. Awareness of Effective Treatments
5. Choice to Participate
6. Sufficient “Dose”
7. Outcomes (Lower Glucose / BMI)
Study Sample Eligibility

• Inclusion
  – Adult UHG enrollees 18 years of age or older
  – Living in one of 44 US geographic regions where YDPP is offered
  – Enrolled in a UHG health plan through an employer (n=759) that offered YDPP
  – Enrolled in the health plan for at least 3 months before & 3 months after the index date

• Exclusion
  – Diagnosed diabetes or receiving anti-glycemic medication
  – Other medication known to affect glucose metabolism (e.g. steroids)
  – Pregnant
  – Clinical condition that could limit lifespan to <2 years

Natural Experimental Design

Propensity-Matched Non-Equivalent Comparison Group Design
Difference-in-Difference Estimation of Outcome Effects

* Adults enrolled in a partnering health plan and employer targeted for prediabetes screening events; no indication of diagnosed diabetes or pregnancy
† Eligible adult health plan enrollees with ≥1 visit to the YDPP
‡ Eligible adult health plan enrollees with 0 visits to YDPP who were propensity-matched to each YDPP User
§ Date that each YDPP User attended their first YDPP visit; Non-Users assigned the same index date as YDPP User to whom they are matched
Data Sources & Outcomes

• UHG enrollment & billing data (Medical claims; Rx)
  – Utilization for all health services
  – Costs for each service standardized across individuals
• Tracking database that captures all YDPP exposure and billing to UHG
  – UHG data for outreach, screening, & enrollment attempts
  – Participant attendance & body weight recorded at each YDPP visit
• Primary outcome
  – Mean per person difference in quarterly (yearly) total healthcare expenditures
• Secondary outcomes
  – Trend in expenditures for “cardiometabolic-class” prescription medications
  – Cost differences in high v. lower risk subgroups (Age; MetS)

Statistical Analysis

• Descriptive statistics
• Adoption/implementation of YDPP
• Reach of employer based screening & YDPP referral
• Study population characteristics of YDPP Users / Non-Users before/after PS matching
• Longitudinal Regression
  – Difference-in-Difference modeling framework
  – Estimates mean (+/- 95% Confidence Interval) difference in the changes in costs for each 1-year period after the index date
• Censoring of PS-matched pair if the other dis-enrolls with UHC
  – Prevents population “migration bias” over time (27% of YDPP users were no longer enrolled in the health plan at 24 months)
Adoption of YDPP Activities 2010-2015

- Screening & coverage
  - 759 employers
- YDPP Delivery
  - 42 states
  - 938 community locations

Yield of Employer-based A1c Screening

Total Health Plan Enrollees associated with the Targeted Employer Groups (N = 498,837)
[Population estimate* of those with A1c levels indicating prediabetes = 115,730]

5.8% of 498,837 employees completed screening

9.7% of 115,730 estimated to have prediabetes by A1c were identified

40.4% of 11,277 confirmed cases attended YDPP at least once

28.6% of 4,554 YDPP Users reached the weight goal

Completed A1c Test (N = 28,839)

Confirmed Prediabetes* (N = 11,277)

Any YDPP Participation (N = 4,554)
=9 YDPP Visits (N = 3,251)
≥5% Weight Loss (N = 1,302)

* A1c result 5.7 – 6.4%
Weight Loss by YDPP Attendance Level

<table>
<thead>
<tr>
<th>Number of YDPP Classes Attended*</th>
<th>N (column %)</th>
<th>Weight Change (pounds), Mean (SD)†</th>
<th>Participants Achieving ≥5% Weight Loss, N (row %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any</td>
<td>4,554 (100.0)</td>
<td>-3.4 (4.8)</td>
<td>1,302 (28.6%)</td>
</tr>
<tr>
<td>1-3 Classes</td>
<td>677 (14.9)</td>
<td>-0.2 (1.4)</td>
<td>3 (0.4%)</td>
</tr>
<tr>
<td>4-8 Classes</td>
<td>626 (13.7)</td>
<td>-1.2 (2.2)</td>
<td>35 (5.6%)</td>
</tr>
<tr>
<td>9-15 Classes</td>
<td>1,450 (31.8)</td>
<td>-3.3 (3.9)</td>
<td>410 (28.3%)</td>
</tr>
<tr>
<td>≥16 Classes</td>
<td>1,801 (39.5)</td>
<td>-5.4 (5.8)</td>
<td>854 (47.4%)</td>
</tr>
</tbody>
</table>

Mean attendance among YDPP Users overall was 12.4 (SD 6.3)

PS-Matched YDPP Users & Non-Users

<table>
<thead>
<tr>
<th></th>
<th>Before Matching</th>
<th>After Matching</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Eligible YDPP Users</td>
<td>All Non-Users*</td>
</tr>
<tr>
<td>N</td>
<td>1,761</td>
<td>361,431</td>
</tr>
<tr>
<td>Gender (% Women)</td>
<td>72.4%</td>
<td>49.5%</td>
</tr>
<tr>
<td>Age Category</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-34</td>
<td>2.5%</td>
<td>15.3%</td>
</tr>
<tr>
<td>35-49</td>
<td>22.1%</td>
<td>33.5%</td>
</tr>
<tr>
<td>50-57</td>
<td>30.8%</td>
<td>19.9%</td>
</tr>
<tr>
<td>58-64</td>
<td>32.2%</td>
<td>16.1%</td>
</tr>
<tr>
<td>65+</td>
<td>12.4%</td>
<td>15.3%</td>
</tr>
<tr>
<td>Age, Mean (SD)</td>
<td>55.0 (8.9)</td>
<td>50.2 (14.0)</td>
</tr>
<tr>
<td>Charlson Comorbidity Score‡, % by cat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>57.1%</td>
<td>71.1%</td>
</tr>
<tr>
<td>1</td>
<td>20.7%</td>
<td>14.2%</td>
</tr>
<tr>
<td>2-3</td>
<td>15.1%</td>
<td>9.9%</td>
</tr>
<tr>
<td>4+</td>
<td>7.1%</td>
<td>4.8%</td>
</tr>
<tr>
<td>Mean Metabolic Risk Score§ mean, (SD)</td>
<td>1.2 (1.1)</td>
<td>0.5 (0.8)</td>
</tr>
<tr>
<td>High Blood Pressure Treatment, %</td>
<td>52.7%</td>
<td>33.0%</td>
</tr>
<tr>
<td>Abnormal Blood Cholesterol Treatment, %</td>
<td>27.2%</td>
<td>15.5%</td>
</tr>
<tr>
<td>Prediabetes Diagnosis, %</td>
<td>40.8%</td>
<td>6.5%</td>
</tr>
<tr>
<td>Recent use of Health Seeking Services‖, %</td>
<td>23.3%</td>
<td>15.3%</td>
</tr>
</tbody>
</table>
### PS-Matched YDPP Users & Non-Users

#### Before Matching vs. After Matching

<table>
<thead>
<tr>
<th>Percentile Cat of Healthcare Costs, % by category</th>
<th>Before Matching</th>
<th>After Matching</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eligible YDPP Users</td>
<td>1,761</td>
<td>1,725</td>
</tr>
<tr>
<td>All Non-Users*</td>
<td>361,431</td>
<td></td>
</tr>
<tr>
<td>Stand. Diff†</td>
<td>0.43</td>
<td>0.02</td>
</tr>
<tr>
<td>&gt;90th percentile</td>
<td>15.5%</td>
<td>15.9%</td>
</tr>
<tr>
<td>75th-90th percentile</td>
<td>27.1%</td>
<td>27.6%</td>
</tr>
<tr>
<td>50th-74th percentile</td>
<td>25.8%</td>
<td>24.6%</td>
</tr>
<tr>
<td>&lt; 50th percentile</td>
<td>31.6%</td>
<td>31.8%</td>
</tr>
</tbody>
</table>

#### Percentile Cat of CVD Rx Costs, % by category

<table>
<thead>
<tr>
<th>Before Matching</th>
<th>After Matching</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;95th percentile</td>
<td>10.7%</td>
</tr>
<tr>
<td>90th-95th percentile</td>
<td>10.1%</td>
</tr>
<tr>
<td>1st-89th percentile</td>
<td>33.2%</td>
</tr>
<tr>
<td>0 (no medication costs in these drug classes)</td>
<td>46.0%</td>
</tr>
</tbody>
</table>

#### Year of First Exposure

<table>
<thead>
<tr>
<th>Year</th>
<th>Before Matching</th>
<th>After Matching</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>3.6%</td>
<td>3.7%</td>
</tr>
<tr>
<td>2011</td>
<td>15.4%</td>
<td>15.6%</td>
</tr>
<tr>
<td>2012</td>
<td>49.9%</td>
<td>49.7%</td>
</tr>
<tr>
<td>2013</td>
<td>31.1%</td>
<td>31.0%</td>
</tr>
</tbody>
</table>

#### Total Healthcare Cost Trends

Mean Per-Person Per-Quarter Expenditures (exclusive of YDPP payments)

![Total Healthcare Cost Trends Graph]

- Baseline period (quarters) vs. Intervention period (quarters)
- PS-Matched Non-Users vs. YDPP Users
Estimations of Net Costs by Quarter & Year

<table>
<thead>
<tr>
<th>Intervention Period</th>
<th>Change in Quarterly Total Costs* for YDPP Users, Mean (95% CI)</th>
<th>Change in Quarterly Total Costs* for PS-Matched Non-Users, Mean (95% CI)</th>
<th>Difference in Net Quarterly Total Costs† Between YDPP Users and PS-Matched Non-Users, Mean (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarter 1</td>
<td>109.2 (58.8, 159.2)</td>
<td>82.0 (26.7, 137.4)</td>
<td>27.5 (-47.2, 102.3)</td>
<td>0.47</td>
</tr>
<tr>
<td>Quarter 2</td>
<td>7.5 (-45.2, 60.1)</td>
<td>57.3 (0.5, 114.2)</td>
<td>-49.3 (-126.7, 28.2)</td>
<td>0.21</td>
</tr>
<tr>
<td>Quarter 3</td>
<td>45.2 (-10.2, 100.7)</td>
<td>12.1 (-46.4, 70.7)</td>
<td>33.1 (-47.3, 114.0)</td>
<td>0.42</td>
</tr>
<tr>
<td>Quarter 4</td>
<td>-10.0 (-66.6, 46.6)</td>
<td>45.8 (-21.0, 112.7)</td>
<td>-55.5 (-143.1, 32.1)</td>
<td>0.21</td>
</tr>
<tr>
<td>Quarter 5</td>
<td>-14.7 (-72.9, 43.6)</td>
<td>27.6 (-38.9, 94.1)</td>
<td>-42.0 (-130.4, 46.4)</td>
<td>0.35</td>
</tr>
<tr>
<td>Quarter 6</td>
<td>-7.0 (-69.7, 55.7)</td>
<td>15.7 (-56.0, 87.5)</td>
<td>-22.6 (-117.8, 72.6)</td>
<td>0.64</td>
</tr>
<tr>
<td>Quarter 7</td>
<td>-32.1 (-99.3, 35.1)</td>
<td>-42.9 (-113.4, 27.6)</td>
<td>11.4 (-85.9, 108.6)</td>
<td>0.82</td>
</tr>
<tr>
<td>Quarter 8</td>
<td>46.8 (-29.4, 122.8)</td>
<td>-85.5 (-158.6, -12.4)</td>
<td>132.5 (27.1, 238.0)</td>
<td>0.01</td>
</tr>
<tr>
<td>Year 1 Overall</td>
<td>39.1 (0.4, 77.8)</td>
<td>49.7 (6.3, 93.2)</td>
<td>-10.2 (-68.4, 47.9)</td>
<td>0.73</td>
</tr>
<tr>
<td>Year 2 Overall</td>
<td>-4.0 (-52.0, 44.0)</td>
<td>-15.9 (-69.5, 37.6)</td>
<td>12.3 (-59.4, 84.1)</td>
<td>0.74</td>
</tr>
<tr>
<td>Year 1 &amp; 2 Overall</td>
<td>20.4 (-16.7, 57.6)</td>
<td>21.0 (-21.0, 63.1)</td>
<td>-0.2 (-56.2, 55.9)</td>
<td>0.99</td>
</tr>
</tbody>
</table>

Stratifications for Age and Metabolic Risk Factor Count
Health Payer Payments for YDPP Delivery

<table>
<thead>
<tr>
<th>Payments to Y</th>
<th>Payment per person</th>
<th>N clients</th>
<th>Total UHG Outlay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payment for completing visit #1</td>
<td>$25</td>
<td>4,554</td>
<td>$113,850</td>
</tr>
<tr>
<td>Payment for completing visit #4</td>
<td>$50</td>
<td>3,877</td>
<td>$193,850</td>
</tr>
<tr>
<td>Payment for completing visit #9</td>
<td>$130</td>
<td>3,251</td>
<td>$422,630</td>
</tr>
<tr>
<td>Payment for 5% to 8.99% weight loss</td>
<td>$145</td>
<td>837</td>
<td>$121,409</td>
</tr>
<tr>
<td>Payment for 9%+ weight loss</td>
<td>$180</td>
<td>465</td>
<td>$83,645</td>
</tr>
<tr>
<td>Payment for completing postcore visit #3</td>
<td>$18</td>
<td>862</td>
<td>$15,516</td>
</tr>
<tr>
<td>Payment for completing each postcore visit #4+</td>
<td>$6</td>
<td>1,632</td>
<td>$9,793</td>
</tr>
<tr>
<td><strong>Total operational intervention cost</strong></td>
<td></td>
<td></td>
<td><strong>$960,694</strong></td>
</tr>
<tr>
<td><strong>Intervention cost per person exposed</strong></td>
<td></td>
<td></td>
<td><strong>$211</strong></td>
</tr>
</tbody>
</table>

Summary

- UHG, YUSA and others have implemented the YDPP at a national scale
- The payer’s cost to offer YDP was $211 per person, resulting in:
  - 3.4 lbs of mean weight loss per person
  - No increase in net total health expenditures over 2 years
  - No net difference in inpatient, outpatient, or Rx specific costs (not shown)
Limitations

• Short follow up duration
• May not generalize to adults identified after screening in primary care settings
• No available data on glycemic outcomes or weight for DPP Non-Users
• Possible residual selection bias by unobserved characteristics associated with health outcomes (and costs) – e.g. YDPP Users may have had different “health seeking” motivations that may have produced higher/lower health expenditures over 2 yrs

Further Policy Evolution Since 2015

ACA - mandates coverage of all U.S. Preventive Services Task Force (USPSTF) A or B recommendations, without cost sharing, by Medicare and all non-grandfathered commercial health plans; ACA also funded the National Diabetes Prevention Program under the CDC

USPSTF (effective August 2015) – “B” evidence rating, recommending health systems offer intensive lifestyle interventions for individuals with cardiovascular risk conditions, including prediabetes, and health payers (public and private) offer access to those interventions at no cost to the individual

USPSTF (effective October 2016) – “B” evidence rating, recommending health care providers perform laboratory-based diabetes screening tests and recommend intensive diabetes prevention services for patients found to have prediabetes; health payers (public and private) offer access to those interventions at no cost to the individual

CMS (effective April 2018) – reimbursement will be provided to registered providers of a CDC-recognized National Diabetes Prevention Program, for Medicare fee-for-service beneficiaries with blood-test evidence of prediabetes
Systems Interventions to Increase Prediabetes Screening, Diagnosis, and Preventive Services

Natural Experimental Questions

- What are the locations and components of health system interventions to amplify prediabetes screening, diagnosis, and preventive intervention delivery?
- Are locations of more intensive health system efforts achieving faster rates of screening, diagnosis, and preventive intervention use?
- Are individuals who use preventive intervention services experiencing reduced need for medications to treat metabolic risk factors? Lower costs?
Planned Design

- Linkages of real world data sources from multiple health payers and from DPP providers
- 2-Stage, Near-Far Matching
  - Hybrid design using components of instrumental variables & propensity matching
  - An IV is a variable strongly associated with the exposure of interest ("attending DPP") but not with an outcome of interest (cost of healthcare) by any means other than through its encouragement of that exposure
  - Likely a stronger method to reduce threat of selection bias
- HRR’s nationally are matched 1:1 based on being...
  - "Near" on HRR-level characteristics associated with diabetes related utilization / cost
  - "Far" on their level of Encouragement to YDPP (~density of DPP providers per sq/mile)
- Within each HRR pair, eligible individuals are PS-matched based on individual characteristics
- 2-stage, least-squares

Planned 2-Stage Matching Approach

- All US HRRs (or 5-digit zip)
- HRR’s with high DPP Encouragement
  - Adults; Prediabetes
- Near & Far Matching of HRR Pairs
- HRR’s with high Usual Care Encouragement (low DPP encouragement)
  - Adults; Prediabetes
- PS Match of Individuals within HRR Pairs
  - Compliers (Take part in DPP)
  - Non-Compliers (Do not take part DPP)
  - Compliers (Take part in usual care)
  - Non-Compliers (Take part in DPP)
- Complier Average Treatment Effect
Questions?

Collaborators

Northwestern University
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