Monthly Campaign Webinar
July 16, 2020
Today’s Webinar

• Together 2 Goal® Updates
  – Webinar Reminders
  – Innovator Track Eye Care Cohort Case Studies
  – Know Diabetes By Heart™ COVID-19 Resources

• Prediabetes Predictive Model—Delivering Patient-specific Risk Estimates at the Point-of-Care
  – Francis Colangelo, M.D., M.S.-HQS, FACP of Premier Medical Associates.
  – John Cuddeback, M.D., Ph.D. of AMGA Analytics

• Q&A
  – Use Q&A or chat feature
Webinar Reminders

• Webinar will be recorded today and available the week of July 20th
  – www.Together2Goal.org

• Participants are encouraged to ask questions using the “Chat” and “Q&A” functions on the right side of your screen
Innovator Track Eye Care Cohort Case Studies

Now available at www.together2goal.org
Know Diabetes By Heart™ COVID-19 Resources

PRACTICAL GUIDE FOR MANAGEMENT OF COVID-19 & TYPE 2 DIABETES

Practical Guide For Management of COVID-19 & Type 2 Diabetes
Today’s Featured Presenter

Francis Colangelo, M.D.,
M.S.-HQS, FACP

Chief Quality Officer
Premier Medical Associates

John Cuddeback, M.D., Ph.D.

Chief Medical Informatics Officer
AMGA
Topics

• Why a predictive model for people with prediabetes?
• Reanalysis of a landmark clinical trial
  – Estimate risk for each individual, rather than an overall average
  – Adapt for clinical use
• Results from initial use for shared decision-making
• How can we make this easier to implement at other health systems?
Topics

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AMGA Foundation: National Diabetes Campaign

Together 2 Goal

Improve care for 1 million people with type 2 diabetes by 2021
AMGA Foundation: National Diabetes Campaign

Together2Goal®

1,082,000 patients, aged 18–89, with improved care

2/3 with net improvement in control on campaign measures
1/3 have new diagnosis—identified through screening

Collective achievement of AMGA members participating in T2G® and reporting data quarterly, through year 3 of the campaign
1 out of 4 people with type 2 diabetes don’t know they have it!

*Early treatment is important, to minimize future complications*
Survey of Together 2 Goal Participants

Which “planks” will you adopt?

31% said they wouldn’t focus on screening

They were already overwhelmed by the number of people with type 2 diabetes
...let alone prediabetes!

For every person with a screening result in the diabetes range,
6 people are identified who have prediabetes
What Is Prediabetes?

Elevated blood sugar, but not high enough to indicate diabetes

Elevated risk of developing type 2 diabetes over 3 years—about 29%

84 million Americans have prediabetes—1 out of 3 adults

Is there an effective way to prevent progression to diabetes?

Is there a way to prioritize—identify those at highest risk?

• Population level
• Patient level—shared decision-making

Prediabetes Criteria (ADA 2020)

<table>
<thead>
<tr>
<th>Test</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting glucose</td>
<td>100–125 mg/dL</td>
</tr>
<tr>
<td>HbA1c</td>
<td>5.7 – 6.4%</td>
</tr>
<tr>
<td>2 hr OGTT</td>
<td>140–199 mg/dL</td>
</tr>
</tbody>
</table>
Diabetes Prevention Program (DPP) Study

Randomized controlled trial

Participants: 3,060 non-diabetic adults at 27 centers, BMI ≥ 24 (or 22 if Asian) with both:

- Impaired glucose tolerance (140–199 mg/dL at 2 hr in a glucose tolerance test, 75 g glucose load)
- Impaired fasting glucose (95–125 mg/dL)

Main outcome measure: Development of diabetes over 3 years

Conducted 1996 – 2001, stopped early because the interventions were so effective

Three study arms:
- No intervention (placebo) → **29% average risk** of developing diabetes over 3 years
- Intensive lifestyle program (“DPP program”) → **average absolute risk reduction 14%**
- Taking metformin (850 mg twice daily) → **average absolute risk reduction 7%**
Topics

• Why a predictive model for people with prediabetes?
• Reanalysis of a landmark clinical trial
  – Estimate risk for each individual, rather than an overall average
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• How can we make this easier to implement at other health systems?
We tend to assume that anyone who would have qualified for a clinical trial will experience the average treatment effect seen in the trial.

But in most trials, some patients benefit, and some don’t—heterogeneity of treatment effect.

Can we predict, using information available at the beginning of the trial, the likelihood that an individual patient will benefit?

   Population perspective → Can we risk-stratify?

At the outset, some patients are at higher risk of the outcome—heterogeneity of baseline risk.

Likelihood of benefit from an intervention depends on individual’s baseline risk for the outcome.
Distribution of Predicted Risk in DPP Study

Predictive model: risk of developing diabetes at 3 years, based on data available at the beginning of the study

Includes all participants in the DPP Study—placebo arm, plus both intervention arms.

c-statistic 0.73, indicating good discrimination

Multiple models developed for some trials. See reference on previous slide.

Heterogeneity of baseline risk is common, often following a distribution similar to that seen in the DPP Study.
Absolute Risk Reduction Seen in DPP Study

Intensive Lifestyle Intervention

Metformin

From the predictive model

http://www.pcori.org/research-in-action/moving-beyond-averages
Topics

• Why a predictive model for people with prediabetes?

• Reanalysis of a landmark clinical trial
  – Estimate risk for each individual, rather than an overall average
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• Results from initial use for shared decision-making

• How can we make this easier to implement at other health systems?
Re-develop Risk Model using Typical EHR Data

Model from DPP Study Data
- HbA1c
- Fasting glucose
- Triglycerides
- History of elevated glucose
- Height
- Waist circumference
- Waist:hip ratio

Adapted Model for Use in EHR
- HbA1c
- Fasting glucose
- Triglycerides
- Age
- Gender
- Race
- BMI
- Smoking status
- Systolic blood pressure
- Hypertension diagnosis
- HDL cholesterol ("good cholesterol")

Reflects tests currently used to detect prediabetes and diabetes
Accommodates missing data (imputed values for most model data elements)
Use Model to Apply Learning from DPP Study in Current Practice

• Confirm that new EHR-based model works...
  – On a separate dataset representing current EHR data
  – On the placebo arm of the DPP Study (all the new variables were measured in the DPP Study)

• Then, for people with prediabetes, use this model to estimate their individual risk of developing type 2 diabetes over 3 years

Multivariable model is a better predictor than any single parameter:  
In the lowest-risk quartile, about 15% of patients have A1c ≥ 6.0  
In the highest-risk quartile, more than 25% of patients have A1c < 6.0

• Apply risk-specific estimates of the effects of the two interventions in the DPP Study
  – Consistent benefit for the lifestyle program (58% relative risk reduction, across all levels of risk)
  – Benefit from taking metformin is concentrated in high-risk individuals
Topics

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Premier Medical Associates

- Eastern suburbs of Pittsburgh, PA
- Formed 1993
- 100 providers
- Part of Highmark Health–Allegheny Health Network IDFS
“It now takes an average of 17 years for new knowledge generated by randomized controlled trials to be incorporated into practice, and even then, application is highly uneven.”
REDUCTION IN THE INCIDENCE OF TYPE 2 DIABETES WITH LIFESTYLE INTERVENTION OR METFORMIN

DIABETES PREVENTION PROGRAM RESEARCH GROUP*
Study Description

✓ 2 AMGA Member Organizations
✓ Patient Stakeholders
✓ Patient and Provider Focus Groups
✓ Patient and Provider Surveys
Patient and Provider Focus Groups

People with prediabetes want a personalized estimate

- Want to know their risk of diabetes
- Quoted ages when multiple family members developed type 2 diabetes

Providers want guidance for shared decision-making

- Aware of DPP Study and “National DPP” offered locally by the “Y”
- Want to support and encourage patients—especially for the intensive lifestyle program
- Feel overwhelmed—need to prioritize
Intensive Lifestyle Intervention

- DPP Programs are Resource-Intensive
  - 16 core sessions: one-to-one, in person
  - 2 monthly maintenance phone contacts
  - Exercise facilities at no cost

- For every 1 kg of weight loss, diabetes incidence drops by 16 percent.

Utilization Savings

✓ CMS Office of the Actuary estimates $2,650 in net cost savings for a Medicare beneficiary over 15 months, by participating in a DPP

✓ Intermountain: Avoiding or delaying progression to diabetes saves Intermountain’s Health Plan $3,500 per patient per year

✓ DPP participation costs about $600
Data retrieved from EHR, displayed in the EHR for validation and editing by the clinician, at Premier Medical Associates.

eCalcs add-in for Allscripts TouchWorks EHR.

Drawn in same timeframe as fasting labs, so assumed to be a fasting blood glucose.
Predictive model results, as displayed in the EHR for shared decision-making, at Premier Medical Associates.
Predictive model results, as displayed in the EHR for shared decision-making, at Premier Medical Associates

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Interpretation: Low Risk Patient
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# PMA Experience—Reach of Project

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<th>5/1/18 – 8/31/19</th>
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<tbody>
<tr>
<td>Total prediabetes</td>
<td>2,518</td>
</tr>
<tr>
<td>Calculation completed</td>
<td>1,881</td>
</tr>
<tr>
<td>Percent with calculation</td>
<td>74.7%</td>
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## Interventions vs. Risk

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During the 15 months, 97 patients were identified as having diabetes, through timely screening.
Of the 901 high-risk patients…

41 were On Metformin before 5/1/2018
150 were Started on Metformin after 5/1/2018

0 were Referred to a DPP before 5/1/2018
487 were Referred to a DPP after 5/1/2018
Patients Referred to YDPP

124 called the YMCA to inquire about program
   64 actually enrolled
Average weight loss 17.8 pounds (7.4%)
Provider Surveys: How confident are you in your ability to estimate the average risk of diabetes progression for your patients with prediabetes?
Topics

• Why a predictive model for people with prediabetes?
• Reanalysis of a landmark clinical trial
  – Estimate risk for each individual, rather than an overall average
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Personalized Risk Estimates at the Point of Care

Two approaches to implementing the model in the EHR:

Build predictive model into EHR — Premier Medical Associates

- Calculator add-in for Allscripts TouchWorks: Galen eCalcs
- Provider needs to access the calculator, but eCalcs obtains data elements from patient’s record and displays them for validation or editing

“Subscribe” to a cloud-hosted SMART app, using FHIR resources — Mercy

- Emerging EHR interoperability standards—Office of the National Coordinator for Health IT (ONC)
- EHR vendors are exposing data elements as “FHIR resources” and enabling integration of cloud-hosted apps
- CDS Hooks can trigger the calculation automatically, upon opening a patient’s record or posting a lab result that suggests prediabetes
- EHR vendors charge a small transaction fee, each time the model is used

EHR — Electronic health record (Premier uses Allscripts, with Galen eCalcs; Mercy uses Epic)
SMART — Substitutable Medical Apps and Reusable Technology
FHIR — Fast Healthcare Interoperability Resources, an HL7 standard
CDS Hooks — Clinical Decision Support Hooks
SMART App

Cloud-hosted SMART app currently being implemented in Epic at Mercy

This is the clinician view, showing data values retrieved for this patient from the EHR, for validation/editing

Model results are displayed at the top of the screen
Cloud-hosted SMART app currently being implemented in Epic at Mercy

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DPP lifestyle intervention yields a 12.0% absolute reduction in risk of diabetes at 3 years, from 20.6% to 8.6%, which corresponds to an NNT of 8

For this intermediate-risk patient, taking metformin yields only a 2.4% absolute reduction in risk, from 20.6% to 18.2%, which corresponds to an NNT of 36
### SMART App

Cloud-hosted SMART app currently being implemented in Epic at Mercy

This is the **clinician view**, showing data values retrieved for this patient from the EHR, for validation/editing

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Changing patient’s race from missing to Black

---

#### Model Results

<table>
<thead>
<tr>
<th>Intermediate Risk group</th>
<th>Model Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>24.6%</td>
<td>3 years diabetes risk (usual care)</td>
</tr>
<tr>
<td>10.3%</td>
<td>3 years diabetes risk (DPP lifestyle)</td>
</tr>
<tr>
<td>19.5%</td>
<td>3 years diabetes risk (metformin)</td>
</tr>
<tr>
<td>-</td>
<td>Relative risk reduction</td>
</tr>
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<td>58%</td>
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</tr>
<tr>
<td>-</td>
<td>Number needed to treat</td>
</tr>
<tr>
<td>7</td>
<td>Number needed to treat (DPP lifestyle)</td>
</tr>
<tr>
<td>19</td>
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---

#### Patient Data

<table>
<thead>
<tr>
<th><strong>Age</strong></th>
<th><strong>Sex</strong></th>
<th><strong>Race</strong></th>
<th><strong>Smoking Status</strong></th>
<th><strong>Hypertension Dx</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>56</td>
<td>Male</td>
<td>White</td>
<td>Current</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**Value in EHR:** 56

**Reference EHR Values:**

#### Body Mass Index (BMI) (kg/m²)

- Normal
- Overweight
- Obesity 1
- Obesity 2
- Obesity 3

#### Systolic BP (mm Hg)

- Normal
- Elevated
- HTN Stage 1
- HTN Stage 2

#### HDL (good) cholesterol (mg/dL)

- Normal
- Elevated

#### Triglycerides (mg/dL)

- Normal

#### Fasting plasma glucose (mg/dL)

- Normal

- Hemoglobin A1c (%) - missing data
SMART App

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Model results are displayed at the top of the screen

Changing patient’s race from missing to Black Asian
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Changing patient’s race from missing to Black, Asian, White

**Patient data**

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**Body Mass Index (BMI) (kg/m²²)**

- Normal
- Overweight
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- Obesity 3

**Systolic BP (mm Hg)**

- Normal
- Elevated
- HTN Stage 1
- HTN Stage 2

**HDL (good) cholesterol (mg/dL)**

- Normal
- Elevated

**Triglycerides (mg/dL)**

- Normal

**Fasting plasma glucose (mg/dL)**

- Normal

**Model results**

- Intermediate Risk group
  - 17.7% 3 years diabetes risk (usual care)
  - 7.4% 3 years diabetes risk (DPP lifestyle)
  - 17.1% 3 years diabetes risk (metformin)
  - 58% Relative risk reduction (DPP lifestyle)
  - 5.0% Relative risk reduction (metformin)
  - 10 Number needed to treat (DPP lifestyle)
  - 110 Number needed to treat (metformin)
Higher-risk Patient

Changing to a different patient, with a higher baseline risk

Same age, sex, race, smoking status, HTN Dx Higher BMI and systolic BP
Lower HDL
HbA1c 6.0% (instead of missing)

Since this patient is at a higher risk, there is more benefit from metformin than we saw with the intermediate-risk patient.
Higher-risk Patient

This is the patient view, displaying model results graphically, at the top of the screen.

Sliders and radio buttons only for attributes that the patient might target changing, to explore “what-if” scenarios.

But… Interpretation is important:

The updated model values correspond to putting the patient into a group of people with a different baseline risk and potentially a different estimated benefit from these interventions.

They do NOT reflect the prospective effect on the risk of diabetes if the patient were to make a change (e.g., stopping smoking, lowering blood pressure, or losing weight). That has not been studied.
Higher-risk Patient

Exploring model behavior...

Former smoker, instead of current smoker
Higher-risk Patient

Exploring model behavior...

Former smoker, instead of current smoker
Reduce BMI from 35 to 32 (8.6% weight loss)
Higher-risk Patient

Exploring model behavior...

Former smoker, instead of current smoker
Reduce BMI from 35 to 32 (8.6% weight loss)
Reduce systolic BP from 148 to 135
Higher-risk Patient

Exploring model behavior...

Former smoker, instead of current smoker
Reduce BMI from 35 to 32 (8.6% weight loss)
Reduce systolic BP from 148 to 135
Reduce triglycerides from 200 to 175

These changes only reduce baseline risk from 31.9% to 28.1% (absolute Δ 3.8%, relative reduction of 11.9%)

For this patient’s original parameters, DPP lifestyle reduces risk to 13.4% (absolute Δ of 18.5%, relative 58%)

In most cases, the estimated benefit of the DPP lifestyle program substantially exceeds the change in baseline risk corresponding to the changes in parameters (weight loss, reduction in BP) that are typically achieved by participating in the program.

This may reflect the value of nutrition education, emphasis on exercise, and group activities. For the DPP lifestyle program, the whole is more than the sum of its parts.
In 2018, John Schultz talked to his doctor, Frank Colangelo, at Premier Medical Associates. John learned he had prediabetes, and his personal risk for developing diabetes was high. That got his attention.

He took the DPP Lifestyle program seriously—healthy eating, getting more exercise. He lost over 30 pounds.

“I’ve had more energy, and I’m doing more things,” Schultz said. “From that meeting with Frank, it was a snowball effect.”

https://www.pcori.org/research-results/pcori-stories/health-risks-each-individual-not-average-patient
August Webinar

• **Date/Time:** August 20, 2020 from 2-3pm Eastern

• **Topic:** T2G Diabetes Bundle Best Practices Collaborative Results

• **Presenter:** AMGA
Questions