Together 2 Goal®

AMGA Foundation
National Diabetes Campaign

Monthly Campaign Webinar

July 16, 2020

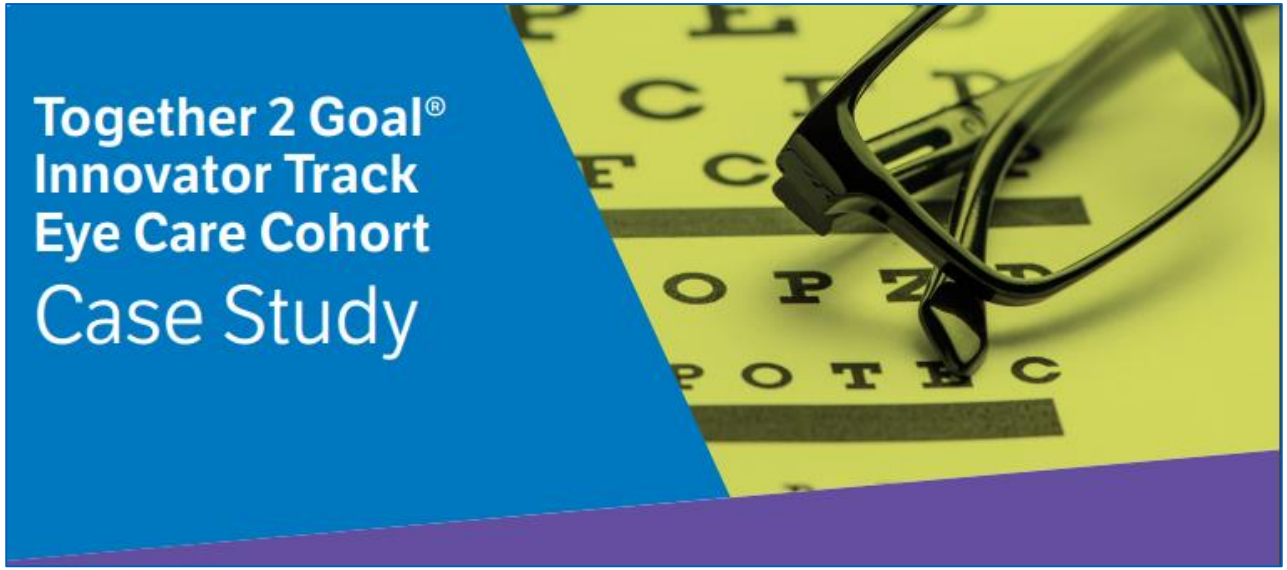
Today's Webinar

- 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

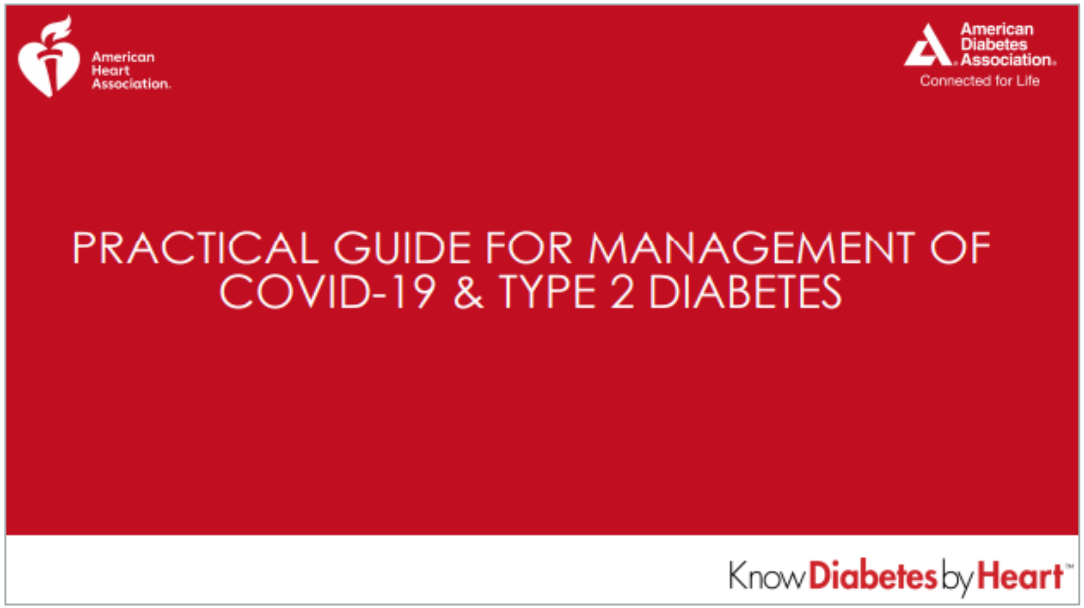
- Webinar will be recorded today and available the week of July 20th
  - www.Together2Goal.org
- Participants are encouraged to ask questions using the “Chat” and “Q&A” functions on the right side of your screen

Innovator Track Eye Care Cohort Case Studies



Now available at www.together2goal.org

Know Diabetes By Heart™ COVID-19 Resources



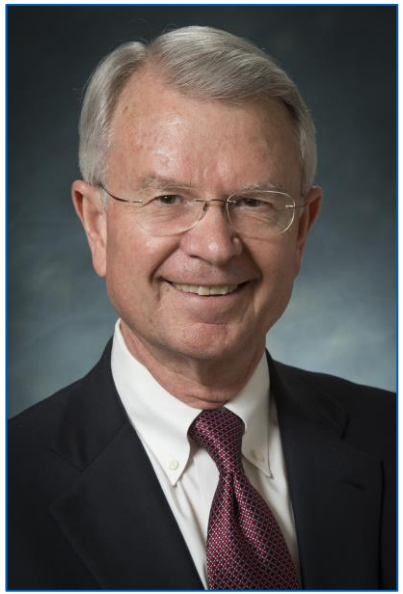
Practical Guide For Management of COVID-19 & Type 2 Diabetes

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

AMGA
Advancing High Performance Health

Predictive Model for Prediabetes: Individual Risk Estimates and Benefit-Based Treatment

Francis Colangelo, MD, MS-HQS, FACP
VP and Chief Quality Officer
Premier Medical Associates

John Cuddeback, MD, PhD
Chief Medical Informatics Officer
AMGA

July 16, 2020

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?

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PCORI Predictive Analytics Resource Center (PARC)

AMGA Foundation: National Diabetes Campaign

Together2Goal®

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

Together 2 Goal®

AMGA™

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)	
Fasting glucose	100–125 mg/dL
HbA1c	5.7 – 6.4%
2 hr OGTT	140–199 mg/dL

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%**

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Heterogeneity of Treatment Effect

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?

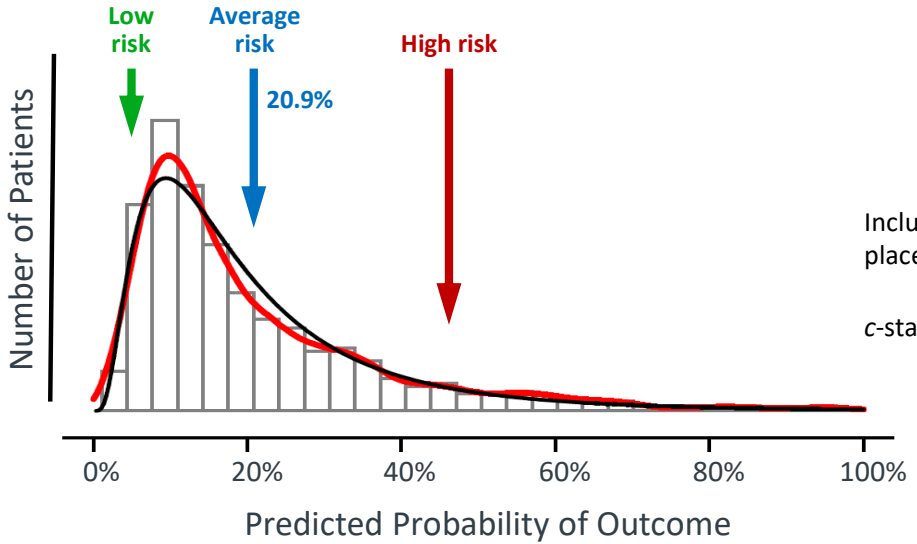
Population perspective → Can we risk-stratify?

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

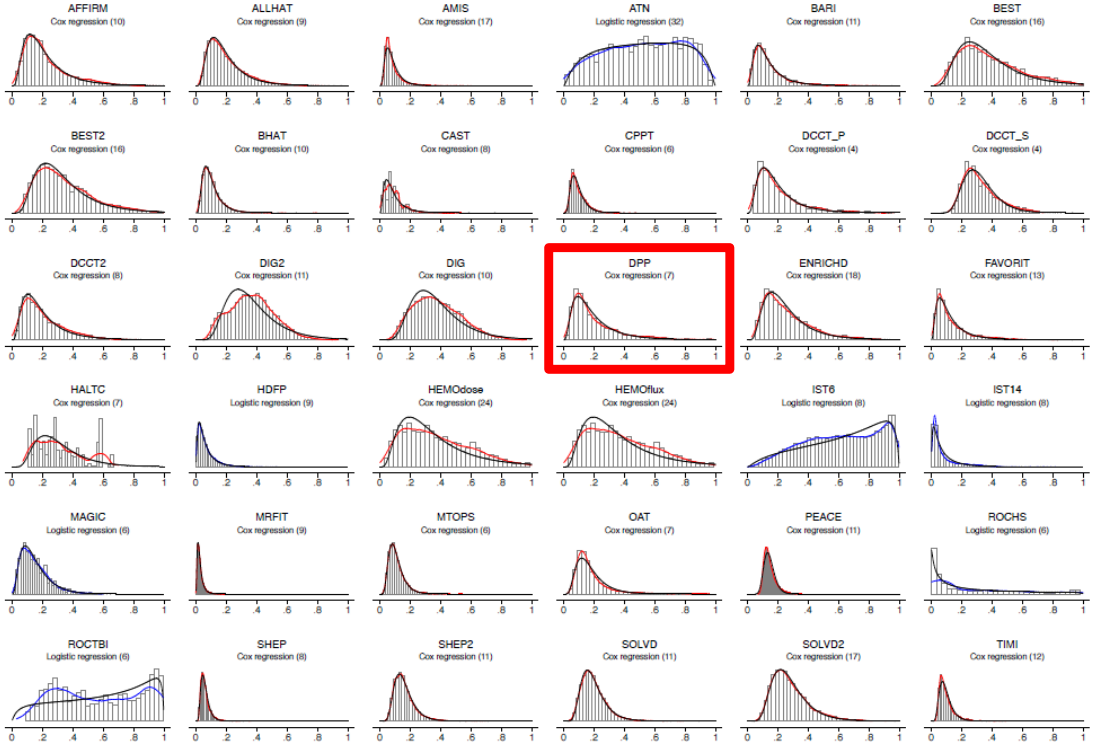


Includes all participants in the DPP Study—placebo arm, plus both intervention arms.

c-statistic 0.73, indicating good discrimination

Kent DM et al. Risk and treatment effect heterogeneity: Re-analysis of individual participant data from 32 large clinical trials. Int J Epidemiol. 2016 Jul 3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5841614/pdf/dyw118.pdf

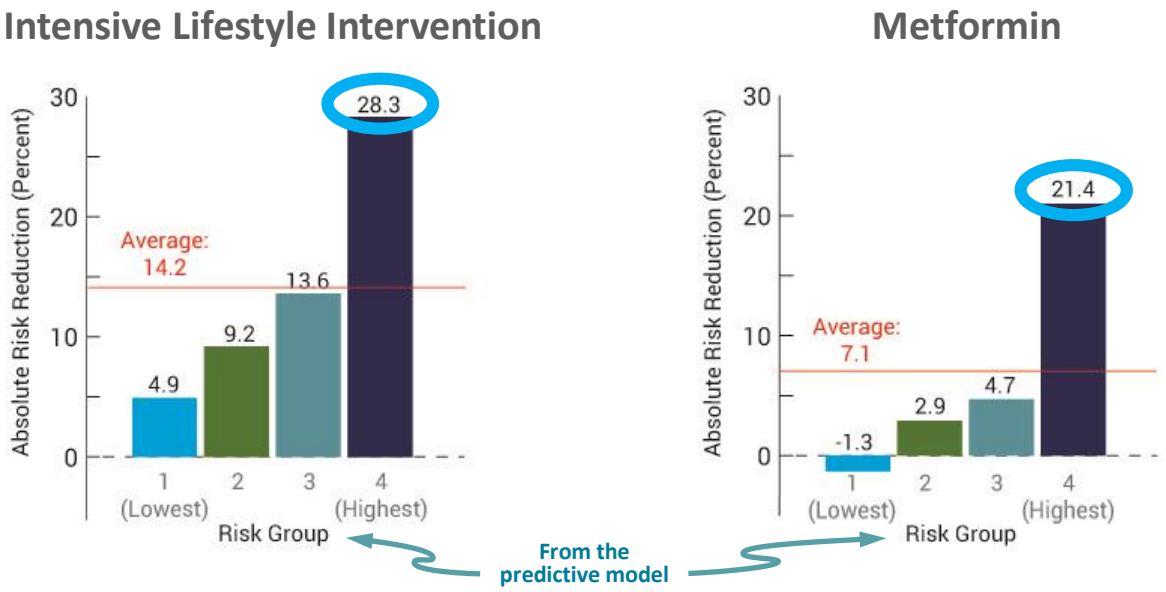
Distribution of Predicted Risk in 32 Randomized Clinical Trials



Heterogeneity of baseline risk is common, often following a distribution similar to that seen in the DPP Study

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

Absolute Risk Reduction Seen in DPP Study



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

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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

Reflects tests currently used to detect prediabetes and diabetes

Accommodates missing data (imputed values for most model data elements)

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”)

OPTUM Labs®

Longitudinal data for over 2 million people with prediabetes

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

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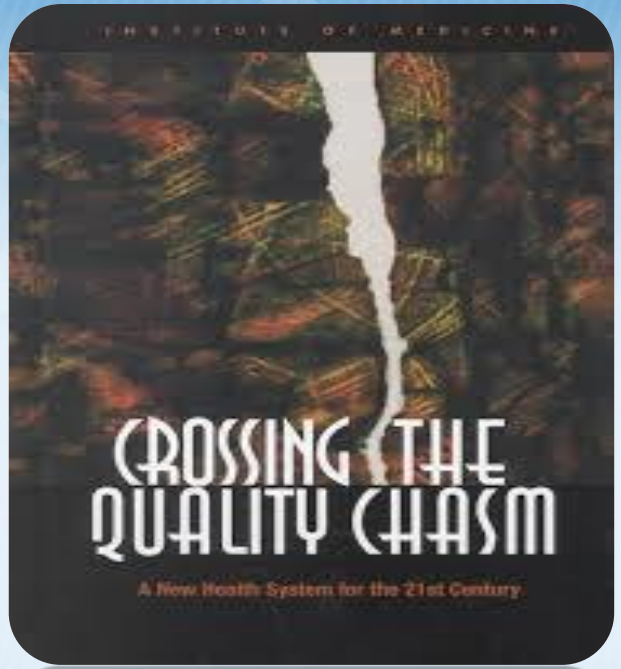
PREMIER MEDICAL ASSOCIATES

Premier Medical Associates

- Eastern suburbs of Pittsburgh, PA
- Formed 1993
- 100 providers
- Part of Highmark Health–Allegheny Health Network IDFS

IDFS – Integrated Delivery and Financing System



"It now takes an average of 17 years for new knowledge generated by randomized controlled trails to be incorporated into practice, and even then, application is highly uneven."

PREMIER MEDICAL ASSOCIATES

Committee on Quality Health Care in America, Institute of Medicine. (2001) *Crossing the quality chasm: A new health system for the 21st century.* Washington, DC: National Academy Press.

The New England
Journal of Medicine

VOLUME 346 FEBRUARY 7, 2002 NUMBER 6

REDUCTION IN THE INCIDENCE OF TYPE 2 DIABETES WITH LIFESTYLE INTERVENTION OR METFORMIN

DIABETES PREVENTION PROGRAM RESEARCH GROUP*

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Study Description

- ✓ 2 AMGA Member Organizations
- ✓ Patient Stakeholders

- ✓ Patient and Provider Focus Groups
- ✓ Patient and Provider Surveys

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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

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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.

PREMIER MEDICAL ASSOCIATES

Health Affairs, *31*(1), 67-75, January 2012. doi: 10.1377/hlthaff.2011.1009

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

PREMIER MEDICAL ASSOCIATES

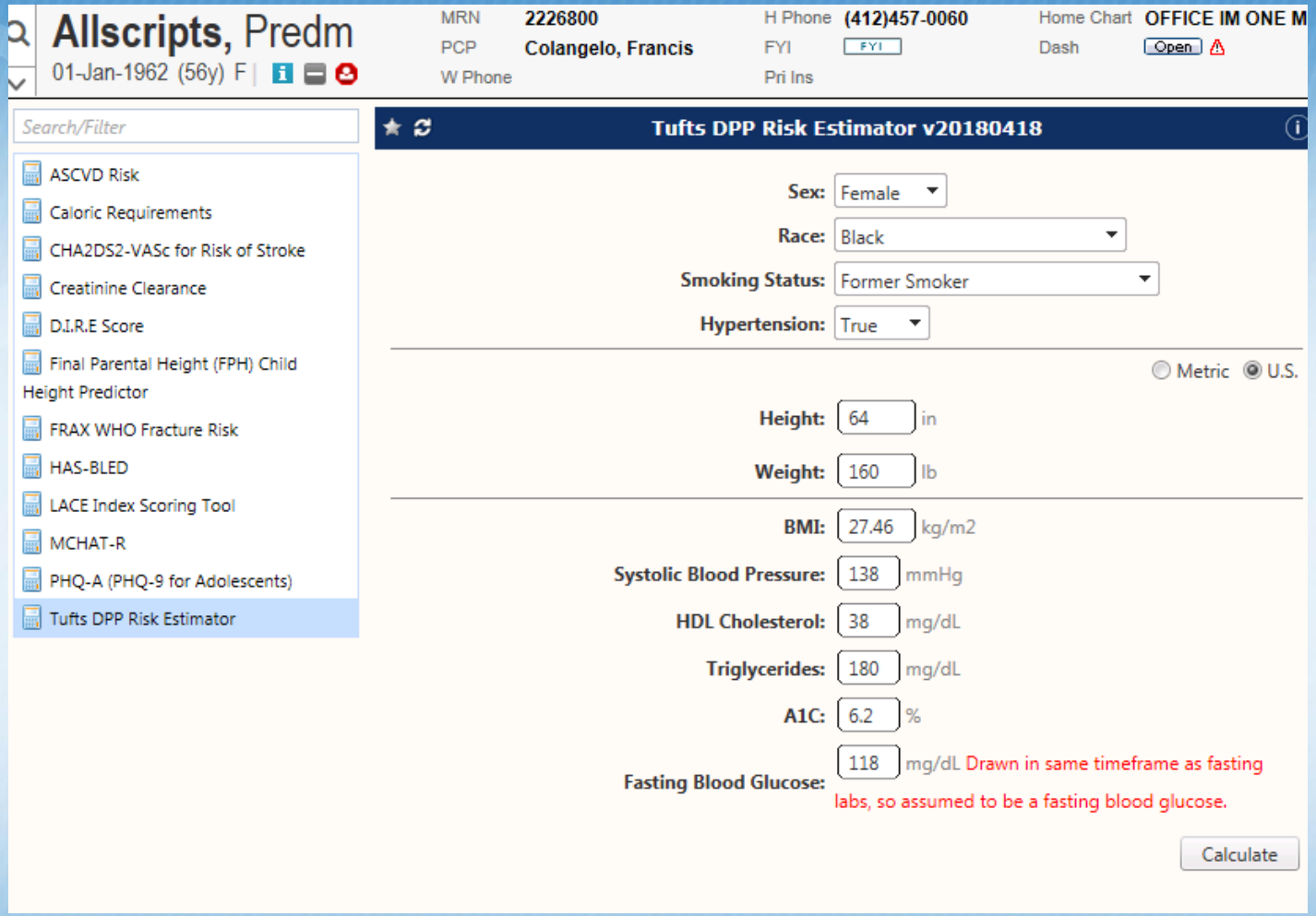
CMS Office of the Actuary. Certification memo. March 14, 2016. https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/Diabetes-Prevention-Certification-2016-03-14.pdf

https://www.ama-assn.org/delivering-care/diabetes/intermountains-prediabetes-effort-signs-10000-plus-patients

Data retrieved from EHR, displayed in the EHR for validation and and editing by the clinician, at Premier Medical Associates

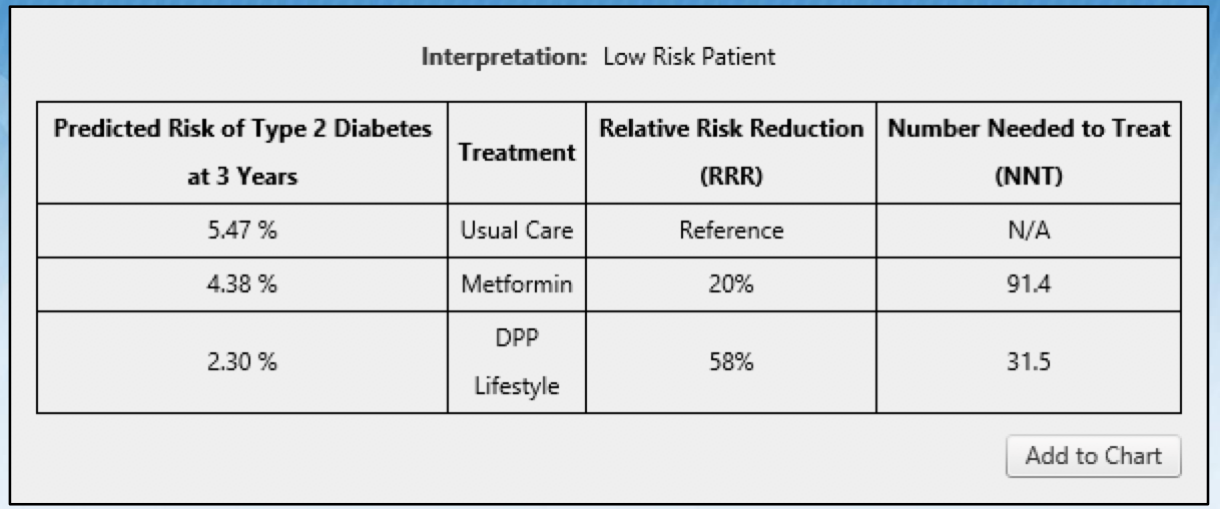
eCalcs add-in for Allscripts TouchWorks EHR

GALEN HEALTHCARE SOLUTIONS



PREMIER MEDICAL ASSOCIATES

Predictive model results, as displayed in the EHR for shared decision-making, at Premier Medical Associates



Interpretation: Low Risk Patient

Predicted Risk of Type 2 Diabetes at 3 Years	Treatment	Relative Risk Reduction (RRR)	Number Needed to Treat (NNT)
5.47 %	Usual Care	Reference	N/A
4.38 %	Metformin	20%	91.4
2.30 %	DPP Lifestyle	58%	31.5

Add to Chart

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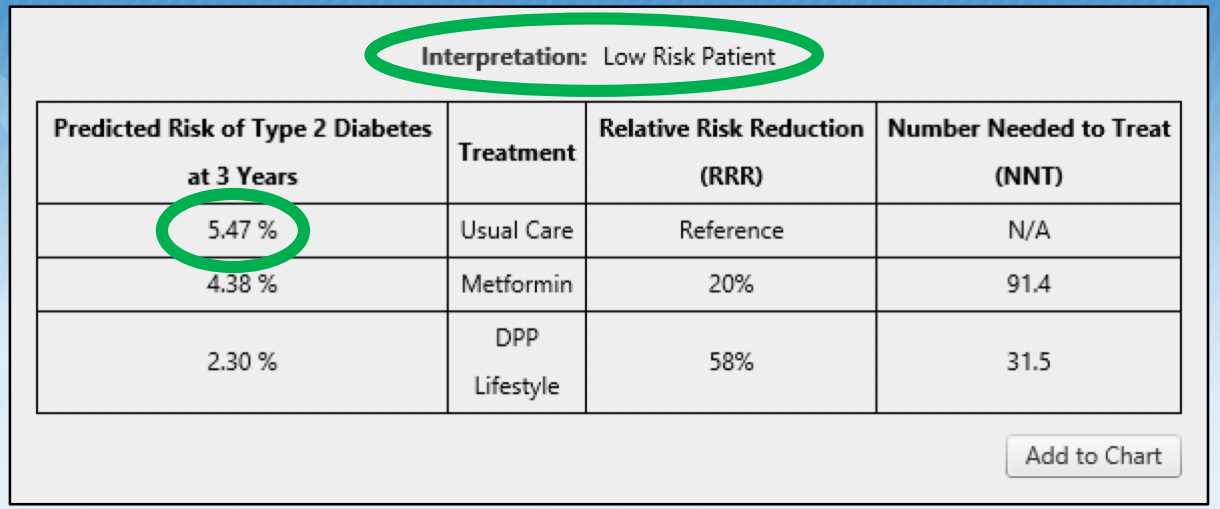

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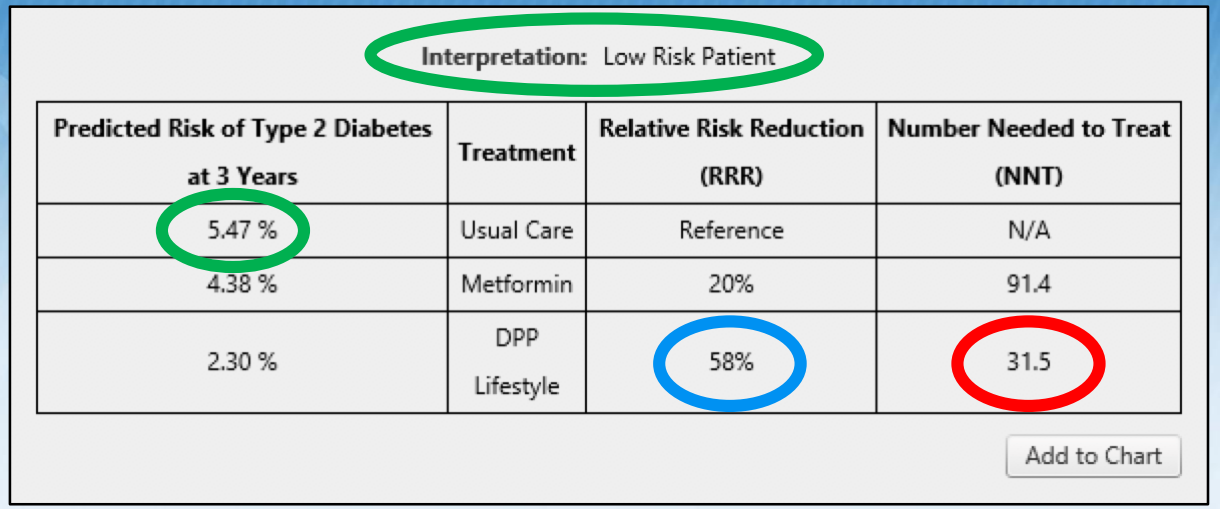

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Interpretation: High Risk Patient

Predicted Risk of Type 2 Diabetes at 3 Years	Treatment	Relative Risk Reduction (RRR)	Number Needed to Treat (NNT)
55.7 %	Usual Care	Reference	N/A
24.5 %	Metformin	56%	4
23.4 %	DPP Lifestyle	58%	4

Add to Chart

PREMIER MEDICAL ASSOCIATES

Predictive model results, as displayed in the EHR for shared decision-making, at Premier Medical Associates

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Add to Chart

PREMIER MEDICAL ASSOCIATES

PMA Experience—Reach of Project

	5/1/18 – 8/31/19
Total prediabetes	2,518
Calculation completed	1,881
Percent with calculation	74.7%

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Interventions vs. Risk

Risk stratification	Intervention ordered
High risk	75.2%
Medium risk	20.6%
Low risk	7.3%

PREMIER MEDICAL ASSOCIATES

Interventions vs. Risk

Risk stratification	Intervention ordered
High risk	75.2%
Medium risk	20.6%
Low risk	7.3%

During the 15 months, 97 patients were identified as having diabetes, through timely screening

PREMIER MEDICAL ASSOCIATES

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

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Patients Referred to YDPP

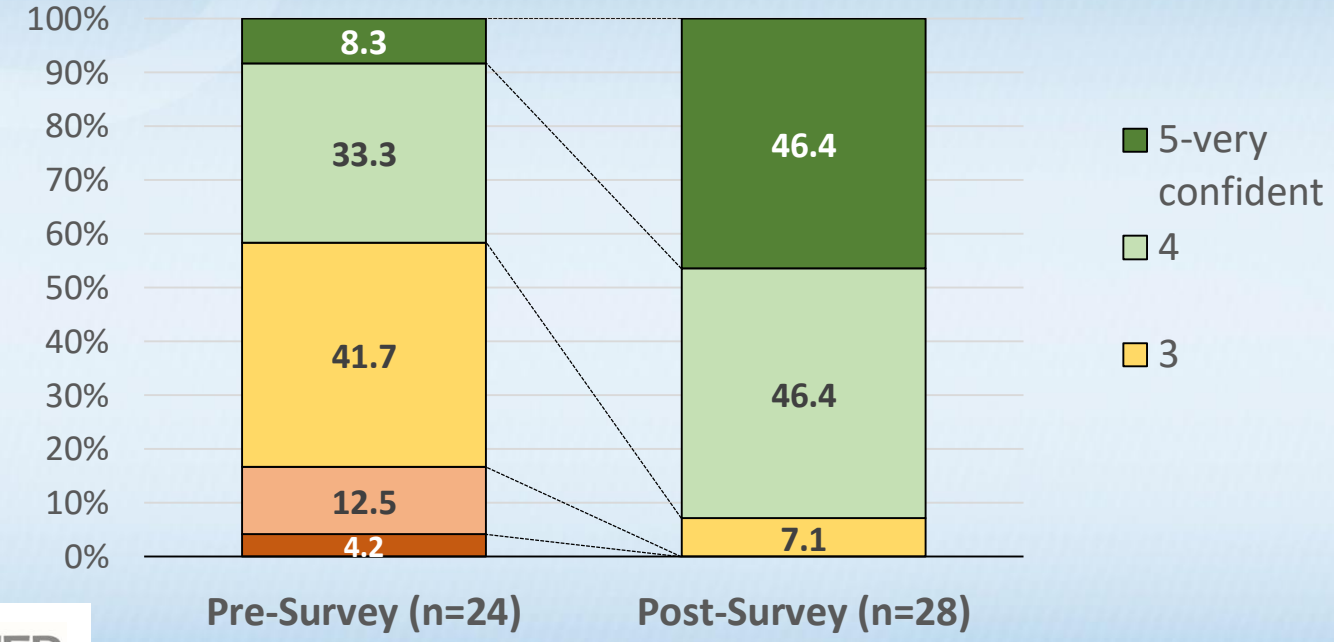
124 called the YMCA to inquire about program

64 actually enrolled

Average weight loss 17.8 pounds (7.4%)

PREMIER MEDICAL ASSOCIATES

Provider Surveys: How confident are you in your ability to estimate the average risk of diabetes progression for your patients with prediabetes?



PREMIER MEDICAL ASSOCIATES

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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

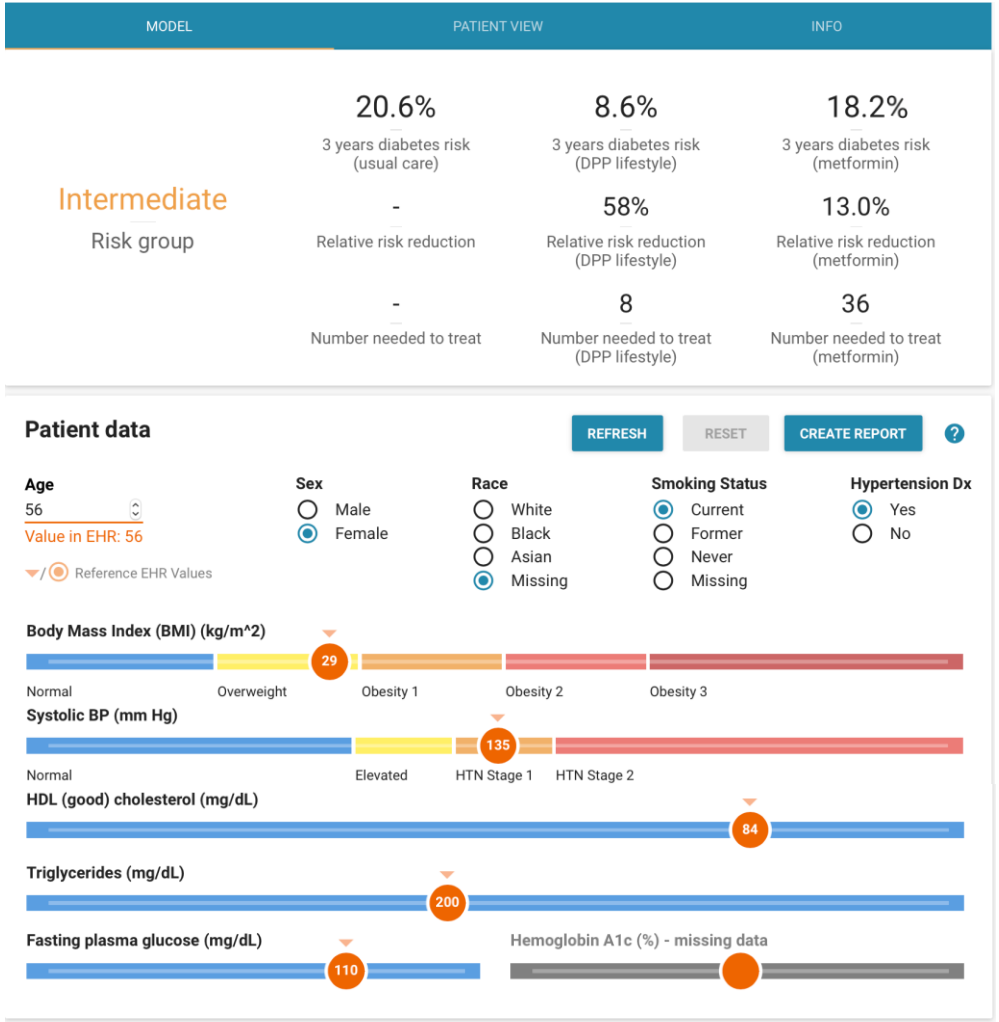
EHR – Electronic health record (Premier uses Allscripts, with Galen eCalcs; Mercy uses Epic)
SMART – Substitutable Medical Apps and Reusable Technology
FHIR – Fast Healthcare Interoperability Resources, an HL7 standard
CDS Hooks – Clinical Decision Support Hooks

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



INTEROPION

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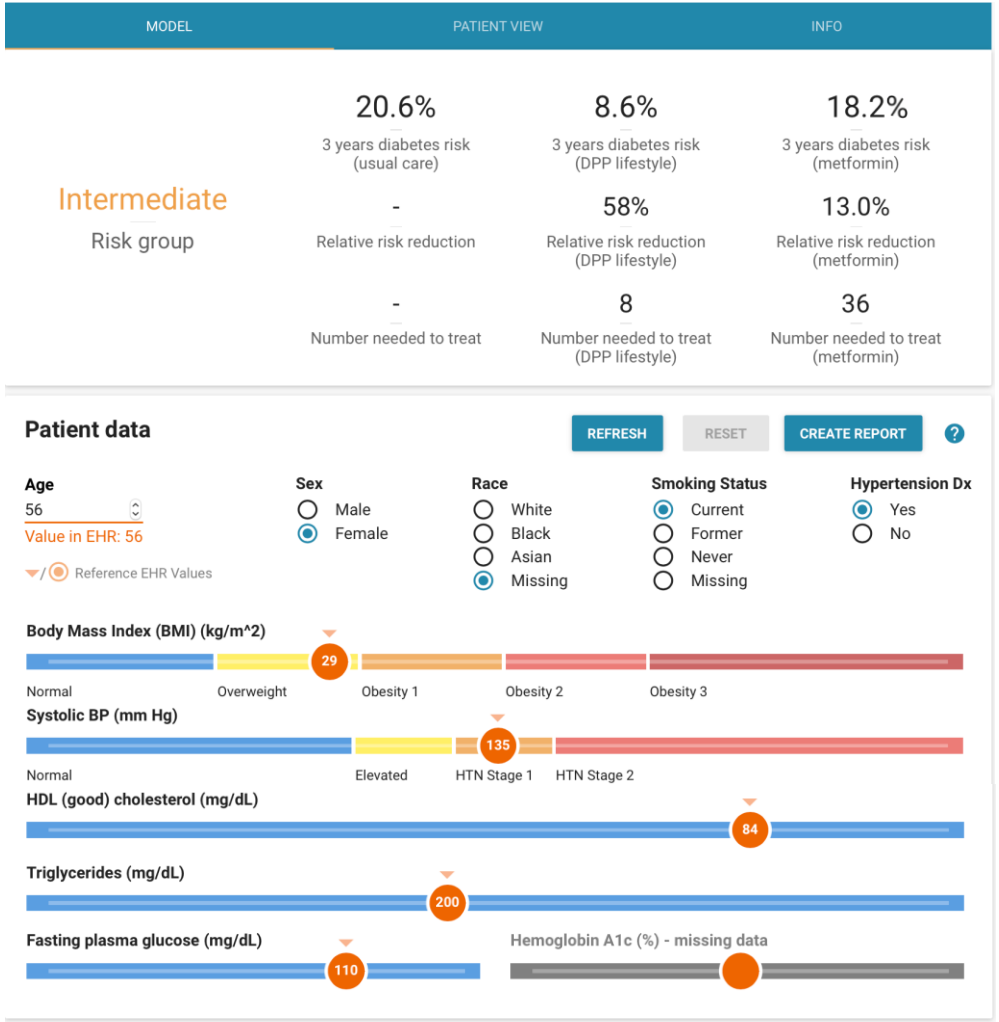
DPP lifestyle intervention yields a 12.0% absolute reduction in risk of diabetes at 3 years, from 20.6% to 8.6%, which corresponds to an NNT of 8

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



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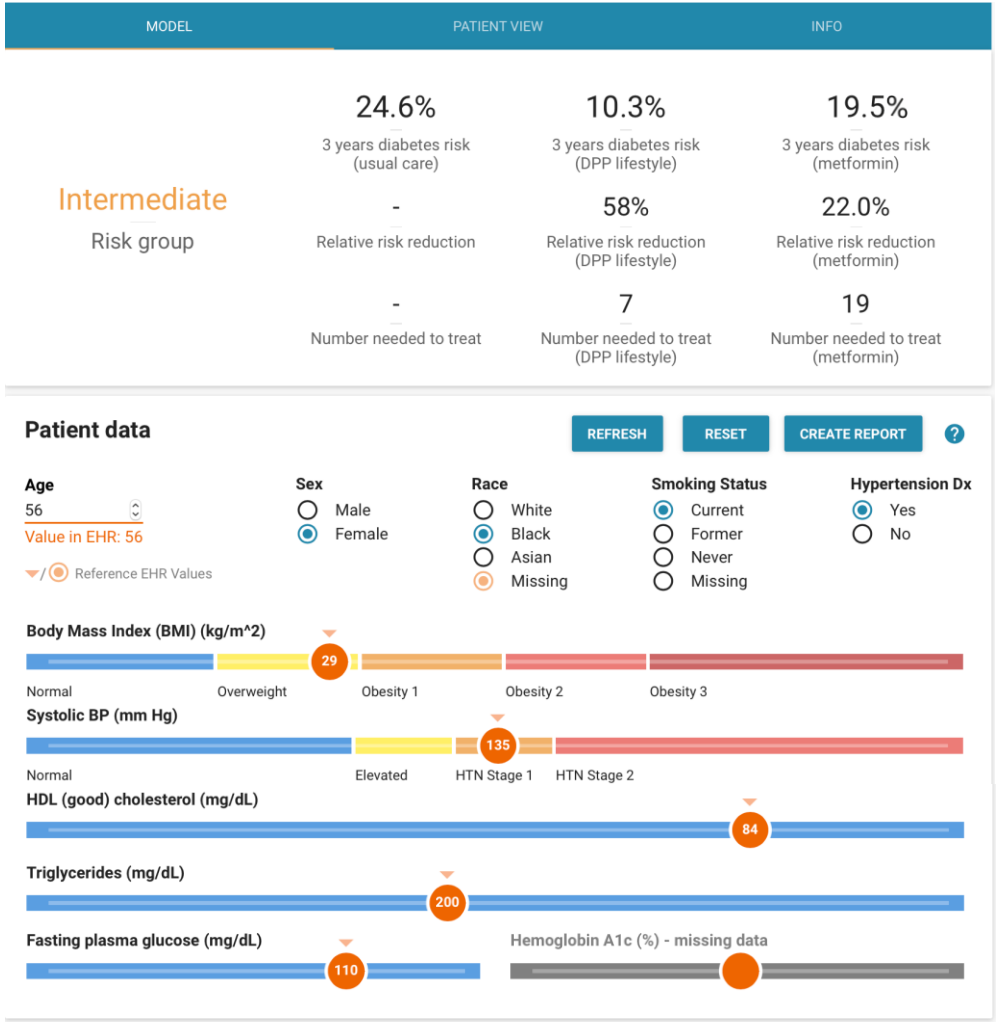
Changing patient's race from missing to Black



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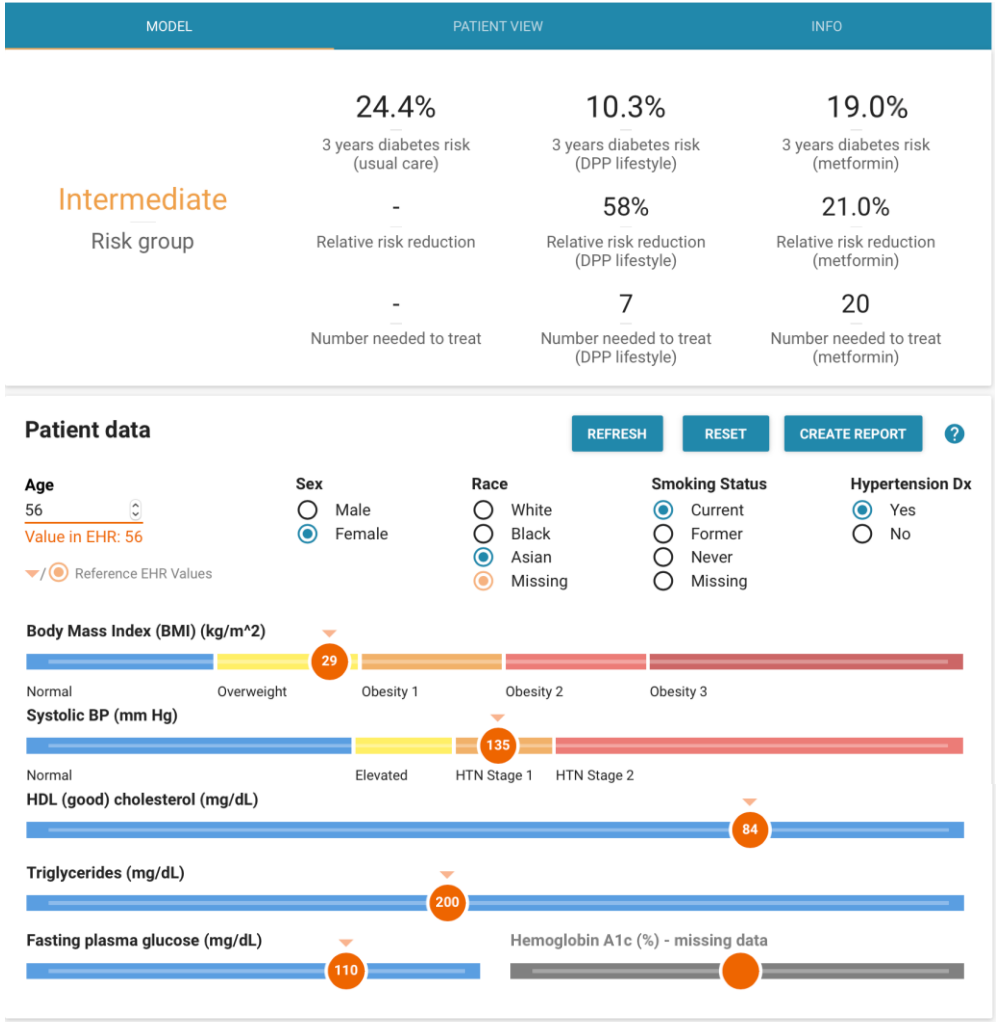
Changing patient's race from missing to Black
Asian



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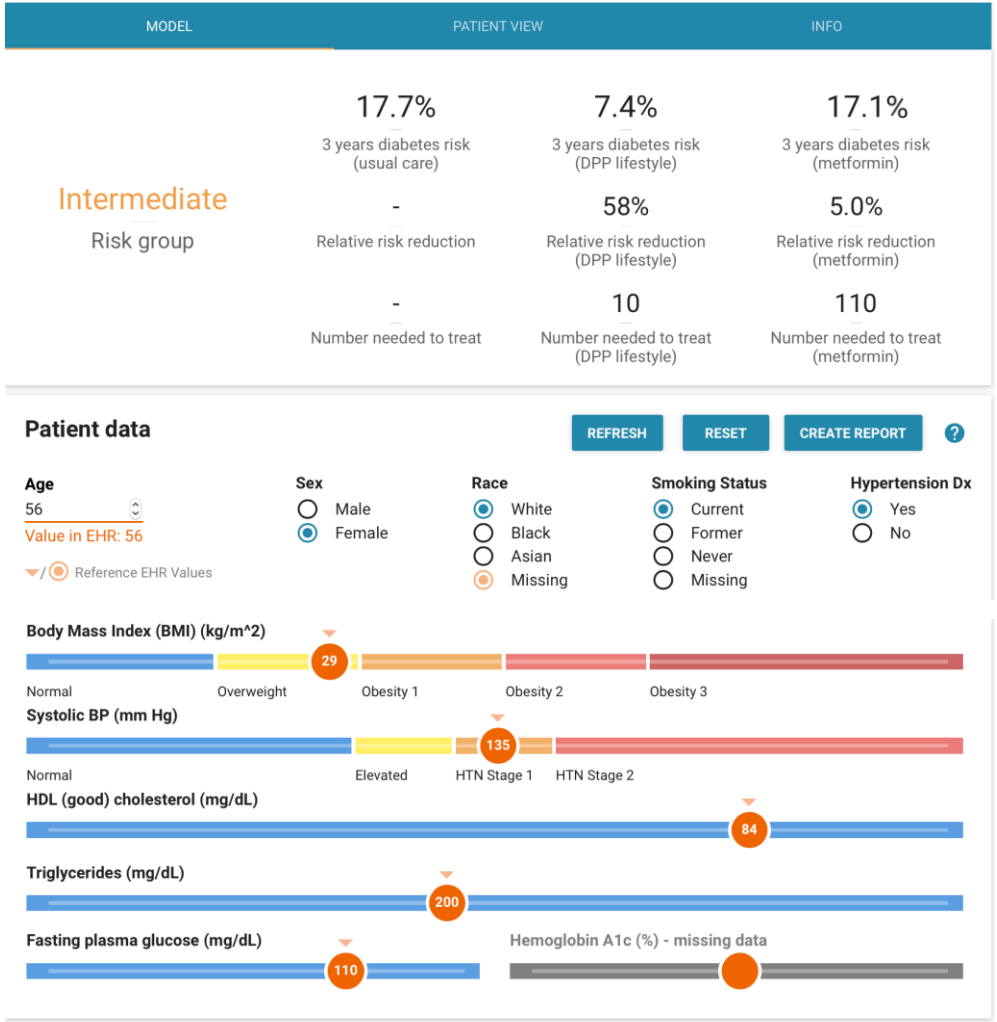
Model results are displayed at the top of the screen

Changing patient's race from missing to
Black
Asian
White



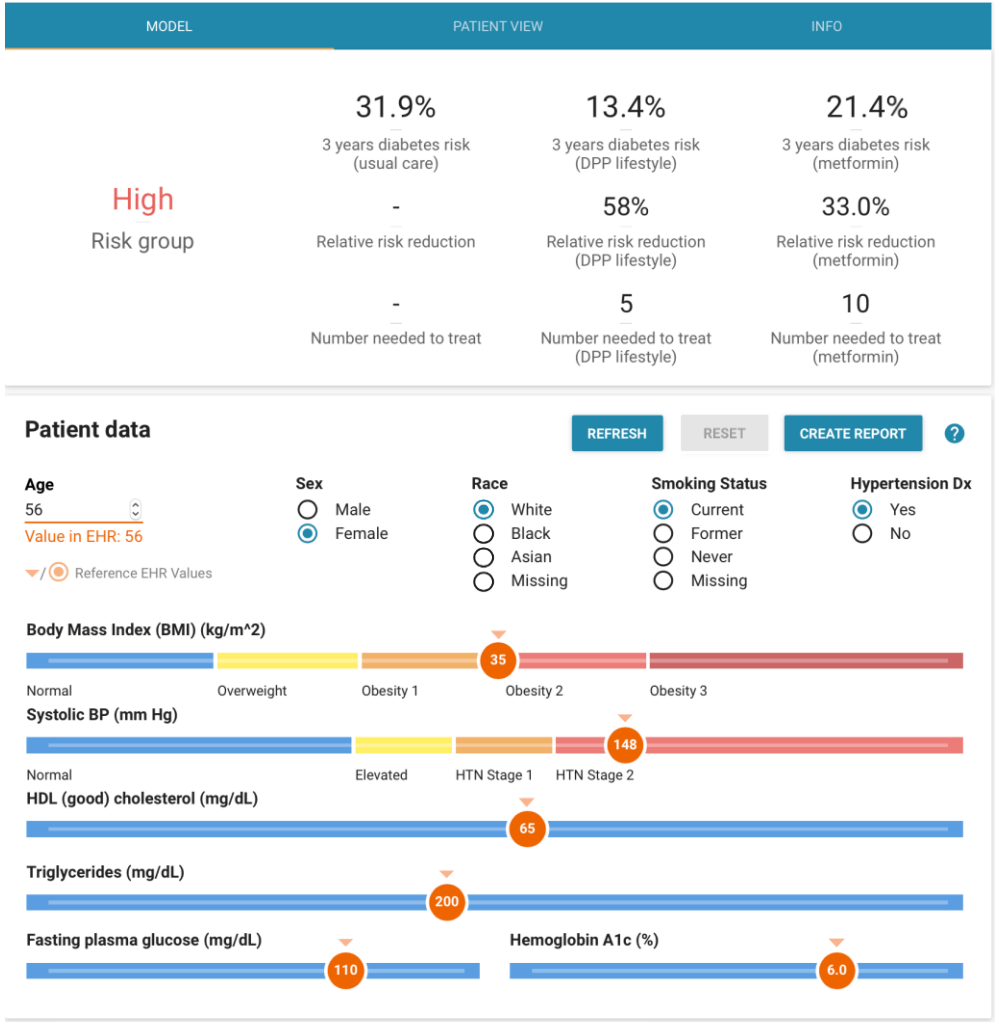
INTEROPION

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

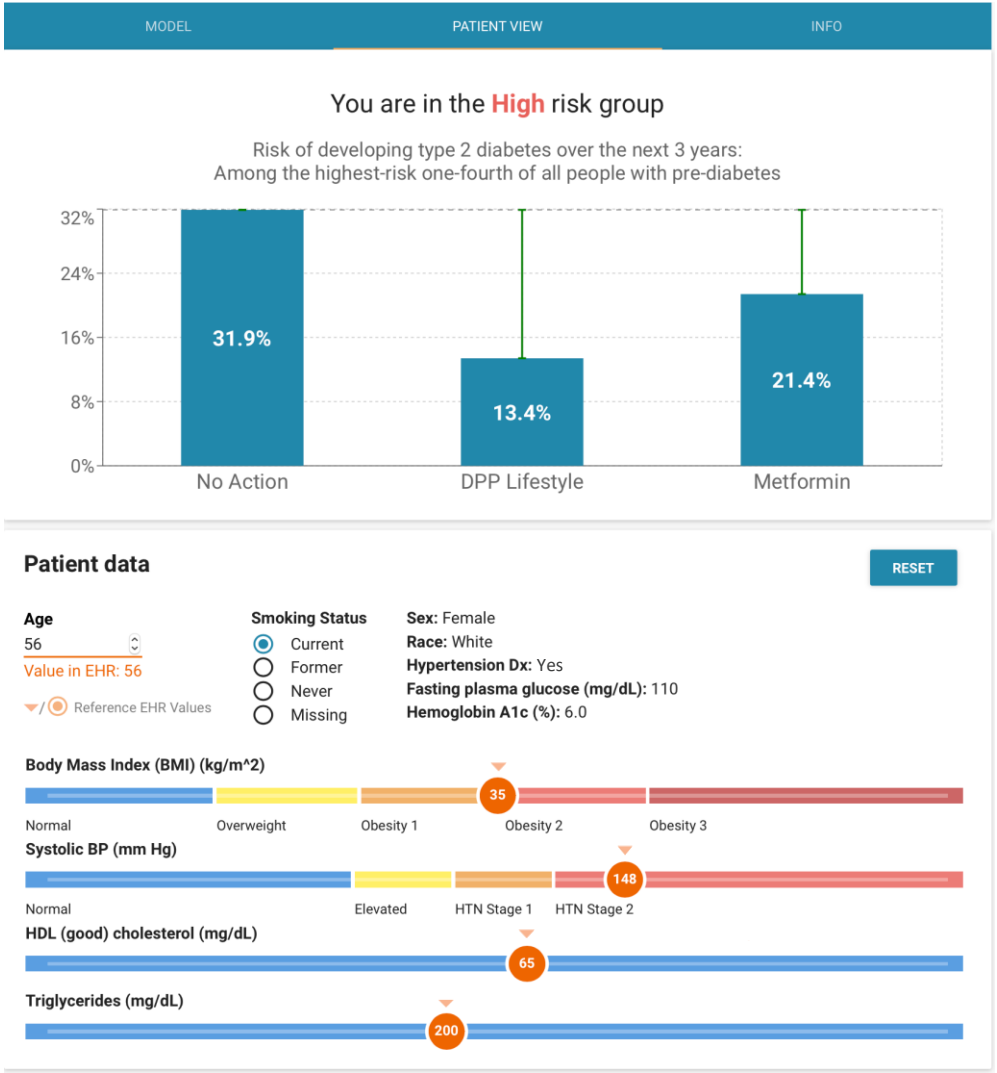
This is the **patient view,** displaying model results graphically, at the top of the screen

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.

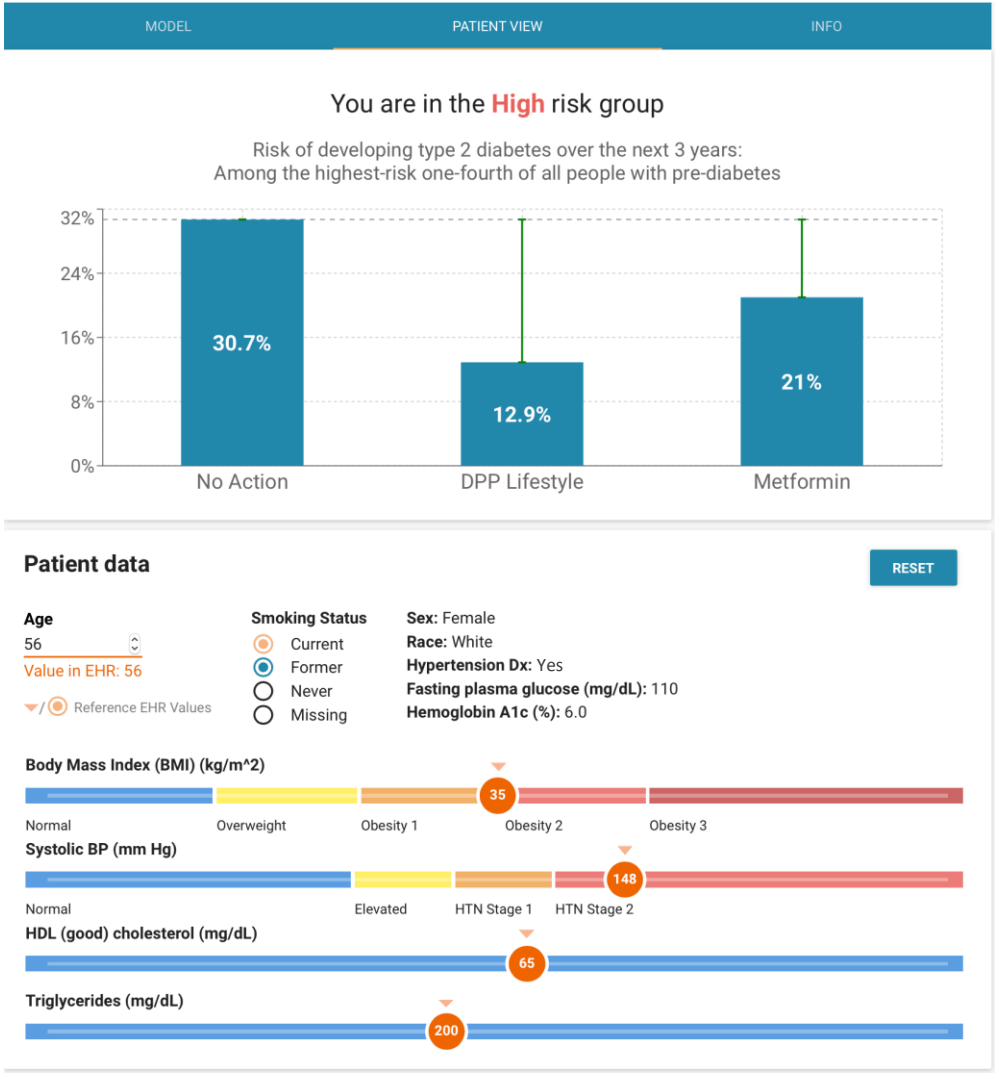


INTEROPION

Higher-risk Patient

Exploring model behavior…

Former smoker, instead of current smoker

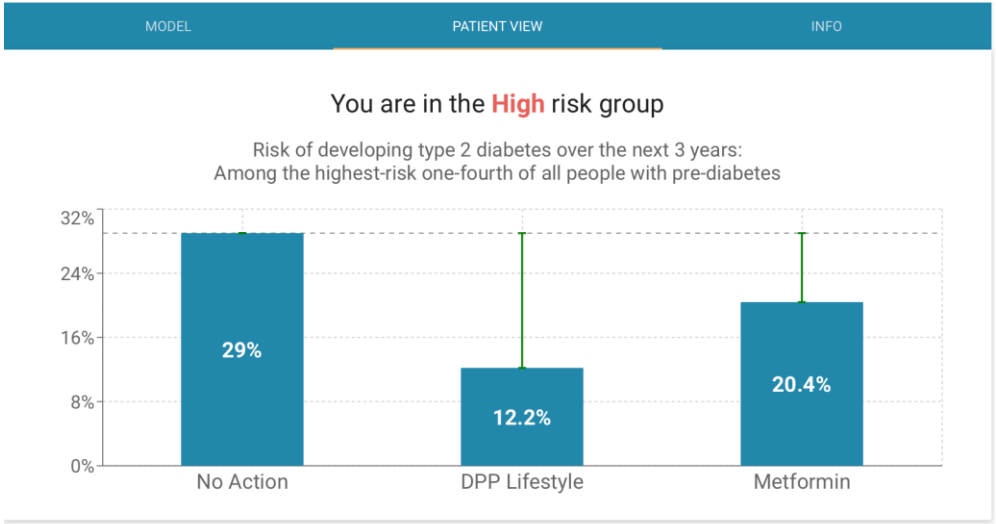


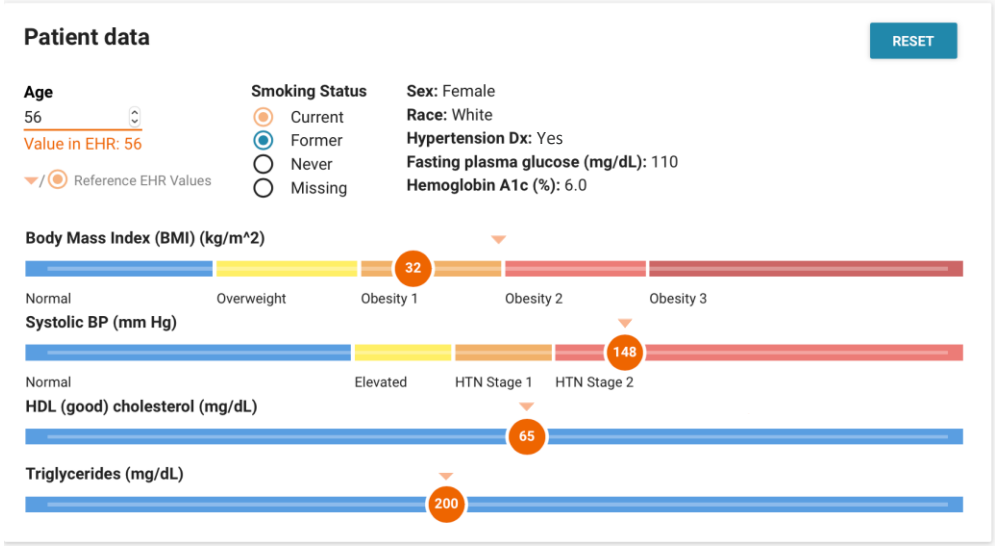
INTEROPION

Higher-risk Patient

Exploring model behavior…

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



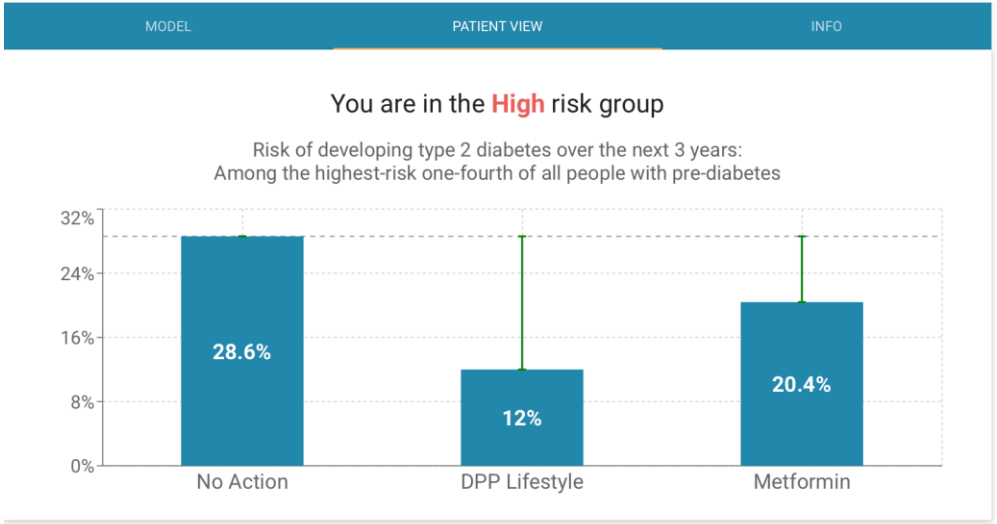


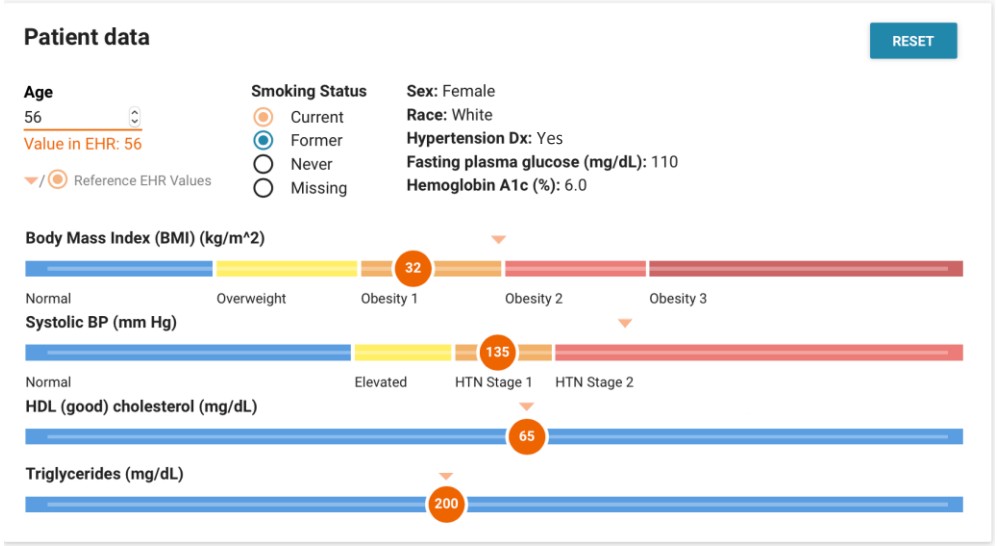
INTEROPION

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





INTEROPION

Higher-risk Patient

Exploring model behavior…

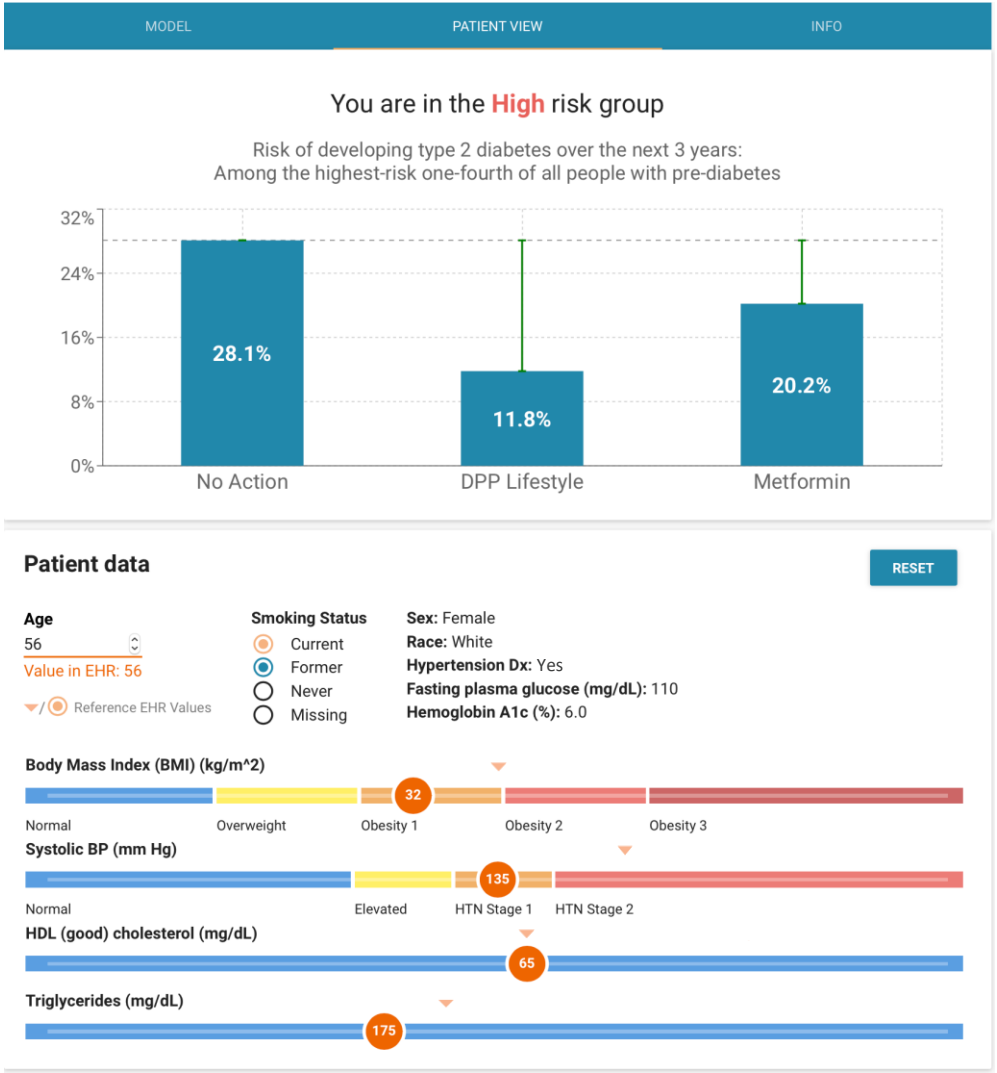
Former smoker, instead of current smoker
Reduce BMI from 35 to 32 (8.6% weight loss)
Reduce systolic BP from 148 to 135
Reduce triglycerides from 200 to 175

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**



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.”

PREMIER MEDICAL ASSOCIATES

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