

## Text for INFO Tab of Prediabetes Predictive Model SMART App

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For people aged 25–75, not pregnant and newly discovered to have prediabetes, this model estimates the risk of developing type 2 diabetes over 3 years.

ADA criteria for prediabetes (other than impaired glucose tolerance, now used primarily in obstetrics):

- HbA1c 5.7–6.4%, or
- fasting plasma glucose 100–125 mg/dL.

The model provides individualized estimates of absolute risk reduction for each of the interventions in a landmark clinical trial, the Diabetes Prevention Program (DPP) Study:

- a year-long intensive lifestyle program, now available as the National DPP program, or
- taking metformin (initially 850 mg once daily, increased to twice daily after 1 month).

(The DPP Study did not examine the effect of both interventions together.)

This app is initialized with data retrieved from the patient’s record in the EHR. On the CLINICIAN VIEW tab, the model results are displayed at the top, including both absolute and relative risk reduction and the number needed to treat (NNT) to prevent one patient with these initial parameters from developing diabetes. The retrieved data are displayed underneath, for review and validation by the clinician.

The model is tolerant of missing data, but data can be added. For example, if smoking status is not retrievable from the EHR, but you know the patient’s smoking history, the prediction will be more accurate if you select the correct value for that variable.

You can explore what-if scenarios by adjusting the patient data values, using the radio buttons or sliders, and model values will be recalculated immediately. **It is important to understand how to interpret these changes.** They put the patient into a group of people with a different baseline risk of developing diabetes and potentially a different estimated benefit from the DPP lifestyle program or taking metformin. 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.

For most patients, 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.

The PATIENT VIEW tab provides a graphical display of the risk of developing diabetes with usual care, with the DPP lifestyle program, and with taking metformin. (These estimates, from the DPP Study, reflect strict adherence to the respective intervention.) The focus of the patient view display is on absolute risk reduction, but relative risk reduction is displayed when you hover the mouse pointer over either of the intervention bars. NNT is displayed only on the clinician view.

## Background

Sponsored by NIH, the Diabetes Prevention Program (DPP) Study involved more than 3,000 people with prediabetes across 27 centers and was conducted in 1996–2001. Without intervention, the risk of developing diabetes within 3 years was 29%. Across all participants, the DPP lifestyle program yielded an absolute risk reduction of 14%, and taking metformin led to an absolute risk reduction of 7%. The study was stopped a year early because these interventions were so effective.

But the impact of these interventions was highly variable across the population. The one-fourth of people at highest risk of progressing to diabetes gained twice the average benefit, in terms of absolute risk reduction, from the DPP lifestyle intervention. Those at lower risk saw proportionally less benefit, but it was still significant (consistent relative risk reduction).

In contrast, nearly all the benefit from taking metformin was seen in the one-fourth of people at highest risk. Those at moderate or low risk gained little or no benefit from metformin.

Long-term follow-up confirmed that the benefit persisted. After 10 years, participants in the lifestyle arm of the DPP Study were one-third less likely to have developed diabetes than people in the placebo arm. Those who did develop diabetes delayed the onset of the disease by about 4 years.

Because the benefit of these interventions depends on the patient's risk of developing diabetes, a new risk model was developed and validated using longitudinal data from more than 2 million people with prediabetes at OptumLabs. It reflects current practice and the current ADA criteria for prediabetes. It was also validated on the placebo arm of the DPP Study.

In this app, the new model is used to estimate the risk of developing diabetes over 3 years. Then, risk-specific estimates from the DPP Study are applied to calculate the benefit of the DPP lifestyle program and taking metformin.