User Manual for the Diabetes Prevention Impact Toolkit

December 2016

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1. INTRODUCTION

The Diabetes Prevention Impact Toolkit was developed by RTI International for the Centers for Disease Control and Prevention (CDC). The purpose of the Impact Toolkit is to project the health and economic effects of the National Diabetes Prevention Program (National DPP) lifestyle change program on state, employer, and insurer populations at risk for type 2 diabetes.

The Impact Toolkit includes three modules, as seen on the homepage (Figure 1):

- The State module provides results at the state level.
- The Employer module allows users to generate customized results for their employee population.
- The Insurer module allows users to generate customized results for their insured population.

<page-header>

Figure 1. Diabetes Prevention Impact Toolkit Homepage

The modules are very similar, with the main difference in the Population Characteristics section of the Input Dashboard. Specifically, in the Employer and Insurer modules, users can choose from a set of predefined populations or enter a customized set of population characteristics, whereas in the State module, users are only offered state populations.

Sections 2.1 through 2.3 describe the Population Characteristics inputs for each module separately. All other sections of this user manual apply to all three modules, except for Section 2.5.7 Productivity Costs, which only applies to the Employer module.

2. INPUT DASHBOARD

For each module (State, Employer, and Insurer), the Population Characteristics section of the Input Dashboard has different features and functions. These Population Characteristics are described in the following sections. Section 2.1 covers the technical details of population characteristics for the State module, Section 2.2 covers the Employer module, and Section 2.3 covers the Insurer module. Sections 2.4 and 2.5 cover the technical details associated with additional sections of the Input Dashboard that are the same in each module (e.g., screening assumptions, cost assumptions).

When you first open the Input Dashboard for one of the modules (Figure 2 shows the Input Dashboard for the State module), you will see a limited set of inputs. To obtain baseline results quickly, make selections from this limited set of inputs and then click "GET RESULTS." If you do not change any of these inputs, results will be generated based on default values for the population. In the State module, you must select a state before clicking "GET RESULTS."

To view the full set of inputs and selections, click "CUSTOMIZE FURTHER." All inputs are set to a default value that reflects the average costs, effects, screening history, and participation rates of a U.S.-based National DPP lifestyle change program. However, your state or organization's inputs and selections may differ from the average. To learn more about how to customize inputs, continue reading Section 2 (Input Dashboard). To learn more about interpreting the Impact Toolkit results, see Section 3 (Output Dashboard). For a checklist of all data items and selection decisions that you can customize, refer to the Data Input Checklists provided for each module on the Impact Toolkit's HELP page. To learn more about an input field in real time, hover over the green circles with an "i" in the center. These "tooltips" display a few key points related to the adjacent text or input field.

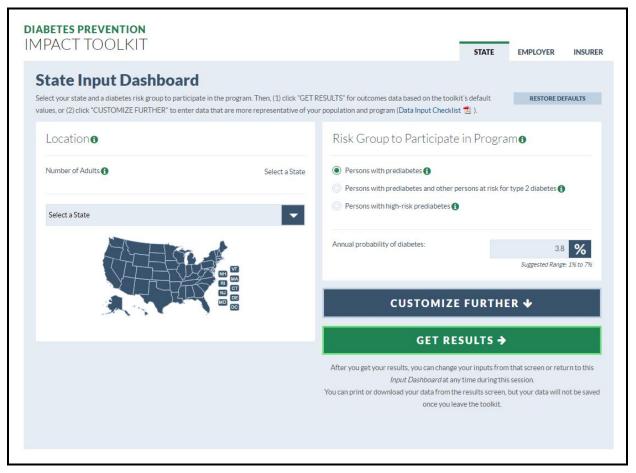


Figure 2. State Input Dashboard

2.1 State Module Population Characteristics

When a state is selected from the dropdown list (or the U.S. map) shown in Figure 2, the Impact Toolkit references a table of state-level population data. The number of adults in your state (or national) selection will automatically populate next to the heading "Number of Adults." Another table stored in the State module contains the state-specific predicted prevalence for each of the risk groups eligible to participate in the National DPP lifestyle change program. The default risk group is set to "Persons with prediabetes," but you can also select a larger group ("Persons with prediabetes and other persons at risk for type 2 diabetes") or a smaller group ("Persons with high-risk prediabetes"). These risk groups only include persons who are eligible for the National DPP (body mass index [BMI] \geq 24 kg/m²). See Section 2.4 for more information on how these groups are defined.

National estimates offered in the State module ("UNITED STATES" selection in the dropdown menu) do not use a prediction equation to predict the prevalence of "Persons with prediabetes" because their prediabetes status is obtained directly from the results of the

National Health and Nutrition Examination Survey (NHANES) laboratory data (i.e., A1C or fasting plasma glucose [FPG] test results). Thus, we used the NHANES data (2011–2014) for the U.S. population selection in the State module, whereas state-level data were based on (1) the prediabetes prediction equation estimated in NHANES (2011–2014) and (2) the state-level characteristics observed in the Behavioral Risk Factor Surveillance System (BRFSS) (2014). Depending on your screening and participation assumptions (see Sections 2.5.1 and 2.5.2), only a fraction of the eligible state residents will end up participating and reducing their risk of progression to diabetes.

2.2 Employer Module Population Characteristics

Before selecting a radio button to designate your population's characteristics, you will first enter your population size (i.e. "Number of Employees" in the Employer module). This number should include all employees, not just those eligible or participating in a prevention program. The default number of employees is set to 1,000 as shown in Figure 3.

					TATE EMPLOYER	INSURE
Employer Ir	nput Da	shboard				
				 Then. (1) click "GET RESULTS" for outcomes data base resentative of your population and program (Data Input output) 		RE DEFAULTS
Population Characteristics 0				Risk Group to Participate in F	Program®	
Number of employees: 1.000			Persons with prediabetes ()			
				Persons with prediabetes and other persons	at risk for type 2 diabetes	9
O Assume national av	verage for popula	tion characteristics 🚯		Persons with high-risk prediabetes 6		
Assume state avera	ge for population	characteristics 🕤				
Assume industry av	verage for popula	tion characteristics 🚯		Annual probability of diabetes:	3.	8 %
Assume occupation		ulation characteristics 🚯			Suggested Ran	ge: 1% to 7%
Enter employee cha	aracteristics 🚯					
				CUSTOMIZE FU	RTHER 🕹	
AGE BREAKDOWN:		SEX BREAKDOWN:				
18-44	54.27 %	Male	53.82 %	GET RESUL	.TS 🗲	
45-64	40.22 %	Female	46.18 %	After you get your results, you can change your in	anuts from that screen or re	turn to this
65-74	5.04 %	Total	100.00%	Input Dashboard at any time		
75+	0.47 %			You can print or download your data from the result once you leave the		not be saved
Total	100.009	6				
RACE/ETHNICITY BREA	AKDOWN:	BODY WEIGHT BREA	KDOWN:			
Non-Hispanic White	66.75 %	Obese	33.90 %			
Non-Hispanic Black	10.36 %	Overweight 🕄	41.58 %			
Hispanic	14.99 %	Normal Weight 🕄	24.52 %			
Non-Hispanic Asian	5.10 %	Total	100.00%			
Other Race/Ethnicity	2.80 %					
Total	100.009					

Figure 3. Employer Input Dashboard

Once you have entered the total number of employees at a firm, you will then select a radio button to determine the population characteristics of your employee population. There are several predefined sets of population characteristics as well as an option to enter your own employee population characteristics (age, race/ethnicity, sex, body weight). The proportion of the population that is eligible for the National DPP will be calculated using the set of population characteristics defined here and a prediction equation estimated in NHANES (2011–2014).

2.2.1 Assume National Average for Population Characteristics

Choose this option if you would like to use national averages for population characteristics and prediabetes rates. National characteristics are survey-weighted estimates from the sample of U.S. persons in NHANES (2011–2014).

2.2.2 Assume State Average for Population Characteristics

Choose this option if you would like to use a particular state's averages for population characteristics and prediabetes rates. State characteristics are survey-weighted estimates from the sample of each state's residents in the BRFSS (2014).

2.2.3 Assume Industry Average for Population Characteristics

Choose this option if you would like to use a particular industry's averages for population characteristics. Industry population characteristics are based on the sample of employed persons in NHANES (2011–2014) and the relative rates of obesity across industry groups reported in Luckhaupt et al. (2014). Industries are defined in NHANES using the U.S. Census Bureau's 2002 Occupation and Industry coding system (U.S. Census, 2016). If you do not see a choice that matches your industry, select state or national averages, or enter your own employee population characteristics.

2.2.4 Assume Occupation Average for Population Characteristics

Choose this option if you would like to use a particular occupation's averages for population characteristics. Occupation population characteristics are based on the sample of employed persons in NHANES (2011–2014) and the relative rates of obesity across occupation groups reported in Luckhaupt et al. (2014). Occupations are defined in NHANES using the U.S. Census Bureau's 2002 Occupation and Industry coding system (U.S. Census, 2016). If you do not see a choice that matches your occupation, select state or national averages, or enter your own employee population characteristics.

2.2.5 Entering Employee Population Characteristics

For customized results based on your organization's unique population characteristics, select the "Enter employee characteristics" option. When this option is selected, you will see that the fields for each characteristic have already been filled with default values that reflect national averages for the employed population in the United States. You can change these values to reflect your own employee population characteristics. Each of the population characteristics breakdowns (age, race/ethnicity, sex, and body weight) are for the overall population. For example, the various age groups in the age breakdown box are for all male and female employees; different age breakdowns for males and females cannot be entered in the Impact Toolkit. To return to the default values at any point, click the "RESTORE DEFAULTS" link in the upper right-hand corner (see Figure 3). This button will clear all of the data that you have entered and restore the default data. The values entered in the employee characteristics fields are used to predict the percentage of employees in each risk group (see Section 2.4 for more information on risk groups).

Age Breakdown

Enter the percentage of your employee population that is in each age group. The sum of these categories should equal 100%.

Race/Ethnicity Breakdown

Enter the percentage of your employee population that is in each race/ethnicity group. The sum of these categories should equal 100%. The "Other Race/Ethnicity" group includes other non-Hispanic races and non-Hispanic multiracial persons based on NHANES 2011–2014 race/ethnicity definitions.

Sex Breakdown

Enter the percentage of your employee population that is in each sex group. The sum of these categories should equal 100%.

Body Weight Breakdown

Enter the percentage of your employee population that is in each body weight group. For the purposes of this tool, include the percentage of underweight employees in the normal weight category. To match National DPP eligibility requirements, the BMI range for overweight is expanded beyond its typical clinical definition ($\geq 25.0 \text{ kg/m}^2$). The BMI ranges for each category are as follows:

- <24.0 kg/m²: Normal weight and underweight
- 24.0 kg/m²–29.9 kg/m²: Overweight¹
- ≥30.0 kg/m²: Obese

¹ We defined overweight with a lower BMI threshold of 24.0 kg/m² to match CDC criteria for participation in the National DPP (CDC, 2015b). State and national estimates use a lower BMI threshold (22.0 kg/m²) for Asian participants in the National DPP (CDC, 2015b); however, the "Enter employee characteristics" does not account for different BMI thresholds by race/ethnicity. This may have a small downward effect on the number of projected participants when a substantial share of the employee population is Asian.

Only overweight and obese employees are eligible for participation. The sum of the three body weight categories should be 100%.

2.3 Insurer Module Population Characteristics

Before selecting a radio button to designate your population's characteristics, you will first enter your population size (i.e., "Number of Adults Insured" in the Insurer module). This number should include all privately insured adults, not just those participating in a prevention program. The default number of privately insured adults is set to 1,000 as shown in Figure 4.



				STATE EMPLOYER INSU
nsurer Inpu	t Dash	board		
			ticipate in the program	Then, (1) click "GET RESULTS" for outcomes data based on the RESTORE DEFAULT
olkit's default values, or (2)	click "CUSTOM	IZE FURTHER" to enter o	lata that are more rep	resentative of your population and program (Data Input Checklist 🔁).
Population Cha	aracteristic	CS 🖯		Risk Group to Participate in Program 🖲
Number of Adults Insured	• •		1,000	Persons with prediabetes
				🕖 Persons with prediabetes and other persons at risk for type 2 diabetes 🚯
O Assume national aver	rage for populati	on characteristics 🕤		Persons with high-risk prediabetes 6
O Assume state average	e for population	characteristics 🔒		
O Assume industry ave	rage for populati	on characteristics 🚯		Annual probability of diabetes: 3.8 %
O Assume occupation a	averag <mark>e</mark> for popu	lation characteristics 🕤		Suggested Range: 1% to 7%
Enter insured adult p	opulation charac	teristics 🕤		
AGE BREAKDOWN:	45.25 %	SEX BREAKDOWN:	48.20 %	GET RESULTS ->
45-64	37.40 %	Female	51.80 %	
65-74	10.91 %			After you get your results, you can change your inputs from that screen or return to this
75+	6.44 %	Total	100.00%	Input Dashboard at any time during this session. You can print or download your data from the results screen, but your data will not be sav
Total	100.00%			once you leave the toolkit.
10101	100.00%			
RACE/ETHNICITY BREAK	KDOWN:	BODY WEIGHT BREAK	KDOWN:	
Non-Hispanic White	75.32 %	Obese	34.50 %	
Non-Hispanic Black	8.96 %	Overweight 🕄	40.93 %	
Hispanic	7.35 %	Normal Weight 🕄	24.57 %	
	5.64 %	Total	100.00%	
Non-Hispanic Asian	2.73 %			
Non-Hispanic Asian Other Race/Ethnicity	2.75 70			

Once you have entered the total number of privately insured adults in your population, you then will select a radio button to determine the population characteristics of your population. There are several predefined sets of population characteristics as well as an option to enter your own privately insured adult population characteristics (age, race/ethnicity, sex, body weight). The proportion of the population that is eligible for the National DPP will be calculated using the set of population characteristics defined here and a prediction equation estimated in NHANES (2011–2014).

2.3.1 Assume National Average for Population Characteristics

Choose this option if you would like to use national averages for population characteristics and prediabetes rates. National characteristics are survey-weighted estimates from the sample of U.S. persons in NHANES (2011–2014).

2.3.2 Assume State Average for Population Characteristics

Choose this option if you would like to use a particular state's averages for population characteristics and prediabetes rates. State characteristics are survey-weighted estimates from the sample of each state's residents in BRFSS (2014).

2.3.3 Assume Industry Average for Population Characteristics

Choose this option if you would like to use a particular industry's averages for population characteristics. Industry population characteristics are based on the sample of employed persons in NHANES (2011–2014) and the relative rates of obesity across industry groups reported in Luckhaupt et al. (2014). Industries are defined using the U.S. Census Bureau's 2002 Occupation and Industry coding system (U.S. Census, 2016). If you do not see a choice that matches your industry, select state or national averages, or enter your own insured population characteristics.

2.3.4 Assume Occupation Average for Population Characteristics

Choose this option if you would like to use a particular occupation's averages for population characteristics. Occupation characteristics are based on the sample of employed persons in NHANES (2011–2014) and the relative rates of obesity across occupation groups reported in Luckhaupt et al. (2014). Occupations are defined in NHANES using the U.S. Census Bureau's 2002 Occupation and Industry coding system (U.S. Census, 2016). If you do not see a choice that matches your occupation, select state or national averages, or enter your own insured population characteristics.

2.3.5 Entering Insured Population Characteristics

For customized results based on your unique insured adult population's characteristics, select the "Enter insured adult population characteristics" option. When this option is selected, you will see that the fields for each characteristic have already been filled with

default values that reflect national averages for the privately insured adult population in the United States. You can change these values to reflect your own privately insured adult population characteristics. To return to the default values at any point, click the "RESTORE DEFAULTS" link in the upper right-hand corner (Figure 4). This button will clear all of the data that you have entered and restore the default data. The Data Input Checklist (see Section 3) can be used as a tool to help collect the required input data. The checklist is also available through a PDF link on the Input Dashboard page. The values entered in the insured adult population characteristics fields are used to predict the percentage of insured adults in each risk group (see Section 2.4 for more information on risk groups).

Age Breakdown

Enter the percentage of your insured adult population that is in each age group. The sum of these categories should equal 100%.

Race/Ethnicity Breakdown

Enter the percentage of your insured adult population that is in each race/ethnicity group. The sum of these categories should equal 100%. The "Other Race/Ethnicity" group includes other non-Hispanic races and non-Hispanic multiracial persons based on NHANES 2011–2014 race/ethnicity definitions.

Sex Breakdown

Enter the percentage of your insured adult population that is in each sex group. The sum of these categories should equal 100%.

Body Weight Breakdown

Enter the percentage of your insured adult population that is in each body weight group. For the purposes of this tool, include the percentage of underweight insured adults in the normal weight category. To match National DPP eligibility requirements, the BMI range for overweight is expanded beyond its typical clinical definition. The BMI ranges for each category are as follows:

- <24.0 kg/m²: Normal weight
- 24.0 kg/m²–29.9 kg/m²: Overweight²
- ≥30.0 kg/m²: Obese

² We defined overweight with a lower BMI threshold of 24.0 kg/m² to match CDC criteria for participation in the National DPP (CDC, 2015b). State and national estimates use a lower BMI threshold (22.0 kg/m²) for Asian participants in the National DPP (CDC, 2015b); however, the "Enter employee characteristics" does not account for different BMI thresholds by race/ethnicity. This may have a small downward effect on the number of projected participants when a substantial share of the employee population is Asian.

Only overweight and obese employees are eligible for participation. The sum of the three body weight categories should be 100%.

2.4 Risk Group to Participate in Program

After defining your population characteristics, based on one of the predefined populations or your own data, select a risk group to participate in the program. Using the radio buttons under the "Risk Group to Participate in Program" heading, you can select from the three risk groups eligible for the National DPP. The annual probability of developing diabetes is different for each risk group. The default annual probability for each risk group is prepopulated in the input box. You can change this number if you would like to assume a higher or lower probability of diabetes. We recommend using the default annual probabilities of diabetes unless you have (1) read this section of the technical report and (2) generated inputs from your own data sources or identified updated data available in the scientific literature.

2.4.1 Persons with Prediabetes

This group includes persons predicted to have prediabetes (and BMI \geq 24 kg/m²). "Persons with prediabetes" have a blood sugar level higher than normal, but not high enough for a diagnosis of diabetes (FPG 100–125 mg/dl or A1C 5.7%–6.4%). The default annual probability of diabetes for persons with prediabetes is 3.8%.

This risk category is the default value for the Impact Toolkit because the American Diabetes Association (ADA) and other organizations recommend that persons with prediabetes be referred to an intensive diet and physical activity behavioral counseling program (ADA, 2016). The National DPP is an example of such a program.

2.4.2 Persons with Prediabetes and Other Persons at Risk for Type 2 Diabetes

This is the largest group, as it includes all "Persons with prediabetes" and "other persons at risk for type 2 diabetes" who have BMI \geq 24 kg/m². This group is generally about 1.5 times larger than the risk group of persons with prediabetes. "Other persons at risk for type 2 diabetes" were defined using criteria from the CDC Prediabetes Screening Test (CDC, 2015). A score of 9 or higher on the Prediabetes Screening Test determines whether a person is at risk for prediabetes. Because this group includes a broader range of persons at risk for diabetes, the default annual probability of diabetes is slightly lower at 3.6%.

2.4.3 Persons with High-Risk Prediabetes

This group is a subset of the group with prediabetes. This group is the smallest (about 34% of the prediabetes group), but it represents those with the highest risk of progressing to diabetes. "Persons with high-risk prediabetes" are defined as persons with an A1C between 6.0% and 6.4% (Selvin et al., 2010) or an FPG between 110 and 125 mg/dl (Nichols et al.,

2010). This risk group has the highest annual probability of diabetes, with a default value of 6.2%. See Section 2.4 of the Technical Report for more information on how thresholds and annual probabilities were determined for each risk group.

2.5 Additional Impact Toolkit Inputs

After selecting your population characteristics and risk group, you can customize additional inputs by clicking on the "CUSTOMIZE FURTHER" button (Figure 5). For these additional inputs, we recommend beginning with "Screening" in the left column and ending with "Medical Costs" in the right column (your choice of screening options will affect subsequent input choice). In other words, read through and customize the inputs as if you were reading a newspaper. First go down the left column, and then go down the right column (note: depending on the browser window or device you are using to view the Impact Toolkit, input fields may appear in a different number of columns).

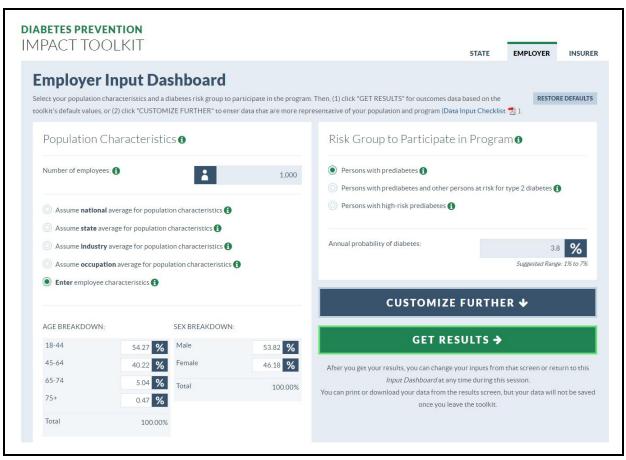


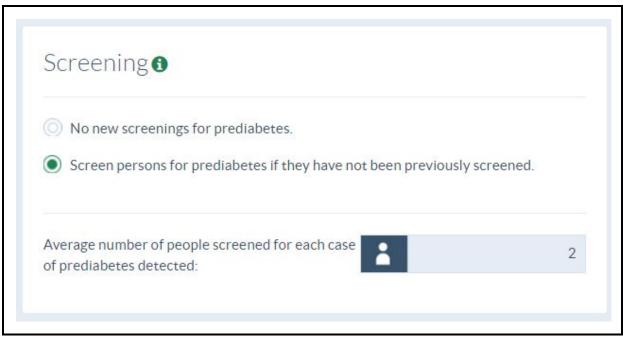
Figure 5. Accessing Additional Modifiable Inputs Using the "CUSTOMIZE FURTHER" Button

Although everyone in your population can be recruited and screened for the National DPP, only a minority of this target population will actually be eligible and willing to participate in the program. If they do participate, they are assumed to benefit from weight loss, diabetes risk reduction, and medical cost reduction associated with this prevention program. In Sections 2.5.1 through 2.5.7, we describe all assumptions related to providing the National DPP in your population. In Section 3, we describe how to interpret the costs and benefits realized by offering this program, as reported in the Output Dashboard.

2.5.1 Screening

In the Screening section, you can choose if you would like to screen potential participants for prediabetes, if they have not already been screened (Figure 6). The default setting for the Impact Toolkit assumes that 46% of your population has undergone screening recently (see Section 2.5.2) and knows their prediabetes status (although this assumption can be altered in the "Program Enrollment and Participation" [see Section 2.5.2]). If you choose to conduct screening for unscreened persons in your population, then screening costs will be incurred (also discussed further in Section 2.5.5).





Screening costs are shown in the screening cost calculation box in the Program Costs section (the box will appear in that section if you have chosen to conduct a screening program). This box calculates the average screening cost per person as the product of the assumed screening cost (\$12.50 in the default setting) and the average number of people

screened per case detected (two in the default setting). This calculation allows us to account for the costs of negative screenings in the overall program costs. For further details on program cost calculations, see Section 2.5.5 on program costs. To assume a different number of people screened for the average screening cost calculation, edit the number in the box for "Average number of people screened for each case of prediabetes detected." An increase in this number would reflect an unscreened population with a lower prevalence of prediabetes, whereas a decrease would reflect an unscreened population with a higher prevalence of diabetes. If you are not sure about the underlying prevalence in your unscreened population, then we recommend using the default setting of two people screened per case detected. This reflects a prevalence of prediabetes of about 50% among unscreened people that agree to participate in a screening program. To our knowledge, there are no extant data on the prevalence of prediabetes among people who participate in a screening program. Although the typical prevalence of prediabetes is lower than 50%, we assumed that it would be higher among a self-selected group of screening participants (i.e., people are more likely to agree to screening if they have risk factors for prediabetes).

2.5.2 Program Enrollment and Participation

In this section, you can enter the percentage of eligible participants that have already been screened for prediabetes (Figure 7). The default setting is 46%, which is based on the percentage of people at risk for diabetes who have been screened in the past 3 years (Bullard et al., 2015; Kiefer et al., 2015). People at risk for diabetes include adults aged 45 or older or those with physical inactivity, family histories of diabetes, high blood pressure, and other risk factors per the ADA (ADA, 2016) and U.S. Preventive Services Task Force (Calonge et al., 2008) criteria for screening for type 2 diabetes. Other analyses have shown that only about 11% of persons with prediabetes in 2010 were both screened and aware of their disease status (CDC, 2013). This 11% value can be entered as an alternative to the default value of 46%.

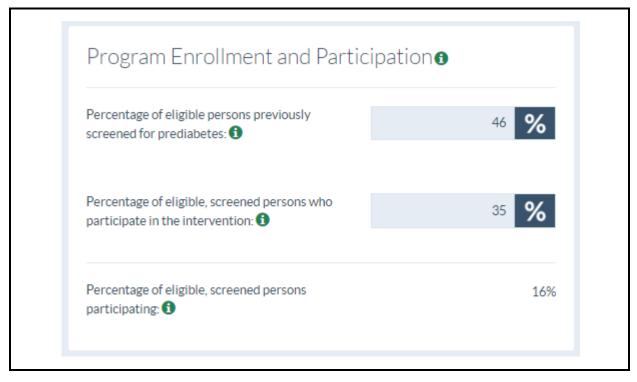


Figure 7. Program Enrollment and Participation Inputs in the Impact Toolkit

If you have chosen to conduct additional screening for your program, then you can also input the "percentage of eligible, previously unscreened persons receiving screening" (the entry field for this input will only be shown if you have chosen to conduct screening in the screening section). The default value is 100%, which assumes that all persons with a BMI ≥24 who have not been screened will receive screening. You can adjust this value downward as appropriate for your population.

Next, you enter your assumed participation rate. The default setting for the participation rate is 35%, which is based on the participation rate in a demonstration of the National DPP with large employers (R. Li, R. Ackermann, personal communication, June 22, 2015). The participation rate might be higher or lower for your population based on the incentives offered for participating or the perceived benefits of participation.

In the final field shown in this section, the program enrollment and participation inputs are used to determine the total percentage of participation among *eligible* adults. The Impact Toolkit calculates this value automatically. For example, if 46% of eligible adults have previously been screened, no additional screening occurs (the default value), and the participation rate is 35%, then the total percentage of eligible adults participating will be 16% (46% x 35%=16%). This percentage is then applied to the predicted prevalence of the selected risk group to get the percentage of projected participants. For example, in the

default setting, the predicted prevalence of "persons with prediabetes" is 29% in the national sample. Thus, $29\% \times 16\% = 4.7\%$ of the total population that will participate in the National DPP if no additional screenings are conducted. However, in a scenario where a screening program is conducted to identify additional eligible persons, the calculation is somewhat more complex (see Equation 1).

Equation 1. Percentage of Screened Population Who Participate in the Intervention

Percentage of screened population who participate in the intervention		% of population previously screened for prediabetes x % of screened persons participating in intervention + [(100% – % of population previously screened for prediabetes) x % of previously unscreened persons receiving screening x % of screened persons participating in intervention]
---	--	--

Similar to the example with no additional screenings, the percentage from Equation 1 (which is used when there are additional screenings) is applied to the predicted prevalence of the selected risk group (e.g., 29% for "persons with prediabetes" in the national sample) to get the percentage of projected participants. For example, if the "% of previously unscreened persons receiving screening" is 100%, then we would calculate the percentage of projected participants as 29% x (46% x 35%) + [(100% – 46%) x100% x 35%], which equals 16% of the total population that will participate in the National DPP if additional screenings are conducted on 100% of the previously unscreened population.

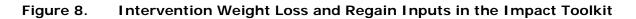
2.5.3 Intervention Weight Loss and Regain Schedule

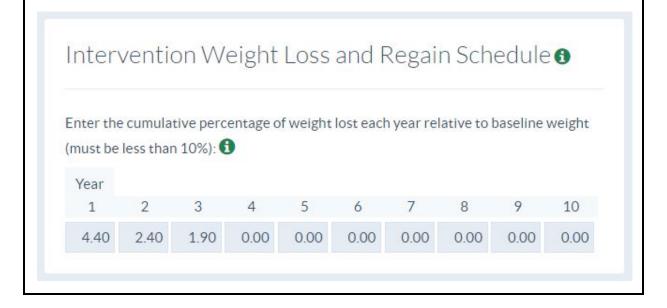
The DPP trial demonstrated that participants in an intensive lifestyle intervention lost about 7.2% of their weight in the first year of the program (Hamman et al., 2006; Knowler et al., 2002). Real-world adaptations of the DPP trial, such as the National DPP, resulted in a smaller weight loss, 4.4% on average at the end of the first year of follow-up (R. Li, personal communication, June 24, 2015). This estimate is based on results from the National DPP and represents the first year weight loss for program participants and is supported by other studies.³ A participant was defined as someone attending at least 4 of the 16 program sessions. Attending at least 9 sessions was associated with a slightly higher weight loss (5.1%) (R. Li, personal communication, June 24, 2015).

The DPP trial and studies of real-world interventions with additional years of follow-up show that the initial weight lost is regained in future years. Based on data from these studies, we assume that about 50% of the weight lost is regained in Year 2, and another 20% is regained in Year 3 (Barte et al., 2010) (Figure 8). In Years 4 through 10, we assume that all

³ In 2012, Ali et al. (2012) reported a 4.1% weight loss at 12-month follow-up for translational programs conducted in the United States and modeled on the Diabetes Prevention Program (DPP) trial's lifestyle intervention.

the weight lost has been regained (0% weight loss relative to baseline weight). These weight loss and regain assumptions are based on group-based type 2 diabetes prevention lifestyle change programs with a minimum of 16 sessions over the first 6 months. A minimum of 6 sessions must be offered in the second 6 months of the program to achieve full recognition status per the criteria set forth by CDC (CDC, 2015b). Although these default settings are based on the best available data for the average National DPP participant, your population and program may differ from the average. You can modify these weight loss and regain assumptions according to the expectations for your program. We limit weight loss to a maximum of 10%; weight loss higher than 10% would lead to results with low credibility under the current model assumptions.





2.5.4 Program Budget

In the default setting, the Impact Toolkit assumes that a state, employer, or insurer will offer the program to all eligible persons who want to participate. However, if the budget is limited for implementing a National DPP lifestyle change program, then you can check the box in this section to set a maximum budget. Once you have checked this box, an additional entry field will appear for you to enter your maximum budget (Figure 9). This budget you enter will limit the number of program participants based on the size of your eligible population, your program costs, and your screening costs (if you choose to screen previously unscreened persons).

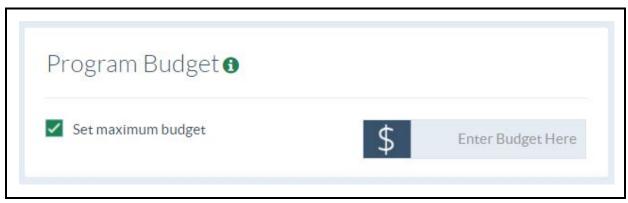


Figure 9. Program Budget Input in the Impact Toolkit

2.5.5 Program Costs

Here you can enter the per person costs of your program. The default cost of \$417 (2013 U.S. dollars) is the per-participant cost of a group-based National DPP lifestyle change program without screening costs included (Li et al., 2015). All costs in this section should be calculated and entered per participant. If you are conducting a screening program (i.e., selected "Screen persons for prediabetes if they have not been previously screened" in the screening section), then this section will also show an "Average Screening Cost Calculation" box. Here, we assume that screening costs are \$12.50 in the default setting. Either the FPG test (\$7.22) or the hemoglobin A1c test (\$17.85) can be used to diagnose prediabetes, so we assume the average cost (\$12.50) of these two tests according to the 2015 Medicare Laboratory Fee Schedule (CMS, 2016a) (Figure 10).

If you do not plan to use one of these tests or believe that your screening costs differ from these estimates, then the screening test costs can be modified in this section. If you plan to use the CDC Prediabetes Screening Test (CDC, 2015) (a questionnaire that can also be used to determine eligibility for the National DPP) to identify potential participants, then your costs may be lower than either of the blood test costs (e.g., the cost of printing and distributing self-administered questionnaires). We also assume that there are "Other screening costs," which include the cost of a brief follow-up visit to discuss the patient's screening test results and receive a referral to a program such as the National DPP. The default cost of \$20 for "Other screening costs" only includes the cost of a brief office visit and not the costs of recruitment for screening. "Other screening costs" are based on the 2015 Medicare Physician Fee Schedule (CMS, 2016b) associated with an evaluation and management visit of low complexity (HCPCS Code 99211) for an established patient (about 5 minutes of face-to-face time at the cost of \$20.02). The average total screening costs per participant are shown in the "Average Screening Cost Calculation" section shown in Figure 10. In the default scenario, the average screening costs total \$65 per participant. This total accounts for the screening test cost (lab costs of \$12.50 in the default), other screening

costs (physician time of \$20 in default), and the cost of negative screenings (number screened per case detected equals 2 in the default). For more information on these assumptions and how the screening costs are calculated, see Section 2.5.5 of the Technical Report. This cost can be adjusted to reflect a more intensive screening program with recruitment costs. All screening costs are included in the overall program costs that are used to calculate net costs and other results in the Output Dashboard.

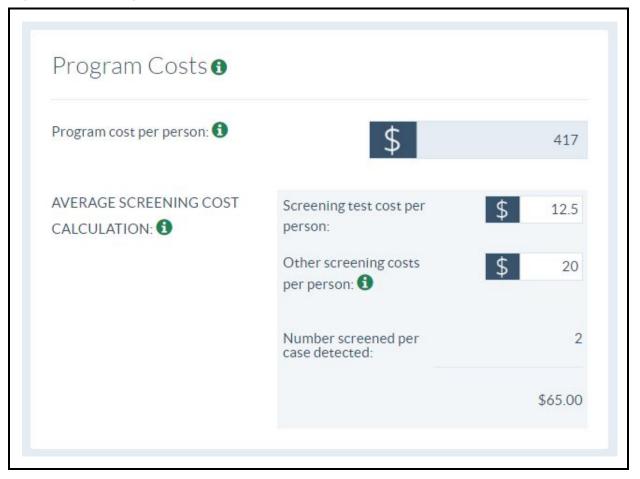


Figure 10. Program Cost Inputs in the Impact Toolkit

2.5.6 Medical Costs

In the year that a person is diagnosed with diabetes, he or she will have substantial medical costs associated with diagnosing and treating their diabetes. In each subsequent year, the person will continue to have medical costs for the treatment of his or her disease, although not as great as the initial year of diagnosis. These are sometimes called diabetesattributable medical costs, and they are defined as the excess medical costs for a person with diabetes compared with a similar person without diabetes. The default values that are provided in the Impact Toolkit reflect the average excess medical costs for persons with diabetes based on a CDC analysis of longitudinal medical claims data from MarketScan (2001–2013) (Shrestha et al., 2016). Based on these data and a review of other cost analyses, we assumed default values of \$6,424 for the first year of diagnosis and \$3,900 for the years after diagnosis (2013 U.S. dollars) (Figure 11). First year costs are approximately 1.65 times greater than subsequent year costs. If you believe that excess medical costs associated with diabetes differ in your population, we suggest maintaining this approximate relationship between the first year costs and the subsequent year costs. We also suggest staying within the suggested range of \$3,300 to \$9,900 for first year costs and \$2,000 to \$6,000 for subsequent year costs. Using excess medical cost estimates outside of these ranges may lead to results with low credibility in the 10-year outcomes projected by the Impact Toolkit. Diabetes-attributable costs in the Impact Toolkit are associated with the first 10 years of costs for a newly diagnosed case of diabetes (Srestha et al., 2016). Medical costs after the first 10 years may be higher.



Figure 11. Medical Cost Inputs in the Impact Toolkit

In the Impact Toolkit, all costs incurred in the future are discounted back to the present using a discount rate assumed in the Medical Cost section of the Input Dashboard. The discount rate input box allows us to account for the fact that the money we have today has more value than money received in the future. This accounts for future inflation, lost investment opportunity, and risk. Applying this discount value allows us to more accurately compare the money that will be spent in the future with the money that is spent today. An annual discount rate of 1.0% to 5.0% is commonly used. Our default value is 3.0%.

2.5.7 Productivity Costs (Employer Module Only)

In the Employer module only, we include productivity costs associated with diabetes. We limit productivity costs to the costs of days of work missed due to diabetes and the value of these days. The value of the days of work missed (per person) is calculated by multiplying the "Days of work missed per year due to diabetes" and the "Daily earnings for persons with diabetes." Days of work missed per year due to diabetes are the excess days of work missed by someone with diabetes compared with a similar person without diabetes (e.g., similar age, sex, comorbidities).

We found that, on average, a person with diabetes will miss 3.3 more days of work each year compared with a similar person without diabetes. The default daily earnings of \$276 was calculated based on wage data from the 2014 Current Population Survey (CPS) (Figure 12). See Section 2.5.7 of the Technical Report for more detail on how default estimates were obtained.

Figure 12. Productivity Cost Inputs in the Impact Toolkit (Employer Module Only)

Productivity Costs ()	
Days of work missed per year due to diabetes 🕄	3.30
Daily earnings for employees 🕄	276

After filling in all the fields discussed in Sections 2.1 through 2.5, click "GET RESULTS" to view your customized results in the Output Dashboard. See Section 3 for information about calculations made in the Output Dashboard and how to interpret results.

3. OUTPUT DASHBOARD

The results in the Output Dashboard are unique to your data inputs. They predict the health and economic outcomes for your program participants as a result of implementing the National DPP lifestyle change program. The results include a set of seven figures and two tables. Each figure has an associated data table that can be viewed by clicking on the "SHOW DATA TABLE" bar below each figure. The data tables include all the data shown in the figure and, in some cases, show additional data not directly used in the figure. The data tables also contain footnotes for some of the data elements that may be helpful. In general, reading the tooltips (green circle with an "i") next to each figure title will provide you with the most relevant information for reading and interpreting the figure. This User Manual and the Technical Report provide further detail as well. To focus on just a few key figures, use the "X" in the upper right-hand corner of each figure to temporarily hide that figure. To restore all the figures, just click "RESTORE RESULTS" in the upper right-hand corner of the Output Dashboard.

3.1 Projected Participants

Figure 13 shows how the projected number of participants is calculated from the total population. The total adult population being considered for the National DPP is shown in the top bar in the figure. This is determined by the total adult population in your state (State module), the number of employees at your company (Employer module), or the number of insured adults (Insurer module). In the second bar from the top, a subset of the total population is projected to be eligible for the intervention based on (1) the assumed population characteristics (Sections 2.1 through 2.3) and (2) the risk group selected in the Input Dashboard (Section 2.4). Next, some or all (depending on your screening inputs, see Sections 2.5.1 and 2.5.2) of the eligible persons have been previously or newly screened, confirming their eligibility for the intervention (shown in the third bar from the top). Among the eligible, screened persons, some or all (depending on your participation inputs, see Section 2.5.2) will participate in the intervention. The predicted number of participants is shown in the bottom bar of this figure. This number is calculated by the Impact Toolkit.

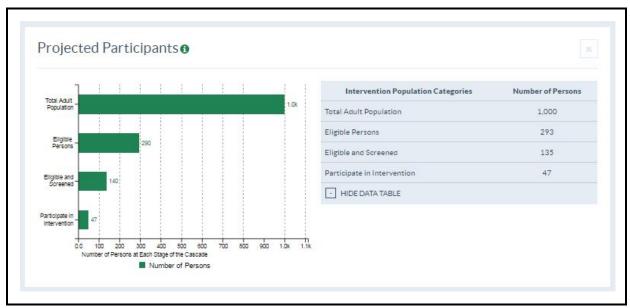


Figure 13. Projected Number of Participants

3.2 Cumulative Projected Cases of Diabetes and Cumulative Years with Diabetes Averted

The chart on the left of Figure 14 shows the effect of the National DPP lifestyle change program on new cases of type 2 diabetes. Specifically, it shows the cumulative number of diabetes cases with and without the National DPP intervention for your population of participants (the projected number of participants is reported in the heading for the chart). The gray line estimates the number of new diabetes cases without the National DPP. The green line represents the number of new diabetes cases with the National DPP. The difference between the two lines represents the cases of diabetes averted at a given point in time. The maximum number of "Cases Averted" in a single year will usually occur in the last year assumed to have some weight loss effect (Year 3 in the default setting). In the chart on the right in Figure 14, the cumulative years with diabetes averted is shown for your population of participants (the projected number of participants is also reported in the heading for this chart). The cumulative years with diabetes averted (by the National DPP lifestyle change program) is the cumulative calculation of the cases averted in each year. Clicking on the "SHOW DATA TABLE" button will open up a table with more information. The table shows the number of "Cases Averted" in each year as well as the "Years of Diabetes Averted."

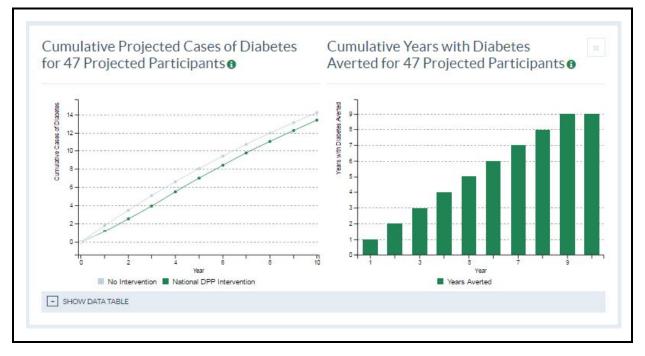


Figure 14. Cumulative Projected Cases of Diabetes

3.3 Cumulative Medical Costs per Participant

Figure 15 shows the difference in cumulative medical costs with and without the National DPP intervention. Results are displayed per participant and can be easily scaled up by multiplying results by your number of participants. The gray bar on the left indicates the cumulative medical costs without the National DPP, and the green bar on the right indicates the cumulative medical costs with participation in the National DPP. The cumulative medical cost savings is the difference between these amounts. Click on the "SHOW DATA TABLE" button to see more detailed information.

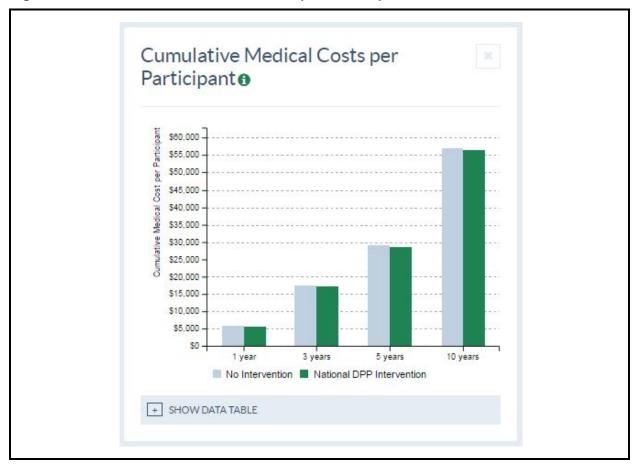


Figure 15. Cumulative Medical Costs per Participant

Results in this figure are largely affected by the medical cost assumptions (Section 2.5.6), the assumed annual probability of developing diabetes for your risk group, and the assumed weight loss effects. Even when the excess medical costs of diabetes are assumed to be large (e.g., \$6,425 in the year of diagnosis and \$3,900 in subsequent years in the default setting), the *average* difference in medical costs can be fairly small. This is due to the fact that (1) only a fraction of participants develop diabetes each year (e.g., 3.8% each year in the default setting for persons with prediabetes), and (2) only a fraction of the projected cases of diabetes are averted among participants (this will depend on the weight loss/regain assumptions).

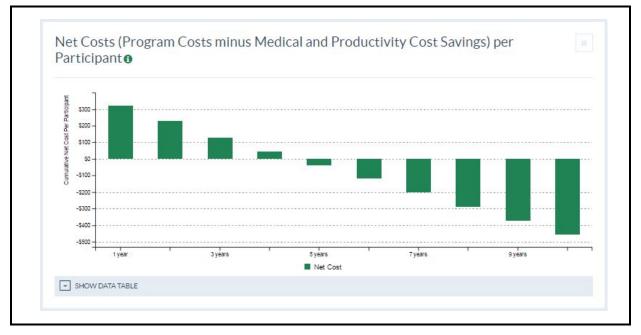
3.4 Net Costs (Program Costs minus Medical Cost Savings) per Participant

Figure 16 uses the cumulative medical costs (Section 3.3) and the cumulative program costs (Section 2.5.2) to generate the cumulative net cost per participant. In the Employer module, productivity costs are also included. In each year, the cumulative medical cost

savings (and productivity cost-savings in the Employer module) are subtracted from the cumulative program cost to produce the cumulative net cost in that year. Results are displayed per participant and can be easily scaled up by multiplying results by your number of participants.

In general, the cumulative net costs decrease over time, so that by Year 10 or sooner, there may be negative cumulative net costs, indicating that the program is cost-saving. Net costs fall because the program cost is only paid once, in Year 1, whereas medical cost savings as a result of program participation occur each year. The net cost calculation is most sensitive to your assumptions regarding the program cost, the weight loss/regain, and the medical costs. Click on the "SHOW DATA TABLE" button to see more information. It should be noted that net costs only include medical and program costs and do not otherwise reflect the health benefits to participants.

Figure 16. Net Costs (Program Costs minus Medical and Productivity Cost Savings) per Participant



3.4.1 Productivity Costs in the Employer Module

In the Employer module, productivity cost-savings are calculated in addition to medical cost-savings. In the net costs figure (see Figure 16), these productivity cost-savings are also subtracted from the overall program costs in each period to get the net costs. For each new case of diabetes, a number of days of work are missed each year due to diabetes (3.3 days in the default setting; see Section 2.5.6). Each day is valued by the average wages assumed for your employee population (\$276 per day in the default setting). For example,

in the default setting, about \$911 in productivity costs are incurred each year for everyone that has developed diabetes in that cycle or a previous cycle. Click on the "SHOW DATA TABLE" button to see the detailed 10year data in the Impact Toolkit.

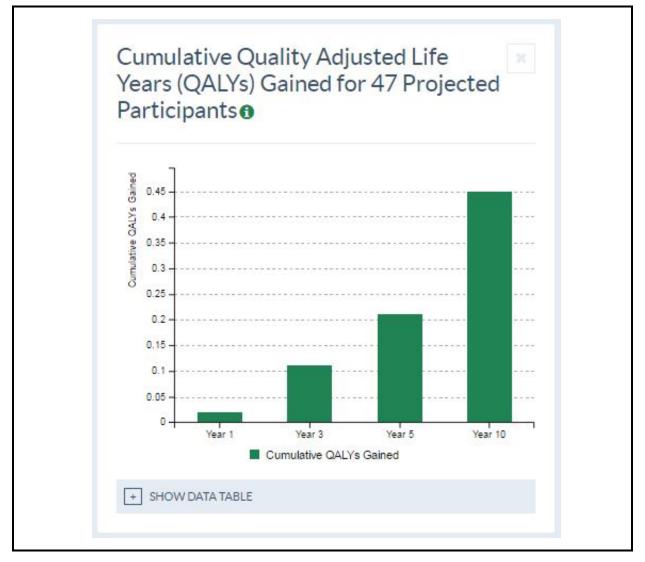
3.5 Cumulative Quality Adjusted Life Years (QALYs) Gained

Figure 17 shows the cumulative quality-adjusted life years (QALYs) gained for your population of participants (the projected number of participants is reported in the heading). QALYs are a combined measure of health and time, allowing us to weight years lived by the health-related quality of life in those years. One QALY is equal to 1 year of life with a perfect quality of life.

When a person develops diabetes, we assume that their quality of life is reduced by about 5%, on average. The estimate of a 5% reduction in quality of life is based on the quality of life decrement associated with progressing from prediabetes to diabetes in the CDC/RTI model of diabetes.⁴ This reduction in quality of life is averted or delayed with each case of diabetes that is averted or delayed (due to the National DPP lifestyle change program). The cumulative QALYs gained (shown in Figure 17) account for averting the reduction in quality of life associated with diabetes as well as the timing of when cases are averted. For instance, if weight losses are maintained throughout the whole 10-year period, then cases of diabetes will be delayed for a longer amount of time and QALY gains will be greater. If weight losses are quickly regained, then these cases of diabetes are not delayed as long and not as many QALYs will be gained.

⁴ A quality of life decrement of 0.04 relative to a baseline utility of 0.84 for persons without diabetes represents about a 5% decrease in quality of life.





3.6 Incremental Cost-Effectiveness Ratio (ICER)

Figure 18 shows the annual net costs per participant, QALYs gained per participant, the Incremental Cost-Effectiveness Ratio (ICER) (net costs divided by QALYs gained), and the Cost per Case Averted (cumulative cases averted or "Years of Diabetes Averted" divided by the Net Costs). The ICER is a measure of the cost-effectiveness or "return on investment" associated with an intervention. It is calculated as the cumulative net costs divided by the cumulative QALYs gained. A lower ICER is better as it indicates that QALYs are gained from the intervention at a lower cost. A negative ICER indicates that the intervention is associated with QALY gains and reduced costs (i.e., a cost-saving intervention). Negative ICERs are shown in Figure 18 as "Cost-saving."

The Cost per Case Averted is found by dividing the cumulative cases averted (as seen in "Cumulative Projected Cases of Diabetes" figure) by the cumulative net cost. A negative cost per case averted means that the program is cost saving by that point in time. Negative costs per case averted are shown in Figure 18 as "Cost-saving."

Figure 18. Incremental Cost-Effectiveness Ratio (ICER)

3.7 Cumulative Years of Life Gained

Developing diabetes is associated with an increased risk of life-threatening events, such as heart attack and stroke. We assumed that persons with diabetes have twice the risk of dying in a given year compared with persons without diabetes, on average (Geiss et al., 1995). When cases of diabetes are averted or delayed (due to the intervention), a small

decrease in the number of diabetes-related deaths is achieved. These deaths averted are associated with a gain in the years of life lived during the 10-year period.

Figure 19 shows the cumulative years of life gained for your participant population as a result of participation in the National DPP (the projected number of participants is reported in the heading). These years of life gained do not account for the quality of life with diabetes as in the QALYs gained figure. Click on the "SHOW DATA TABLE" button to see more information. Results are calculated dynamically in the Output Dashboard and are often rounded to accommodate the best display of the results given the space restrictions. To view the unrounded results, download your results in Microsoft Excel using the green button in the upper right-hand corner of the Output Dashboard (see Section 4.2).

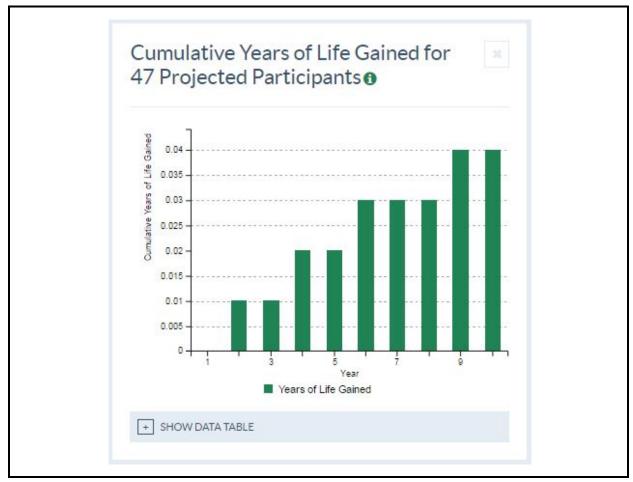


Figure 19. Cumulative Years of Life Gained

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4. EXPORTING RESULTS FROM THE IMPACT TOOLKIT

4.1 Printing Results to a PDF

To print results to a PDF, click the green "PDF" icon at the top of the Output Dashboard. This will generate a report of your customized results, including all figures (even figures that may have been discarded using the "X" in the upper right-hand corner of each output figure). The report will be downloaded to your computer. Open the report and print it or save it to the appropriate location on your computer.

4.2 Exporting Results to Excel

To generate an Excel workbook with your results data, click the green "XLSX" icon at the top of the Output Dashboard. The report will be downloaded to your computer. Open the report and save it to the appropriate location on your computer.

The first tab in the workbook is "User Inputs." This tab displays all default input values, as well as the values used in your analysis. The subsequent tabs each correspond to the output figures described in Sections 3.1 through 3.7. These tabs contain the data used to create the graphs, but they do not include the figures. This format allows you to create customized graphs and perform additional analyses. Also, downloading your results in Excel allows you to see all results *without* rounding. Because results are calculated dynamically in the Output Dashboard, they are sometimes rounded to accommodate the best display of the results given the space restrictions.

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5. COMPARING SCENARIOS IN THE IMPACT TOOLKIT

The Impact Toolkit has the ability to calculate health and economic projections for any combination of the more than 20 user-modifiable inputs. If you are projecting the health and economic impacts of a National DPP for your state, employee, or insured population, then you may be interested in testing the sensitivity of these impacts to changing inputs, such as program costs. Other key inputs that may differ in your population and program include the weight loss and regain schedule, the use of a screening program, and the percentage of eligible, screened persons that participate.

There are several ways to compare scenarios in the Impact Toolkit. Choose the method that best fits your needs:

- 1. Use the panel of Selected Inputs to modify input values while viewing results in the Output Dashboard.
 - a. In this method, the panel of Selected Inputs is populated with your current input values. By changing them and clicking "MODIFY," you can instantly view the recalculated results in the Output Dashboard. This approach is suitable for comparing individual outcomes, such as the net cost in Year 3; however, if you are comparing multiple outcomes, it is difficult to recall more than one number from the previous results.
- 2. Output your initial results to a pdf or Excel workbook. Modify inputs using the panel or the full Input Dashboard, get new results, and output the new results to a pdf or Excel workbook for comparison.
 - a. This method for comparing scenarios is more time-consuming; however, it allows for a more detailed comparison of results across all the outcomes projected by the Impact Toolkit. Generating a pdf will provide you with a report containing all the figures and tables generated in the Output Dashboard. In contrast, the Excel workbook only contains the tables from the Output Dashboard. If you are proficient with Excel, then more sophisticated comparisons and figures can be generated using Output from multiple scenarios.
- 3. Open two browser windows or tabs, and generate two sets of results to view.
 - a. This method is convenient and allows you to compare multiple results simultaneously by switching between windows or tabs. The Input Dashboard will only remember one set of inputs (the last set of inputs used) if you return to it to generate another scenario. Note: Different browsers may have different settings for saving previously entered data, such as Input values in the Impact Toolkit.

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