SPECIAL DIABETES PROGRAM FOR INDIANS

DEMONSTRATION PROJECTS / INITIATIVES

DIABETES PREVENTION PROGRAM

FINAL DATA REPORT

Prepared by the SDPI Coordinating Center

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I. EXECUTIVE SUMMARY

Participant Accrual and Data Submission: The Special Diabetes Program for Indians (SDPI) Diabetes Prevention (DP) Programs began enrolling American Indian and Alaska native adults with pre-diabetes in January 2006 and submitted data to the Coordinating Center through July 2016. Assessments were completed at baseline, after completing the 16-session DP curriculum (referred to as the follow-up assessment), and annually on approximately the yearly anniversary of the first attended DP class. In addition, mid-year glycemic measurements were obtained between the annual assessments. Since recruitment was ongoing, the Coordinating Center received up to 10 ½ years of data on participants who enrolled early in the program and remained active, whereas data received from participants who enrolled later in the program may only include the baseline assessment. The Coordinating Center received baseline assessments for 8,652 eligible participants. Follow-Up assessments were obtained on 65% (5,639) of the enrolled participants. There were 12,499 submitted annual assessments for years 1 through 10, and 10,456 submitted mid-year glycemic measurements through Year 10½. Not surprisingly, programs with a larger user population size recruited more participants on average than programs with smaller user populations.

Attendance and Retention: The 8,652 DP participants attended a combined total of 108,455 DP classes. Individual lifestyle coaching was offered both during and after a participant was attending the DP curriculum sessions; DP participants attended 103,970 one-on-one lifestyle coaching visits. In addition to individual lifestyle coaching, programs offered their participants a wide variety of supplemental activities after the DP curriculum in an effort to reinforce the curriculum lessons, referred to as After-Core; combined DP attendance at these After-Core activities was 47,155. Participant retention was a struggle for most programs, with 35% of participants not returning for the follow-up assessment and 67% attrition of enrolled participants by Year 5. The most common reasons reported for participants becoming inactive were scheduling difficulties and unable to contact.

Assessment Data: More female (75%) than male (25%) participants enrolled in the program, and the average age of participants was 47.1 years old. At baseline, the average Body Mass Index (BMI) was 35.9, and 30% of participants reported they were already engaging in an active level of aerobic physical activity – at least 150 minutes of *moderate* physical activity per week or at least 60 minutes of *vigorous* physical activity per week.

Seven percent of DP participants were diagnosed with diabetes during the DP Program. Females were less likely to convert to diabetes than males, and participants who attended all 16 classes and had at least six lifestyle coaching visits in the first year were also less likely to convert to diabetes. In addition, participants who lost a greater percentage of their body weight by the follow-up assessment were less likely to convert to diabetes.

A summary of important DP outcomes at the baseline, follow-up, and annual assessments is provided in Table E.01. This table summarizes the measured outcomes for all participants who have completed an assessment at any time point (unpaired data), thus presenting results as comprehensively as possible. Readers are cautioned against inferring trends over time in all tables with unpaired data.

Table E.02 presents changes in important DP outcomes from baseline to follow-up and from baseline to annual assessments years 1 through 10 (paired data). Participants for whom change cannot be calculated due to a missing assessment or data item are excluded. For most outcomes, median changes are reported (rather than mean changes) due to the potential for misleading effects of extreme changes. An exception was made for weight loss, where the mean percent change in weight from baseline is reported. The weight loss goal was defined by percent change in weight, and reporting the mean percent change in weight facilitates comparisons with previous reports and other interventions. At the follow-up assessment the mean weight loss was 3.8% of baseline weight, but the percentage of weight loss maintained decreased after the follow-up assessment. **The majority of participants had small but consistent improvements in weight, BMI, LDL, HDL, triglycerides, total cholesterol, blood glucose, physical activity and dietary habits at most time points, but waist and blood pressure did not show consistent improvement.**

A fact sheet summarizing the SDPI Diabetes Prevention Program follows Table E.02.

Comparison with National DPP Requirements: In 2015 the Centers for Disease Control and Prevention launched the Diabetes Prevention Recognition Program, referred to as the National DPP, in 2015. Although there are differences in the program design and evaluation, the intervention offered by the SDPI Diabetes Prevention Program was similar to that required by the National DPP, and the SDPI Diabetes Prevention Program would have met the National DPP standards for curriculum, intervention duration and intensity, session attendance and participant eligibility. However, although 36% of the SDPI Diabetes Prevention Program participants lost 5% or more of their baseline weight at follow-up and 31% lost 5% or more of their baseline weight at Year 1, the mean weight loss among SDPI Diabetes Prevention Program participants was less than the National DPP standard of 5% weight loss at 6 months and 12 months.

Table E.01: Summary of SDPI DP Program Outcomes at Each Assessment (Unpaired Data)

Outcome	Baseline (N=8652)	Follow-up (N=5639)	1st Annual (N=3903)	2nd Annual (N=2616)	3rd Annual (N=1885)	4th Annual (N=1343)	5th Annual (N=918)	6th Annual (N=661)	7th Annual (N=518)	8th Annual (N=357)	9th Annual (N=212)	10th Annual (N=86)
Weight (pounds)	218.5	208.7	208.6	209.2	209.5	206.1	205.4	203.2	205.5	203.3	200.1	200.4
Body Mass Index (BMI)	35.9	34.4	34.5	34.6	34.7	34.2	34.2	34.0	34.3	34.1	33.9	33.5
Waist (inches)	44.4	42.6	42.6	42.8	43.0	42.7	42.7	42.6	42.8	42.6	42.6	42.8
Systolic BP (mm Hg)	126.7	125.3	126.1	126.9	127.6	127.6	127.7	128.1	128.8	127.5	128.1	128.5
Diastolic BP (mm Hg)	78.5	77.5	77.6	77.8	77.9	77.9	77.8	77.6	77.3	76.0	75.7	74.2
LDL (mg/dl)	109.9	106.9	107.7	107.4	105.9	106.6	106.4	108.2	107.7	106.6	105.0	104.7
HDL (mg/dl)	46.1	46.8	48.2	48.6	48.6	49.7	49.7	50.3	49.7	50.7	50.3	52.7
Triglycerides (mg/dl)	156.2	146.4	149.1	150.5	149.2	147.5	143.0	144.8	142.5	138.9	139.1	133.9
Total Cholesterol (mg/dl)	183.9	180.1	183.1	183.2	181.6	183.1	182.3	184.8	182.4	181.0	179.7	180.8
Participants with Glycemic Measure in Normal Range	15%	43%	39%	38%	35%	34%	34%	36%	37%	37%	27%	25%
Participants Reporting Active Physical Activity*	30%	53%	42%	39%	39%	40%	36%	33%	32%	39%	37%	28%
Healthy Diet Score	3.5	3.8	3.7	3.7	3.7	3.7	3.7	3.7	3.8	3.7	3.6	3.7
Unhealthy Diet Score	2.9	2.4	2.5	2.6	2.6	2.6	2.7	2.7	2.7	2.7	2.6	2.8

* 30 minutes or more per day of moderate physical activities, five or more days a week; **or**
20 minutes or more per day of vigorous physical activities, three or more days a week.

Table E.02: Summary of SDPI DP Program Outcome Changes from Baseline (Paired Data)

Outcome	Follow-up (N=5639)	1st Annual (N=3903)	2nd Annual (N=2616)	3rd Annual (N=1885)	4th Annual (N=1343)	5th Annual (N=918)	6th Annual (N= 661)	7th Annual (N=518)	8th Annual (N=357)	9th Annual (N=212)	10th Annual (N=86)
Mean Percent Weight Loss (pounds)*	-3.8	-2.8	-1.9	-1.5	-1.5	-1.1	-1.1	-1.3	-1.2	-0.7	0.1
Median Change in Body Mass Index (BMI)	-1.2	-0.7	-0.5	-0.3	-0.4	-0.2	-0.2	-0.3	-0.2	0.1	0.1
Median Change in Waist (inches)	-1.5	-1.0	-0.5	-0.3	0.0	0.0	0.5	0.5	0.3	1.0	1.0
Median Change in Systolic BP (mm Hg)	-2.0	0.0	0.0	0.0	0.0	2.0	2.0	1.0	2.0	3.0	0.0
Median Change in Diastolic BP (mm Hg)	-1.0	0.0	-1.0	0.0	0.0	0.0	0.0	-1.0	-2.0	-2.0	-5.5
Median Change in LDL (mg/dl)	-3.0	-2.0	-3.0	-4.0	-3.0	-4.0	-3.8	-5.0	-6.0	-6.0	-6.3
Median Change in HDL (mg/dl)	0.0	1.9	1.0	2.0	2.0	2.0	3.0	2.0	3.0	3.0	5.0
Median Change in Triglycerides (mg/dl)	-7.0	-6.0	-5.0	-3.0	-4.0	-8.0	-8.0	-6.0	-9.0	-3.5	0.0
Median Change in Total Cholesterol (mg/dl)	-4.0	-2.0	-3.0	-3.0	-3.0	-3.0	-4.0	-3.5	-6.0	-6.0	-3.0
Change in % Glycemic Measure in Normal Range	28.0	24.0	21.9	20.2	19.9	18.9	21.8	24.5	24.8	14.6	18.8
Change in % Physically Active	22.6	10.4	8.5	4.9	6.0	2.3	0.7	-0.7	7.9	2.9	-4.9
Median Change in Healthy Diet Score	0.3	0.2	0.2	0.2	0.2	0.3	0.3	0.3	0.2	0.2	0.4
Median Change in Unhealthy Diet Score	-0.5	-0.3	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2	-0.2	-0.1

* The change in weight is presented as the mean rather than the median because the weight loss goal is defined by percent change in weight, and reporting the mean percent change in weight facilitates comparisons with previous reports and other interventions.

SDPI DIABETES PREVENTION PROGRAM

Special Diabetes Program for Indians

Diabetes Prevention Program

GOAL:

Prevention of diabetes in American Indians and Alaska Natives with pre-diabetes through changes in lifestyle behaviors

8,652

Participants enrolled:

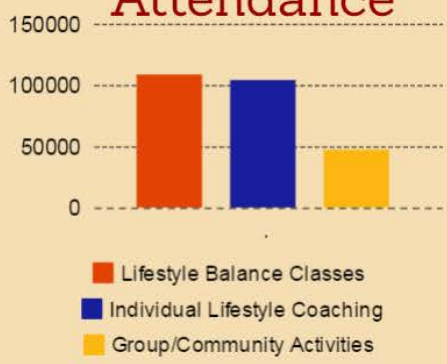
American Indian and Alaska Native adults with pre-diabetes (at high risk for developing diabetes)

Did You Know?

15.9% of American Indian/Alaska Native adults suffer from Type 2 Diabetes – the highest rate of any racial/ethnic group in the nation[1]

Weight loss and exercise can prevent or delay Type 2 diabetes[2]

Attendance



Group & Community Activities:

- Cooking classes
- Exercise activities
  - Walking
  - Biking
  - Dancing
  - Rowing
- Weight loss challenges
- Cultural activities
- Gardening

.....and much more!

48,000

Total Pounds Lost

Participants who lost more weight were less likely to develop diabetes

46 programs serving over 80 tribes across the U.S.

Participant Successes:

- Increased exercise
- Healthier diets
- Lower blood sugars
- Lipid improvements
- Slight but consistent weight loss

Participant Challenges:

- Motivation
- Making time for the program
- Meeting weight loss goals

26,790 Submitted Assessments

Program Challenges: Recruitment, retention, and no comparison group

2006 SDPI DP 2016

The SDPI DP Program was a unique translational, community-based intervention because it lasted over *10½ years*, enrolled over 8,500 participants, and **1,223 individuals** remained in the program for 5 years or more

[1]https://www.cdc.gov/diabetes/pdfs/data/2014-report-estimates-of-diabetes-and-its-burden-in-the-united-states.pdf

[2]https://www.cdc.gov/diabetes/basics/prevention.html

II. INTRODUCTION

This is the final data report for the Special Diabetes Program for Indians (SDPI) Diabetes Prevention (DP) Program. The goal of the DP Program was to prevent diabetes in American Indians and Alaska Natives with pre-diabetes through changes in lifestyle behaviors. This report summarizes a small fraction of the data which were collected on over 8,500 participants over 10½ years. The DP Program began with 36 Demonstration Projects in a formal collaborative planning process starting in October 2004, and the majority of programs began recruiting participants, implementing program activities, and submitting data to the Coordinating Center (CC) in January 2006. The DP Demonstration Projects not only implemented the diabetes prevention intervention but also collected and submitted data gathered on and from participants, potential participants, program staff, support persons, and community members. There were 20 categories of forms, 15 of which were submitted to the CC on a regular basis. These forms are referred to here as the full evaluation forms. Participant assessments were obtained at baseline (before starting the 16-session diabetes prevention curriculum, the first aspect of the intervention), after completing the curriculum, approximately one year after starting the intervention, and annually thereafter. In addition, a glycemic measure was obtained between annual assessments to verify that the participant had not developed diabetes. Beginning on August 1, 2009, in order to allow the program staff to focus their energies on providing services rather than on costly and labor-intensive data collection efforts, a shorter, more focused set of data collection forms, referred to here as the minimum dataset collection forms, was implemented (5 forms, with participant data only). Participants whose baseline assessment was on the older forms transitioned to the new forms after completing their first annual assessment. Program funding changed on September 29, 2010, and the 9 new programs who joined the SDPI DP Program effort and the 28 programs with continued funding became the DP Program Initiatives. At the same time, most of the 8 original programs that were not refunded under the Initiatives continued to submit data on select participants through August 31, 2011. In 2011, data submission switched from paper forms to a web-based data entry system. The Initiatives submitted data to the CC through July 31, 2016. The data in this report are based on the data collection forms submitted to the CC by both the Demonstration Projects and the Initiatives programs.

III. BACKGROUND

As a result of United States Congressional direction, the IHS established the SDPI Diabetes Prevention and Cardiovascular Disease Risk Reduction Demonstration Projects in 2004 as a grant program in which IHS, Tribal and urban Indian health programs could compete for funding to participate in a collaborative process to plan, develop, and implement a common set of activities in two areas: 1) primary prevention of diabetes and 2) cardiovascular disease risk reduction in individuals with diabetes.

The activities for the diabetes prevention demonstration project [called the SDPI Diabetes Prevention Program (DP)] are based on the results of the National Institutes of Health (NIH) Diabetes Prevention Program (DPP) research study, completed in 2002, which found that it is possible to prevent diabetes through moderate weight loss, physical activity, and healthy eating habits. The activities of the DP Program include: 1) diabetes screening, 2) recruitment of individuals with prediabetes, 3) implementation of a 16-week education curriculum on healthy behaviors and skill-building to prevent diabetes, and 4) individual lifestyle coaching sessions, exercise regimens, and follow-up support to reinforce the DP curriculum. Thirty-six Tribal, IHS, and urban Indian programs participated in the Demonstration Projects phase of the SDPI Diabetes Prevention Program, which occurred from October 2004 through September 2010.

The approach of the cardiovascular disease (CVD) risk reduction demonstration project [called the SDPI Healthy Heart Project (HH)] is based on current national standards for diabetes care and the IHS Standards of Care for Individuals with Type 2 Diabetes, which encourage aggressive control of risk factors for diabetes complications. These factors include, but are not limited to: blood pressure, blood glucose level, cholesterol, smoking, and weight. The activities of the HH program include recruitment of individuals with Type 2 diabetes to participate in an intensive, monthly, clinic-based case management approach to diabetes care, which includes three components: 1) individual case management, 2) disease management, and 3) self-management education. Thirty (30) Tribal, IHS, and urban Indian programs participated in the Demonstration Projects phase of the SDPI Healthy Heart Project, which occurred from October 2004 through September 2010.

Congress also directed the IHS to evaluate these activities for their effectiveness. The evaluation plan for the demonstration projects was developed during the first year of funding, called the planning year, through a collaborative process involving DDTP, CC, and DP/HH staff, and is based on a public health program evaluation model. Since previous research has proven the efficacy of the program activities, the evaluation was not designed as new research; rather, it was designed to demonstrate the successful translation or implementation of these proven activities in diverse American Indian and Alaska Native communities and to document their impact. The program evaluation included data collection to answer outcomes and process evaluation questions, including information on what factors were associated with successful participants and programs. The intensive data collection using the full evaluation data

collection forms began in January 2006 and ended on July 31, 2009, except for those participants who had not completed their first annual assessment before that time. Beginning August 1, 2009, in order to allow the program staff to focus their energies on providing services rather than on a costly and labor-intensive data collection effort, the SDPI Demonstration Projects began using the minimum dataset collection forms, which focused the data collection on only a small set of data elements that is necessary to: 1) evaluate the intermediate outcomes of diabetes prevention and CVD risk reduction interventions among SDPI participants, and 2) evaluate the long-term outcomes of the interventions among SDPI participants, i.e., prevention of diabetes and reduction of CVD.

When it became evident that the Demonstration Projects were successful in achieving the desired outcomes, Congress appropriated additional funding to continue the SDPI Diabetes Prevention Program (DP) and the SDPI Healthy Heart Project (HH) through a competitive application process. With the additional funding, in October 2010 the DP and HH programs transitioned from demonstration projects to evidence-based health care programs and were named the SDPI Initiatives. The purpose of the Initiatives was three-fold: 1) allow successful applicants to continue or newly implement one of the two interventions; 2) document activities and outcomes; and 3) disseminate information and best practices from the SDPI Demonstration Projects to other Tribal, IHS, and urban Indian health settings.

The IHS selected the University of Colorado Denver, previously known as the University of Colorado at Denver and Health Sciences Center (UCDHSC), to serve as the national Coordinating Center for both the Demonstration Projects and the Initiatives phases of the SDPI. The Coordinating Center supported the activities of all programs. It was responsible for the overall day-to-day coordination of the programs, communications between and among DDTP and the programs, data management and analysis, and technical assistance and training for program staff. This is the final data report prepared by the Coordinating Center for IHS and the programs.

IV. DETAILED DATA REPORT

1. PARTICIPANT ACCRUAL AND DATA SUBMISSION

Table 1.01 presents the number of participants enrolled (also referred to as accrual) by each program, the total number of participants enrolled overall, and the user population size of each program (Small: < 5000, Medium: 5000-9999, Large: >= 10,000). An individual was considered officially enrolled when the CC received the baseline assessment documenting eligibility which was obtained on or before starting the intervention. The CC received baseline assessments on 8,652 participants who met the following eligibility criteria: American Indian or Alaska Native, at least 18 years of age, glycemic measure in the pre-diabetes range at baseline or prior to baseline, no glycemic measure in the diabetes range at baseline (unless followed by a subsequent glycemic measure not in the diabetes range to rule out diabetes before beginning the intervention), no previous diagnosis of diabetes, not pregnant, and not on dialysis. A potential participant could be excluded if a provider determined that participation could be problematic due to active alcohol or substance abuse or any other significant medical condition or circumstance. The pre-diabetes range was defined as 100 to 125 mg/dl for fasting blood glucose, 140 to 199 mg/dl for the 2-hour oral glucose tolerance test, and 5.7 to 6.4% for A1c. This report excludes data from 89 participants who did not meet (or document) these eligibility criteria sufficiently, including 46 participants who were enrolled based on Metabolic Syndrome rather than pre-diabetes. (Metabolic Syndrome was added as an inclusion criterion for a short period of time.) Each program was expected to work towards an enrollment goal of 48 participants per year. The final accrual of 8652 participants represents 49.3% of the overall enrollment goal (17,559) for up to 121 months of recruitment; programs were permitted to stop recruitment after January 2016. Table 1.01 lists each program's cumulative enrollment goal, which is dependent upon when each program received funding. Programs that were part of both the Demonstration Projects and Initiatives phases were expected to enroll 48 participants per year beginning in January 2006 and ending in January 2016. Programs that were part of the Demonstration Projects only were expected to enroll 48 participants per year beginning in January 2006 and ending in September 2010. Programs that were part of the Initiatives phase only were expected to enroll 48 participants per year beginning in April 2011 and ending in January 2016. Two programs listed in Table 1.01 have different enrollment goals from all the other programs, due to a differing consortium composition for these particular programs between the Demonstration Projects and Initiatives phases.

Figure 1.01 displays the cumulative semi-annual total of participants enrolled by all programs, actual versus expected. The expected average rate of accrual differed slightly during various periods, depending upon the number of programs receiving funding under the Demonstration Projects and Initiatives phases.

Figure 1.02 shows the percentage of the enrollment goal attained for each program, listed from highest to lowest. Two programs achieved over 100% of their enrollment goal. The highest percentage of enrollment goal achieved by a program was 111.2%, which represents 490 enrolled participants out of a target number of 484 participants. The lowest percentage was 13.2%, which represents 30 enrolled participants out of a target number of 228 participants. The bars are shaded based on the user population size of the program. Figure 1.03 compares the ranges and averages of the enrollment goal percentages attained according to the user population size of the programs.

Table 1.02 reports the number of assessments submitted at each time point, including the mid-year (glycemic measure) assessments (depicted as Year 1.5, Year 2.5, etc.). For each time point, Table 1.02 also reports the percentage of participants with a submitted assessment of those who began the program early enough to have completed the given assessment. For example, there were 70 participants who started the DP program who could have completed the Year 10.5 assessment mid-year assessment (data not shown), but only 13 Year 10.5 mid-year assessments were received, for a 19% return rate. These rates do not take into account the myriad reasons why a participant may have become inactive or missed a particular assessment. The submission rate percentages are based on an idealized potential number which assumes no participant converts to diabetes, moves, passes away, leaves the program, or misses an assessment. Submission totals and rates are also presented by program user population size. These submissions represent a total of 17,731 person-years of participation in the DP program.

Table 1.01: DP Participant Accrual

ID	Baseline Assessments Received			Population Size *
	N	Goal	% of Goal	
1	490	484	101.2	Large
2	112	484	23.1	Small
3	208	484	43.0	Medium
4	170	398	42.7	Medium
5	82	228	36.0	Medium
6	165	228	72.4	Large
7	191	484	39.5	Small
8	217	484	44.8	Medium
9	119	228	52.2	Small
10	196	484	40.5	Medium
11	412	484	85.1	Large
12	296	484	61.2	Large
13	112	228	49.1	Medium
14	300	484	62.0	Large
15	239	484	49.4	Medium
16	382	484	78.9	Large
17	345	484	71.3	Large
18	195	484	40.3	Small
19	218	484	45.0	Large
20	103	484	21.3	Medium
21	114	228	50.0	Small
22	216	484	44.6	Large
23	102	484	21.1	Small
24	125	484	25.8	Medium
25	30	228	13.2	Medium
26	434	484	89.7	Large
27	121	484	25.0	Small

Table 1.01: DP Participant Accrual (Continued)

ID	Baseline Assessments Received			Population Size *
	N	Goal	% of Goal	
28	197	228	86.4	Medium
29	58	228	25.4	Small
30	336	484	69.4	Large
31	278	484	57.4	Large
32	160	484	33.1	Small
33	218	484	45.0	Medium
34	156	484	32.2	Medium
35	111	484	22.9	Small
36	290	484	59.9	Large
37	118	181	65.2	Small
38	94	232	40.5	Medium
39	258	232	111.2	Large
40	92	232	39.7	Medium
41	84	232	36.2	Small
42	76	232	32.8	Small
43	114	232	49.1	Small
44	57	232	24.6	Large
45	224	232	96.6	Large
46	37	232	15.9	Small
TOTAL	8652	17559		
MIN	30		13.2	
MAX	490		111.2	
MEAN	188		49.3	

*Total user population of the organization: small indicates less than 5,000, medium indicates 5,000-9,999 and large indicates 10,000 or greater.

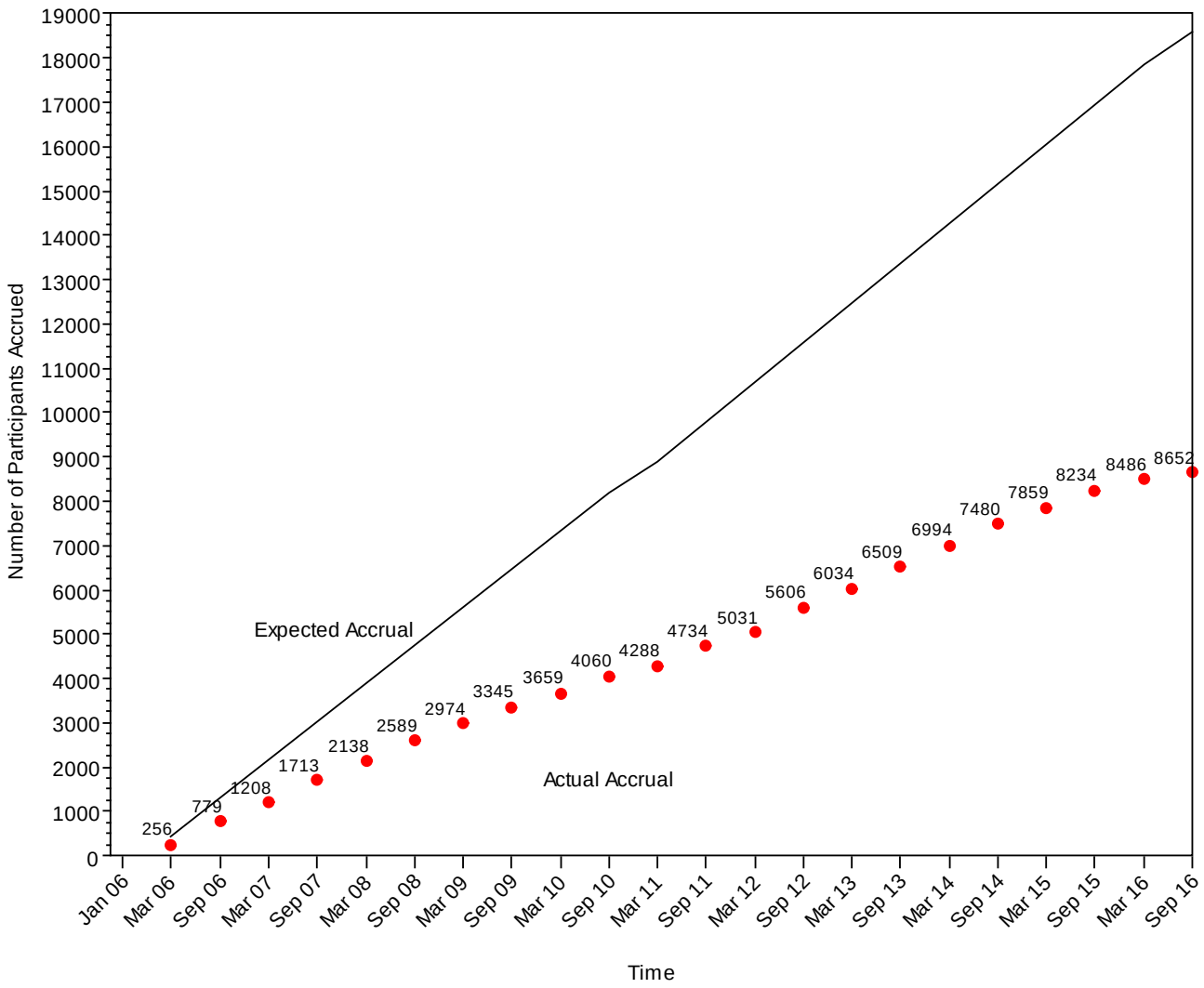


Figure 1.01: DP Participant Accrual over Time

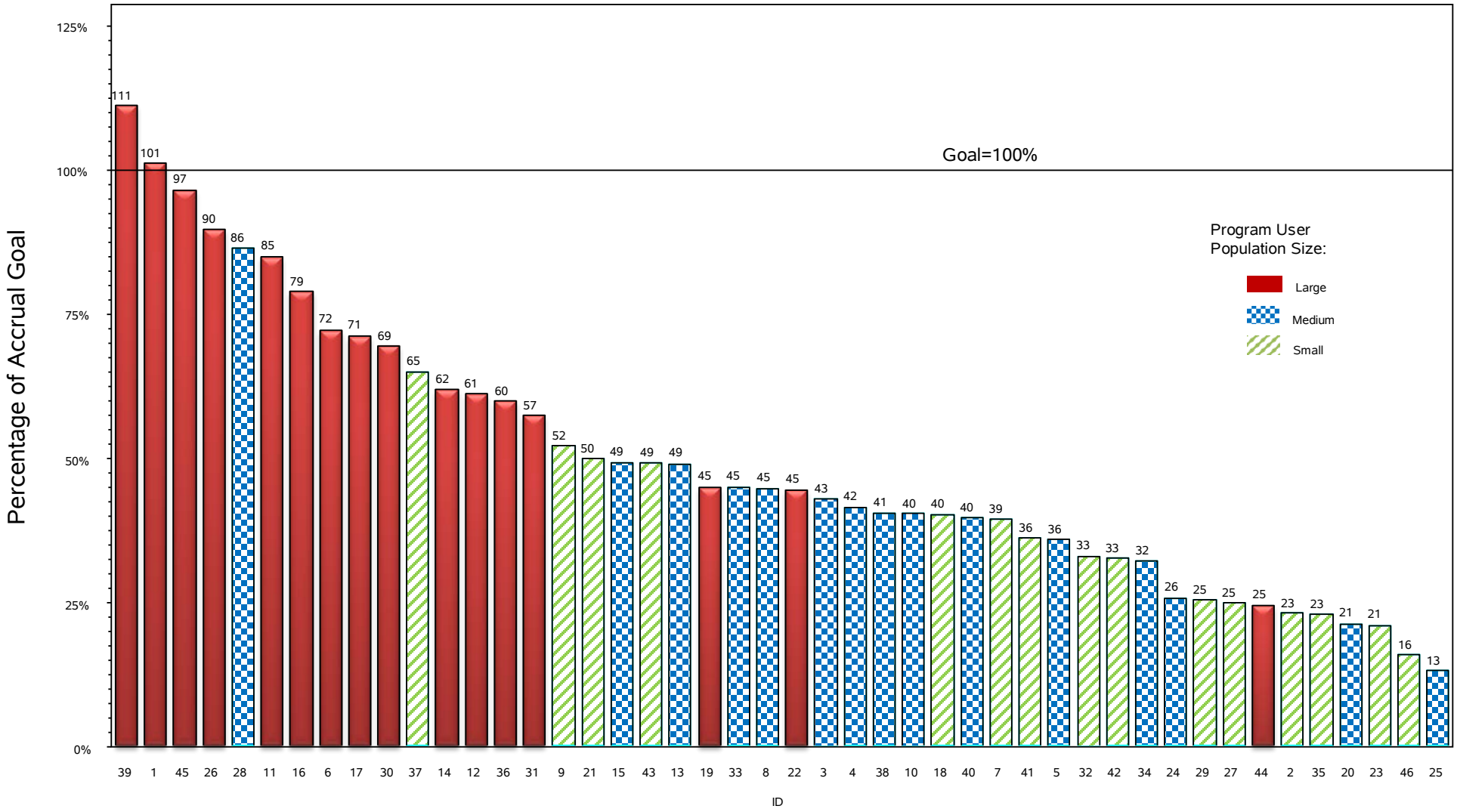


Figure 1.02: DP Percentage of Accrual Goal Achieved

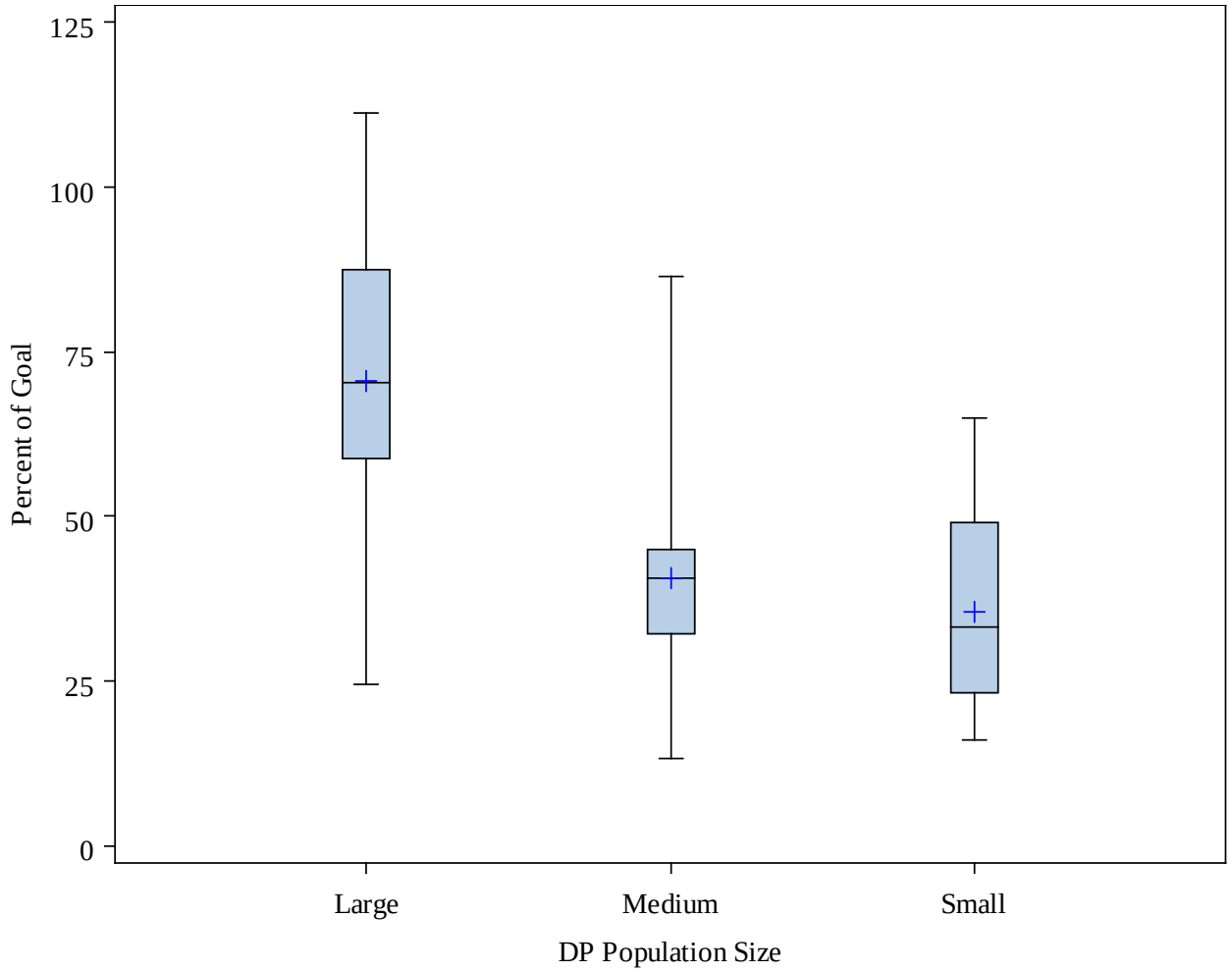


Figure 1.03: DP Percentage of Accrual Goal Achieved by Program User Population Size

Note:

- the vertical lines above and below the box extend to the minimum and maximum values of the percentages
- the "+" in the box interior represents the mean (average)
- the horizontal line inside the box represents the median (middle value)
- the length of the box represents the interquartile range (the distance between the 25th and the 75th percentiles)

Table 1.02: DP Assessment Forms Submitted (Including Mid-Year)

Time Point	All Programs		By Program User Population Size					
			Small (N = 15)		Medium (N = 15)		Large (N = 16)	
	Number Submitted	Submission Rate (%)	#	%	#	%	#	%
Baseline	8652	.	1712	.	2239	.	4701	.
Follow-Up	5639	66%	1095	65%	1517	68%	3027	66%
Year 1	3903	48%	803	50%	1232	57%	1868	42%
Year 1.5	3145	41%	633	41%	1008	48%	1504	36%
Year 2	2616	36%	536	37%	837	41%	1243	32%
Year 2.5	2258	33%	424	32%	748	38%	1086	30%
Year 3	1885	29%	377	30%	632	33%	876	27%
Year 3.5	1634	28%	330	29%	546	31%	758	25%
Year 4	1343	24%	295	27%	450	27%	598	21%
Year 4.5	1112	22%	226	23%	363	23%	523	21%
Year 5	918	20%	194	21%	310	21%	414	18%
Year 5.5	791	19%	159	19%	265	19%	367	18%
Year 6	661	17%	122	15%	233	18%	306	16%
Year 6.5	598	17%	118	16%	205	17%	275	16%
Year 7	518	16%	101	15%	174	16%	243	16%
Year 7.5	461	16%	87	14%	176	18%	198	15%
Year 8	357	14%	69	13%	127	15%	161	14%
Year 8.5	300	14%	51	11%	120	16%	129	14%
Year 9	212	13%	43	11%	83	14%	86	12%
Year 9.5	144	12%	28	10%	59	14%	57	11%
Year 10	86	13%	18	9%	34	16%	34	13%
Year 10.5	13	19%	2	9%	1	4%	10	43%
Total Annual Assessments	12,499	.	2558	.	4112	.	5829	.
Total Mid-Year Assessments	10,456	.	2058	.	3491	.	4907	.
Total Assessments	37,246	.	7423	.	11,359	.	18,464	.

2. ATTENDANCE AND RETENTION

Attendance:

DP attendance data are shown in Table 2.01. The 8,652 DP participants attended a total of 108,455 DP sessions. Individual lifestyle coaching was offered both during and after the participant was attending the DP curriculum sessions; DP participants attended 104,177 one-to-one lifestyle coaching visits. In addition to the lifestyle coaching, programs offered their participants a wide variety of supplemental activities after the DP curriculum, referred to as After-Core; combined DP attendance at these After-Core activities was 47,642. The attendance data are also reported by program user population size.

Table 2.01 also includes the mean number of lifestyle coaching visits per participant per year in program. Lifestyle coaches ideally meet one-to-one with each participant monthly during the DP curriculum and at least quarterly in the After-Core phase. The mean number of lifestyle coaching visits per participant per year in program was calculated by first summing the number of lifestyle coaching visits for each participant and then dividing by the total length of time (in years) the participant was active in the program. Adjustments were made for lifestyle coaching visits close together in time and for short periods of enrollment. The resultant number of lifestyle coaching visits per participant per year in program ranges between 0 and 12 for each participant (0 to 12 lifestyle coaching visits per year). Although the overall mean number of lifestyle coaching visits per participant per year in program was 3.1 visits, there was great variability among programs, with one program achieving a mean of 8.25 lifestyle coaching visits per participant per year in program.

Table 2.01 also reports the mean number of After-Core activities per participant per year in After-Core. There were no restrictions on the number of After-Core activities a program could offer or the number a participant could attend. Although the overall mean number of After-Core activities per participant per year in After-Core was 2.1 activities, there was great variability among programs, with one program achieving a mean of 9.76 After-Core activities per participant per year in After-Core.

Retention:

Participant retention was a struggle for most programs, with only 66% of participants returning for the follow-up assessment and 29% returning for the Year 3 assessment (see Table 1.02, previous chapter). Figure 2.01 shows the probability of remaining in the DP program over the 10½ years of implementation. There is a steep drop-off in the first few months (DP curriculum) and thereafter the rate of attrition declines. Figure 2.02 depicts the same graph by gender, showing that females had a slightly higher retention rate than males. Figure 2.03 depicts the retention rates by program user

population size, showing that the programs with a larger user population size had worse retention overall, and the programs with a smaller user population size had the best retention after two years.

Figure 2.04 depicts the reasons participants became inactive as reported by program staff. When more than one reason was reported, the participant's *primary* reason for becoming inactive was used (when possible). The most common reasons participants became inactive were "unable to contact" and "other reason" followed by "scheduling difficulties." Seven percent of DP participants were diagnosed with diabetes during the program. Five percent of DP participants had been active when their DP Demonstration Project did not continue on to the Initiatives phase. It is unknown how many of the DP participants who were active as of July 31, 2016 (N = 2911) will become inactive due to program close-out or will transition to another diabetes prevention program within the community. Currently, many DP programs are continuing to offer the intervention to their participants, without centralized data submission.

Table 2.01: DP Attendance

Type of Attendance		All Programs	By Program User Population Size		
			Small (N = 15 programs, 1712 participants)	Medium (N = 15 programs, 2239 participants)	Large (N = 16 programs, 4701 participants)
DP Classes	Total attendance	108,455	21,620	30,431	56,404
	Mean per participant	12.5	12.6	13.6	12.0
	Mean per participant in those graduating to After Core	15.7	15.5	15.8	15.7
Lifestyle Coaching Visits	Total attendance	103,970	22,497	36,472	45,001
	Mean per participant per year in program (0 to 12)	3.1	2.8	3.7	2.9
After-Core Activities (only applicable if participant graduated to After Core)	Total attendance	47,115	9,470	15,688	21,997
	Mean per participant per year in After Core (0 to 86)	2.1	1.9	2.2	2.1

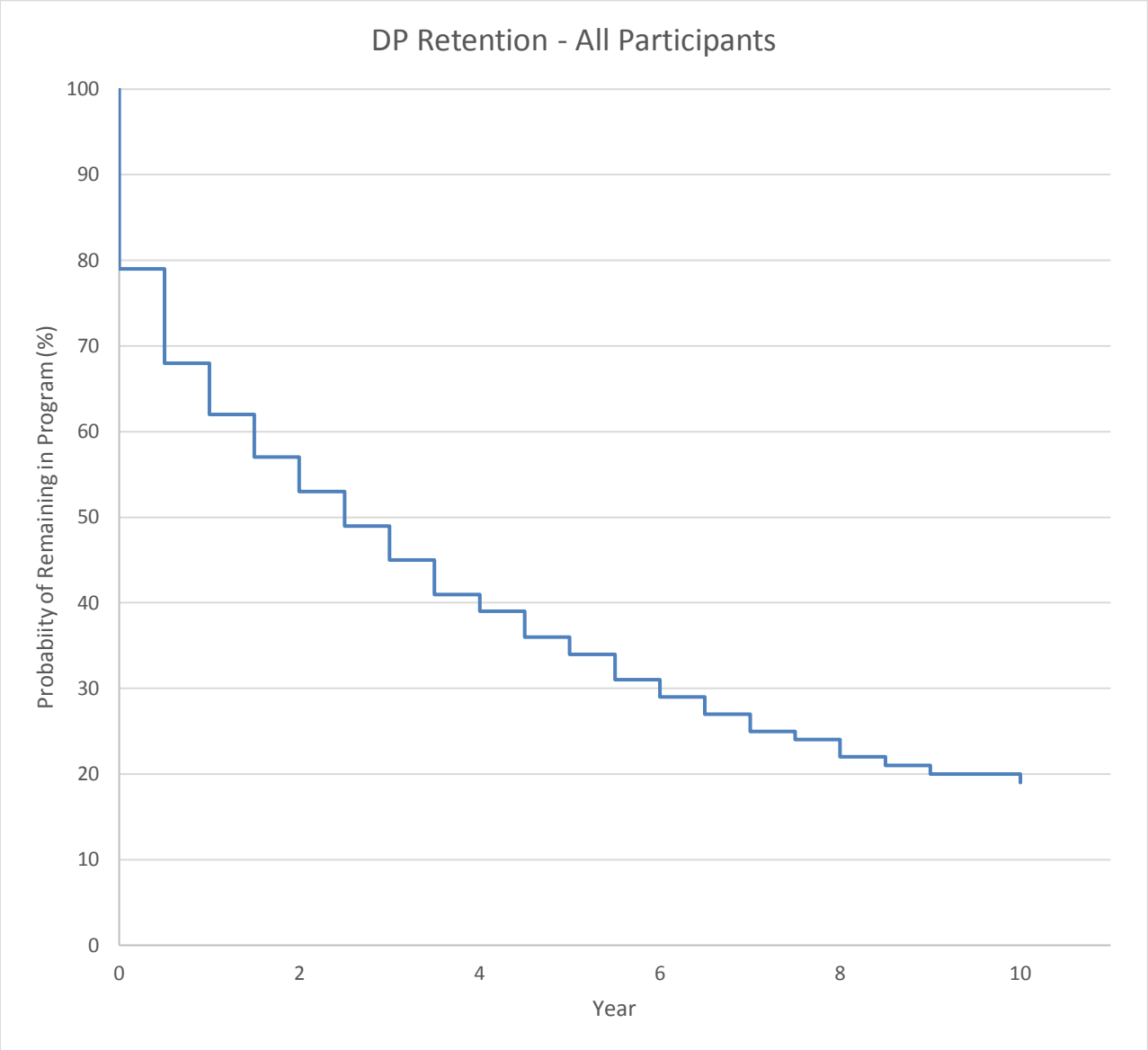


Figure 2.01: DP Retention (Probability of Remaining Active in the DP Program)

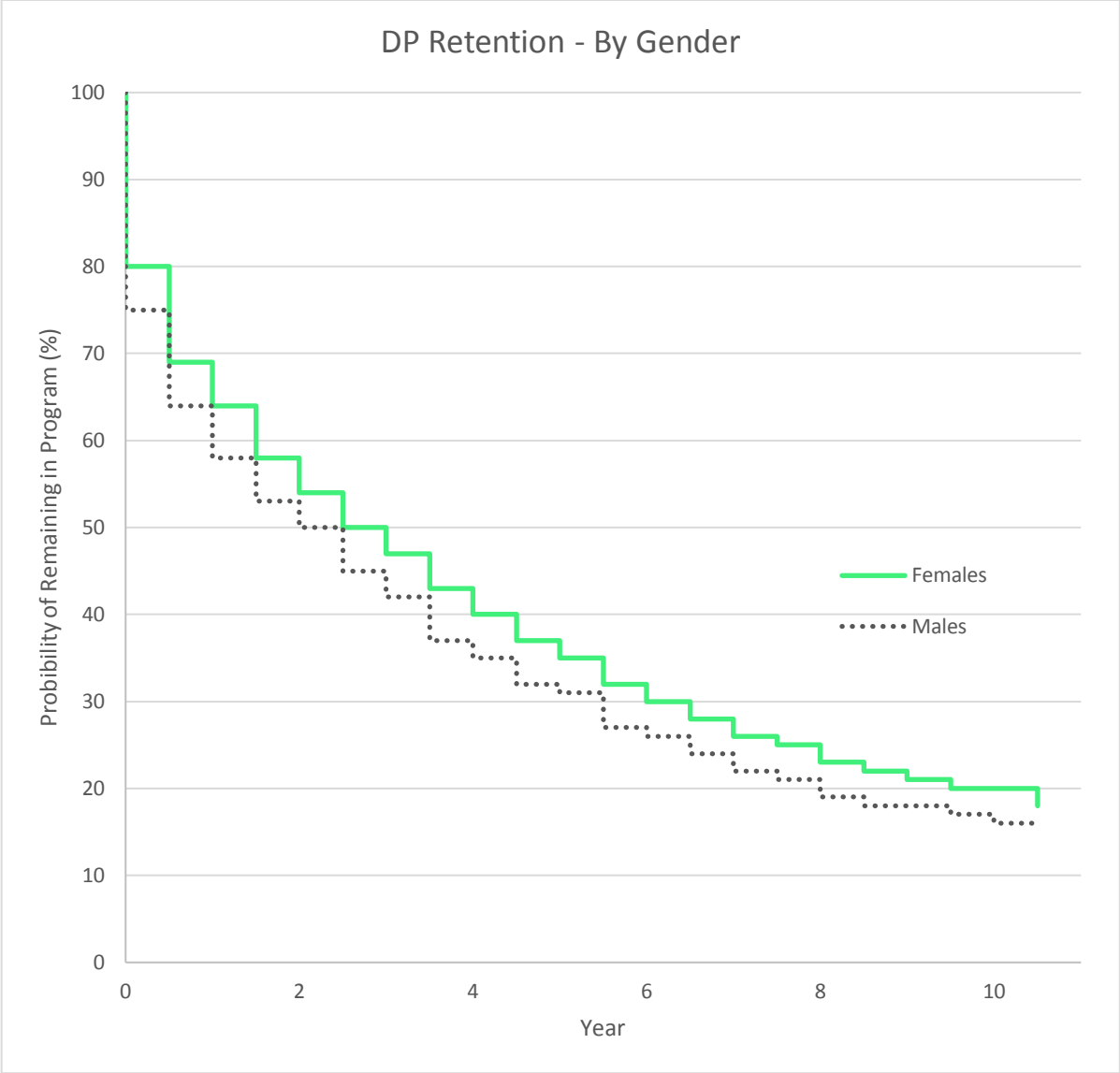


Figure 2.02: DP Retention by Gender (Probability of Remaining Active in the DP Program)

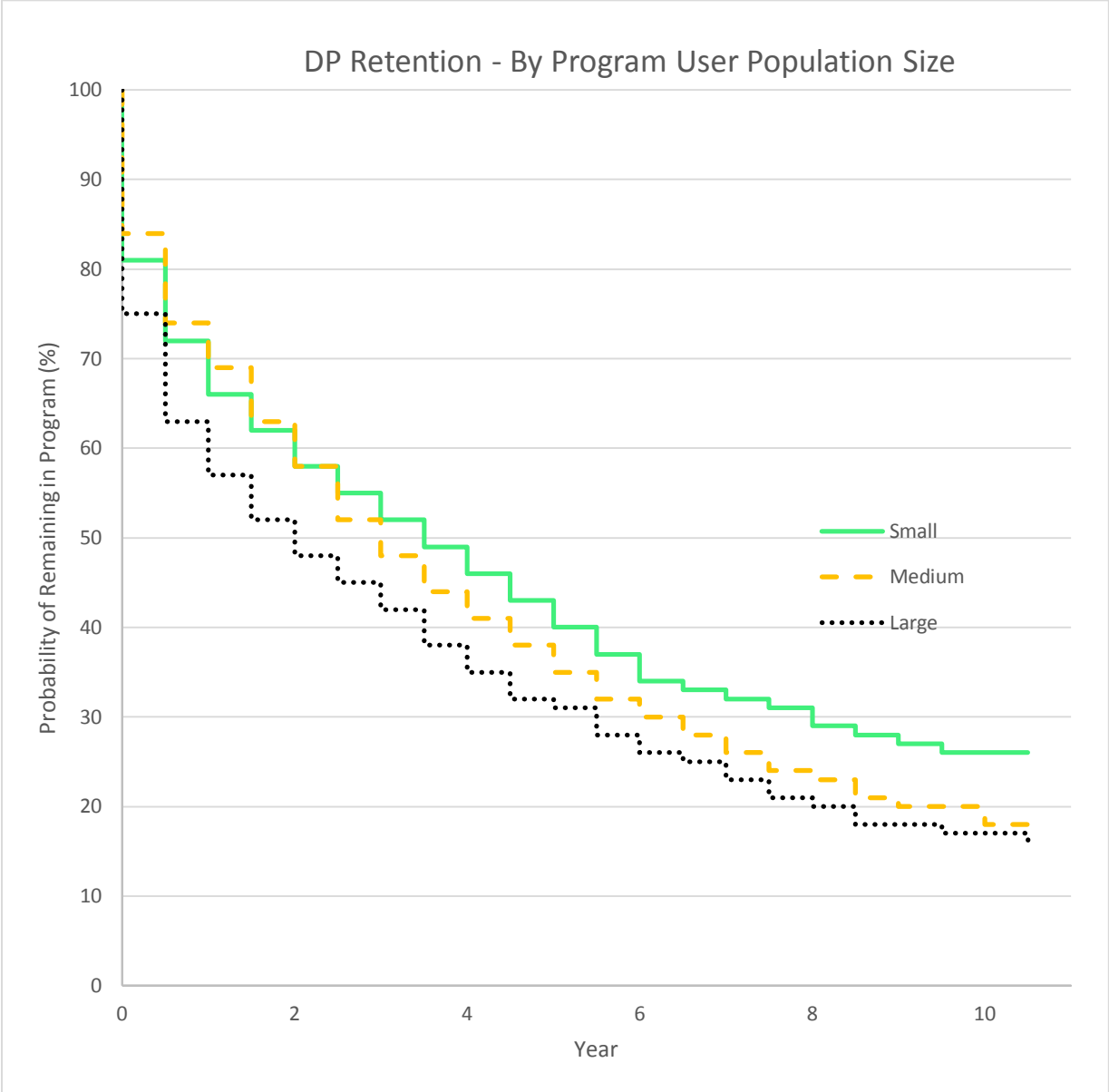


Figure 2.03: DP Retention by Program User Population Size (Probability of Remaining Active in the DP Program)

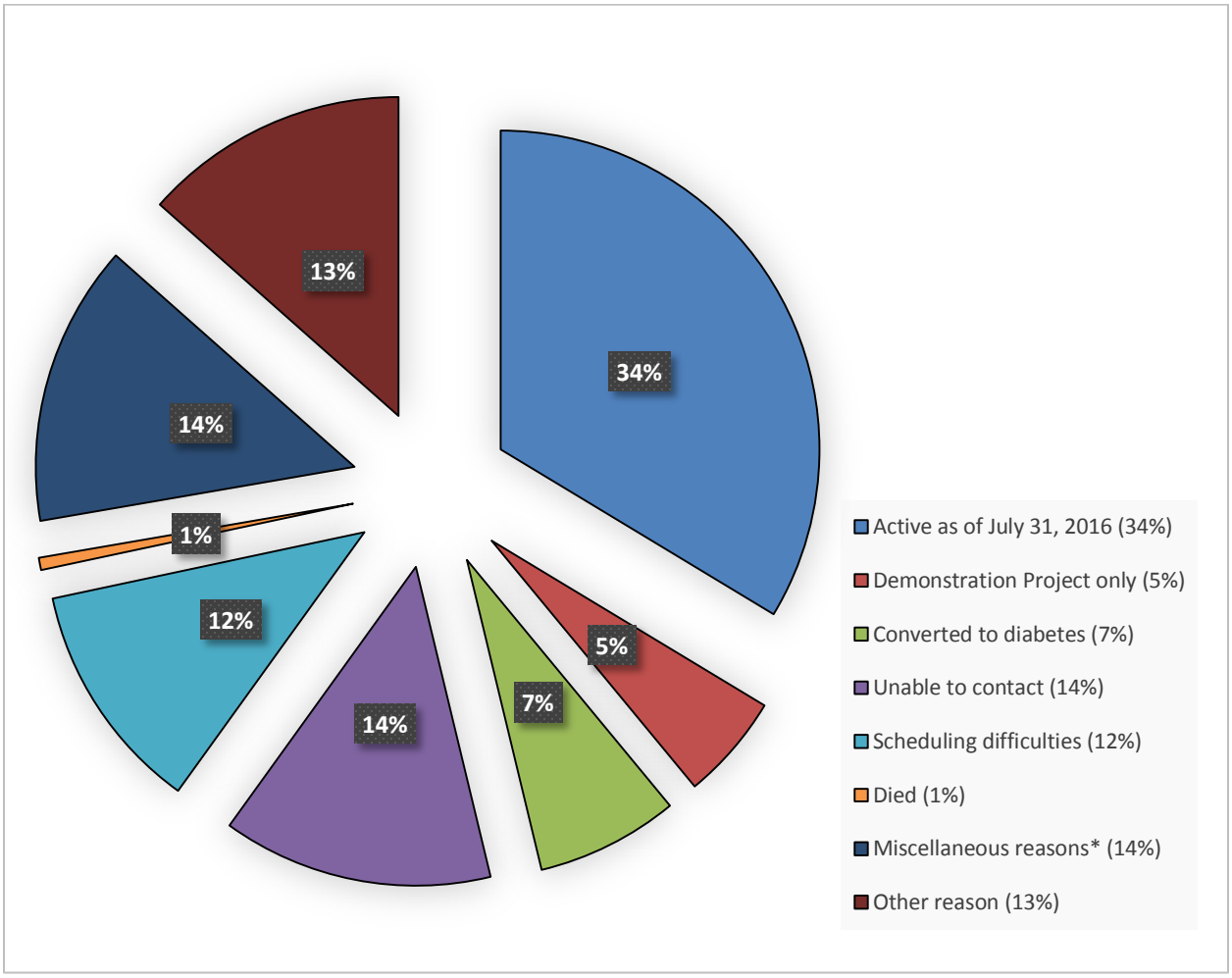


Figure 2.04: DP Reasons Participant Became Inactive

*Miscellaneous reasons: Moved (5%), Did not like program (3%), Health problems (2%), Family problems (2%), No reason given (1.5%), Pregnancy (1%), Transportation (0.5%)

3. ASSESSMENT DATA

This section includes data from all submitted assessments. This report is based on both the full evaluation data collection forms and the minimum dataset collection forms, which means only data relating to those demographics, clinical measurements, and lifestyle measurements which were collected in both phases are presented.

In the tables and graphs presented in this section, the number of participants is different at each time point because 1) participant start times in the program vary and not all participants were expected to have completed all assessments by program close-out, 2) many participants became inactive, and 3) some participants missed assessments during the program but returned for later assessments. For example, the number of Year 5 assessment forms is greater than the number of Year 6 assessment forms because of 1) participants who were not due for the Year 6 assessment at the time of program close-out, 2) participants who became inactive before completing the Year 6 assessment, and 3) participants who missed the Year 6 assessment but came back for later assessments. Readers are cautioned against inferring trends over time in all tables with unpaired data.

A. Baseline Data:

Baseline demographic characteristics of DP participants can be found in Table 3A.01, which shows that:

- There are more female participants (75%) than male participants (25%).
- The average age of the DP participants was 47 years old, with 4% being younger than age 25 and 9% age 65 or older.
- The participants ranged in age from 18 to 93 years at baseline.

Comorbidities (i.e., the coexistence of two or more pathologies, or disease processes, in the same individual) among DP participants at baseline are shown in Table 3A.02. The most common conditions, in addition to pre-diabetes, were back pain (38%), high blood pressure (37%), and arthritis (24%). Males had higher rates of heart disease and high blood pressure, while females had higher rates of anemia and depression.

Table 3A.03 compares the baseline characteristics of DP participants who returned for any assessment after the baseline assessment (i.e., a follow-up, annual, or mid-year assessment) with those participants having only a baseline assessment. The majority of the participants who did not return for any non-baseline assessment became inactive during the DP curriculum; 342 participants returned for an annual or mid-year assessment after missing the follow-up assessment. Participants who became inactive during the DP curriculum were given the option of re-starting the DP Program at a later date, and 346 participants did re-start, 22 of them more than once. The data from the last program start is included in

this report, not the data from the previous attempt(s). Table 3A.03 indicates that the participants who continued in the program past baseline were more likely to be female, were older, were less likely to smoke, were more likely to return the questionnaire, and ate unhealthy foods less frequently than participants having only a baseline assessment. Female participants who continued in the program past baseline weighed less and had slightly higher systolic blood pressures, HDL levels, and total cholesterol levels (perhaps related to the higher HDL levels).

Table 3A.01: DP Gender and Baseline Age

Baseline age (years)	Female		Male		All	
	N	Mean	N	Mean	N	**Mean**
	6467	46.9	2185	47.5	8652	**47.1**
Age category:	N	**%**	N	**%**	N	**%**
18 – 24 years	254	4%	63	3%	317	**4%**
25 – 34 years	1029	12%	337	15%	1366	**16%**
35 – 44 years	1462	23%	501	23%	1963	**23%**
45 – 54 years	1852	29%	610	28%	2462	**28%**
55 – 64 years	1276	20%	453	21%	1729	**20%**
65 years and older	594	9%	221	10%	815	**9%**

Table 3A.02: DP Baseline Rates of Comorbidities

Comorbidity	Female		Male		All	
	N	%	N	%	N	%
Heart Disease	5,928	3.5%	1,979	8.5%	7,907	**4.8%**
High Blood Pressure	5,968	33.0%	1,987	47.6%	7,955	**36.7%**
Lung Disease	5,944	3.8%	1,981	3.0%	7,925	**3.6%**
Ulcer/Stomach Disease	5,923	7.3%	1,983	6.5%	7,906	**7.1%**
Kidney Disease	5,952	0.8%	1,986	1.2%	7,938	**0.9%**
Liver Disease	5,947	1.9%	1,980	2.5%	7,927	**2.0%**
Anemia or Other Blood Disease	5,949	7.2%	1,989	1.8%	7,938	**5.8%**
Cancer	5,952	1.3%	1,979	1.5%	7,931	**1.4%**
Depression	5,925	21.6%	1,987	13.8%	7,912	**19.6%**
Arthritis	5,890	24.4%	1,955	22.2%	7,845	**23.8%**
Back Pain	5,942	37.3%	1,987	39.0%	7,929	**37.7%**

Table 3A.03: DP Baseline Characteristics Post-Baseline versus Baseline-Only Participants

Baseline Variable	Baseline Assessment Only			At Least One Post-Baseline Assessment		
	Female (N = 1861)	Male (N = 714)	All (N = 2575)	Female (N = 4534)	Male (N = 1447)	All (N = 5981)
Gender (% male)	-	-	28%	-	-	24%
Age (years)	44.4	44.5	44.4	47.9	49.0	48.2
Weight (pounds)	212.8	243.9	221.4	208.5	243.9	217.1
BMI (kg/m^2)	36.5	35.5	36.2	35.9	35.5	35.8
Waist (inches)	44.9	45.6	45.1	43.7	45.5	44.1
Systolic BP (mm Hg)	124.7	130.1	126.2	125.9	130.3	127.0
Diastolic BP (mm Hg)	77.4	81.2	78.4	78.0	80.5	78.6
HDL (mg/dl)	47.3	41.1	45.6	48.1	40.6	46.3
LDL (mg/dl)	108.6	110.7	109.2	110.2	110.2	110.2
Triglycerides (mg/dl)	150.3	171.7	156.3	151.5	171.4	156.3
Total Cholesterol (mg/dl)	182.0	181.6	181.9	185.9	181.5	184.9
Non-Smoker (%)	74%	68%	72%	79%	77%	78%
Questionnaire returned? (%)	90%	89%	90%	95%	95%	95%
Physically Active (%)	26%	40%	30%	27%	43%	31%
Healthy Diet Score	3.5	3.4	3.5	3.5	3.4	3.5
Unhealthy Diet Score	3.0	3.2	3.0	2.8	3.0	2.9

Values reported are means or percentages.

96 participants who started the program after January 2016 and did not complete a follow-up assessment were excluded.

342 participants did not complete the follow-up assessment but returned for at least one annual or mid-year assessment.

B. Diabetes Incidence:

Figure 3B.01 compares the cumulative incidence of diabetes of a subset (N = 648) of DP Program participants with participants in the National Institutes of Health (NIH) Diabetes Prevention Program (DPP). These 648 DP Program participants were recruited during the first three years of the DP Program when an oral glucose tolerance test was required at baseline, and these participants had both impaired fasting blood glucose and impaired glucose tolerance. These 648 DP participants also met the age and BMI eligibility criteria for the NIH DPP. As shown in Figure 3B.01, the cumulative incidence of diabetes of these SDPI DP participants was better than that of the NIH DPP placebo participants but not as good as the NIH lifestyle participants. The crude incidence rate of the NIH DPP Lifestyle participants was 4.8%, the crude incidence rate of the NIH DPP Placebo participants was 11%, and the crude incidence rate of the SDPI DP participants was 7.7%. In addition to the differences in participant characteristics, which we attempted to mitigate by using a subset of SDPI DP participants more closely matching the NIH DPP participants, there were also differences in program design and realization. For example, the retention rate was much better in the NIH DPP study. If the SDPI DP participants who were more likely to convert to diabetes were also more likely to drop out of the program, this could bias the results. Please use caution in interpreting Figure 3B.01.

The remaining 8004 SDPI DP participants either did not have both impaired fasting blood glucose and impaired glucose tolerance or did not receive an oral glucose tolerance test to make that determination. Therefore, the cumulative incidence of diabetes in these 8004 participants is naturally much lower than that seen in participants with both impaired fasting blood glucose and impaired glucose tolerance. Even though there is no comparison group for the SDPI DP participants as a whole, comparisons can be made between subgroups of the SDPI DP population.

Figure 3B.02 compares the cumulative incidence of diabetes of DP participants with excellent early attendance (defined as attending all 16 DP curriculum sessions and at least six lifestyle coaching visits in the first year) with the remaining DP participants (considered to have fair or poor early attendance). The cumulative incidence of diabetes of the participants with fair or poor early attendance was worse over time than that of participants with excellent early attendance. Figure 3B.03 shows that the cumulative incidence of diabetes of male DP participants was worse over time than that of female participants. Figure 3B.04 compares the cumulative incidence of diabetes by the percentage of baseline weight lost at the time of the follow-up assessment. The top line is the cumulative incidence of diabetes for DP participants who lost less than 3% of their baseline weight by follow-up; their cumulative incidence of diabetes is worse than that of participants who lost 3% to 5% or greater than 5% of their baseline weight.

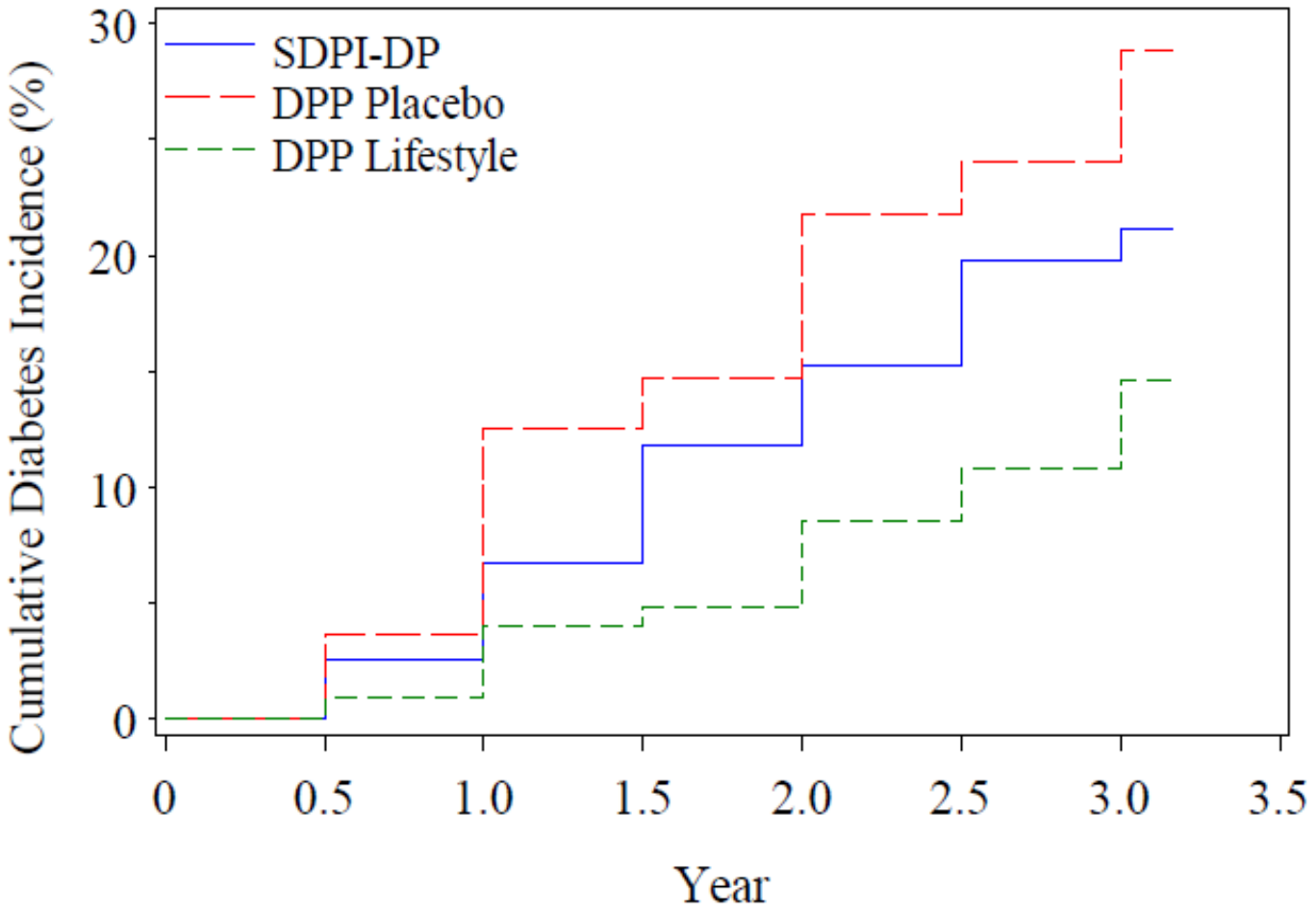


Figure 3B.01: DP Cumulative Incidence of Diabetes in Participants with Eligibility Criteria Similar to NIH DPP (N = 648)

Note: Results of NIH DPP and SDPI-DP are superimposed in the graph for comparison, but participant characteristics and study design were not identical.

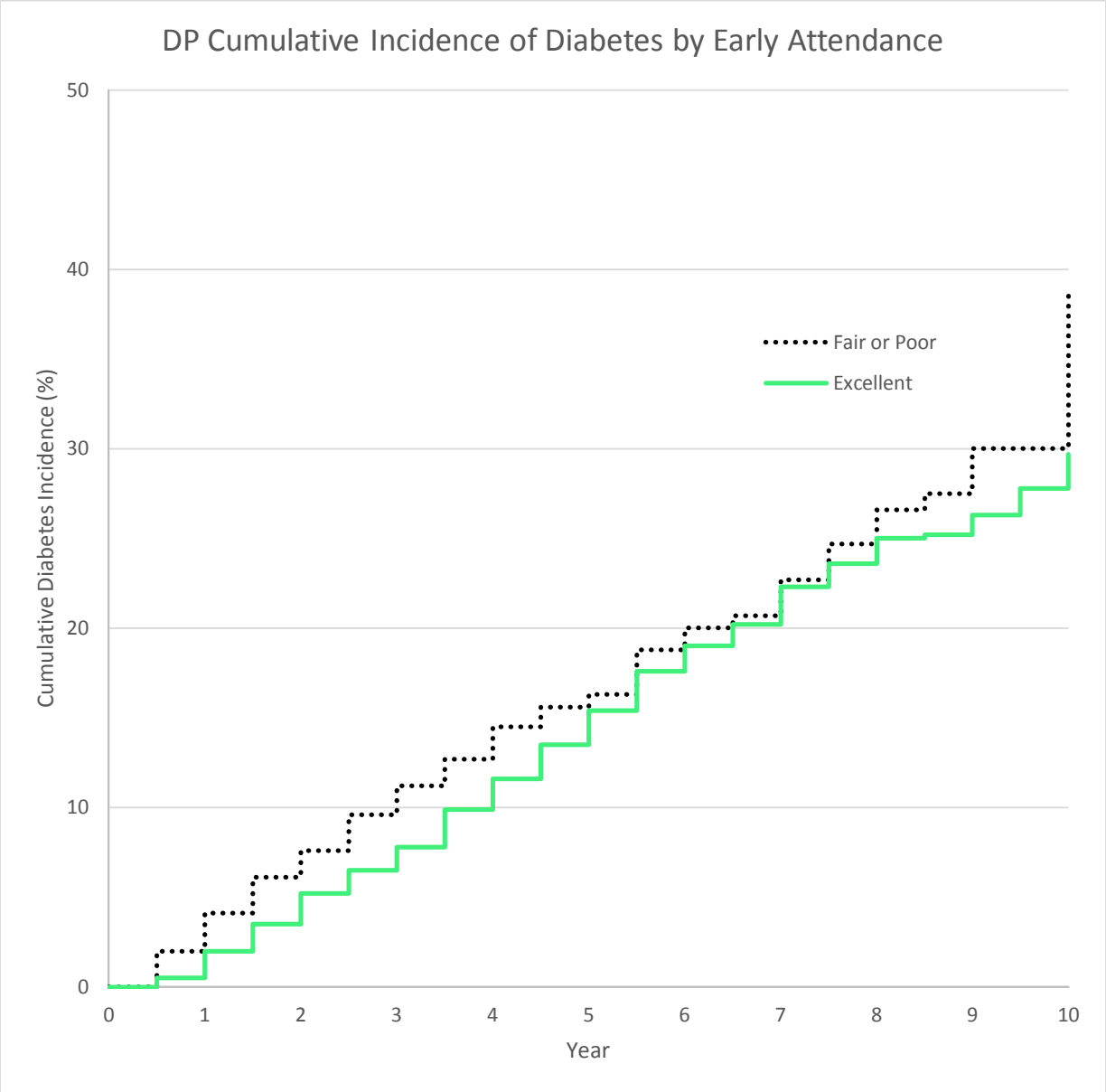


Figure 3B.02: DP Cumulative Incidence of Diabetes by Early Attendance (All Participants)

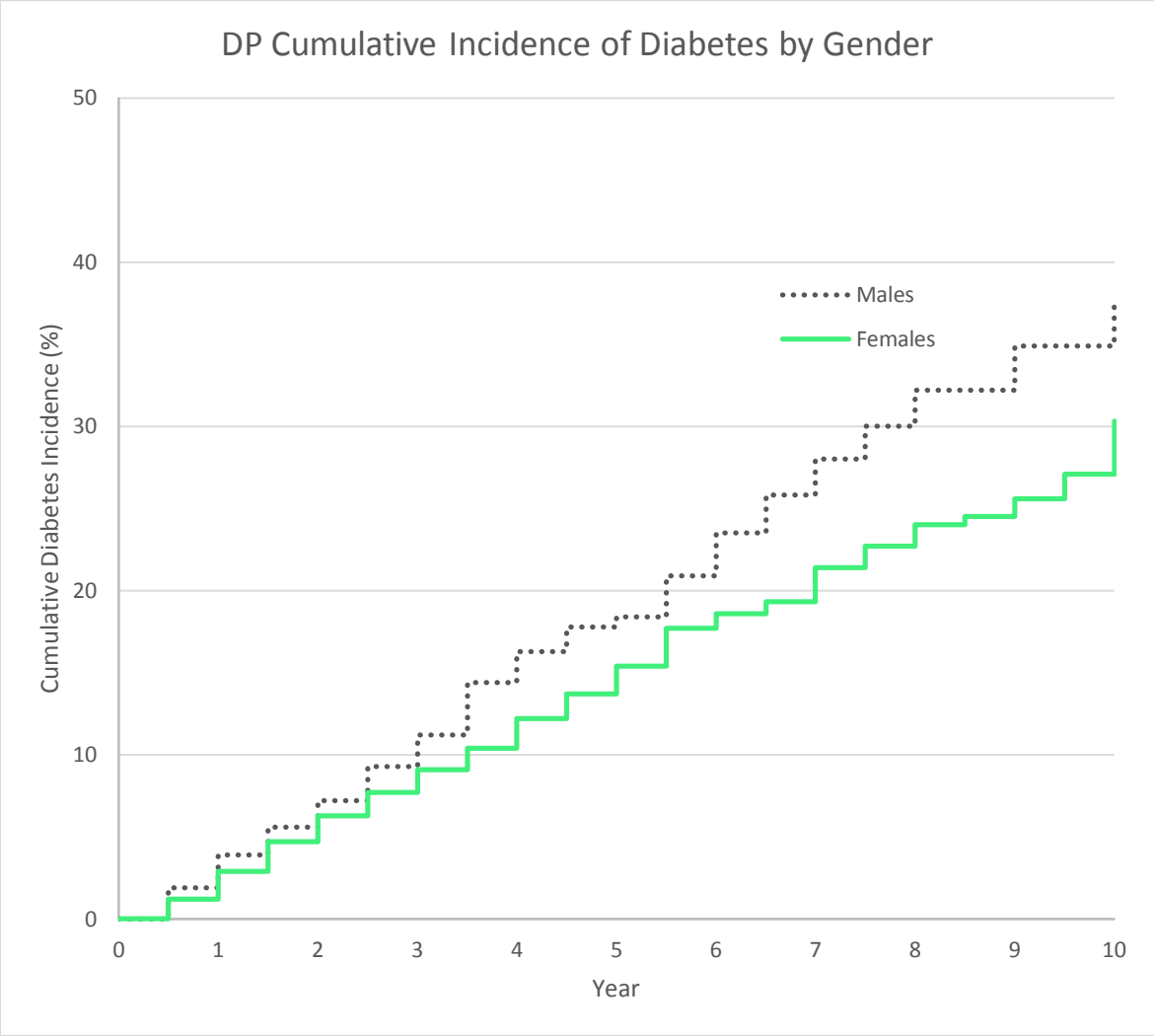


Figure 3B.03: DP Cumulative Incidence of Diabetes by Gender (All Participants)

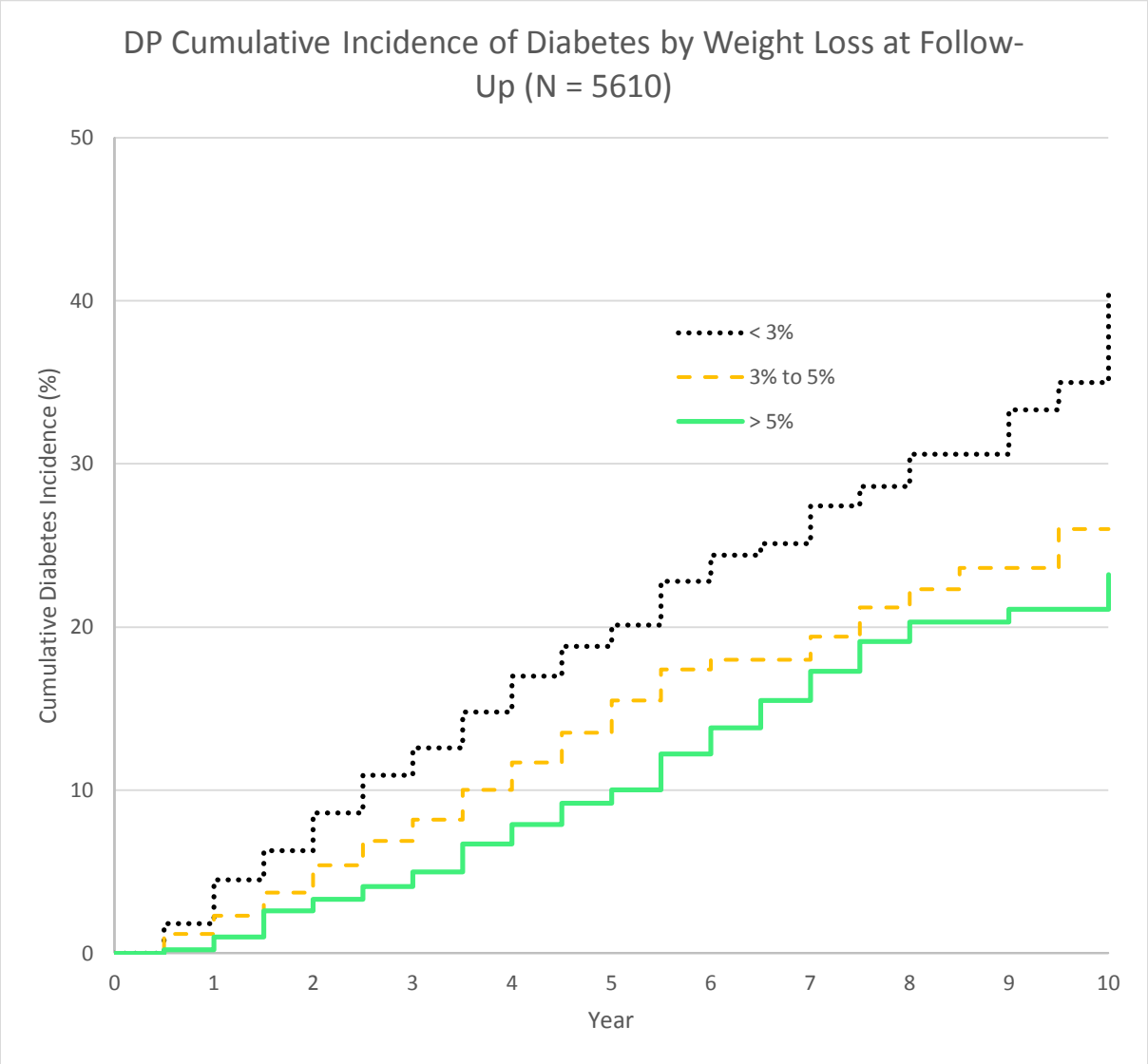


Figure 3B.04: DP Cumulative Incidence of Diabetes by Weight Loss at Follow-Up (N = 5610)

C. Secondary Clinical Measurements:

Table 3C.01 summarizes the clinical measurements for the participants at each assessment (unpaired data), and Table 3C.02 summarizes the same measurements by gender (unpaired data). The findings show that:

- The average weight of the participants was 218.5 pounds at baseline.
- The average weight of the participants was 208.7 pounds at follow-up, however, only 65% of participants completed the follow-up assessment.

Tables 3C.03 and 3C.04 present changes in clinical measurements from baseline to later time-points using paired data. Tables 3C.05 and 3C.07 summarize the percentages of DP participants achieving goals for primary outcomes at each assessment (unpaired data). Tables 3C.06 and 3C.08 summarize the percentages of DP participants meeting recommended targets for secondary outcomes at each assessment (unpaired data). The percentage of participants achieving recommended targets at the follow-up and annual assessments is greater than or equal to the baseline percentage for most secondary outcomes at most time points, with the exception of systolic blood pressure (Table 3C.06).

Please note that there was a wide range of changes in the clinical variables among DP participants. Figure 3C.01 shows such an example. The weight change of DP participants from baseline to follow-up ranged from a loss of 99 lbs. to a gain of 44 lbs. The mean change or mean percent change can be influenced by such extreme values, which is why it is helpful to also look the median changes. In this report, the median changes and the mean changes were similar for the clinical outcome measurements reported, so both median changes (Table 3C.03 and 3C.04) and changes in means (Figures 3C.02 through 3C.09).

Figures 3C.02 through 3C.09 depict the means of clinical measurements at baseline and at the comparison time point (follow-up or annual assessment) using paired data. Figure 3C.10 depicts the percentage of participants having their glycemic measure(s) in the normal range, also using paired data. For each time point, only the participants who had data at that time point and at baseline are included. For example, in Figure 3C.07: DP LDL Changes from Baseline (Paired Data), there were 80 participants who had LDL measured at baseline and at Year 10. The mean baseline LDL for these 80 participants was 113 mg/dl and the mean LDL at Year 10 was 105 mg/dl. **The majority of participants had small but consistent improvements in weight, BMI, LDL, HDL, triglycerides, total cholesterol, blood glucose, physical activity and dietary habits at most time points, but waist and blood pressure did not show consistent improvement.**

Table 3C.01: DP Clinical Measurements at Each Assessment (Unpaired Data)

	Baseline		Follow-up		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean
Weight (pounds)	8,642	**218.5**	5,610	**208.7**	3,861	**208.6**	2,583	**209.2**	1,866	**209.5**	1,329	**206.1**	907	**205.4**	656	**203.2**	512	**205.5**	352	**203.3**	209	**200.1**	84	**200.4**
Body Mass Index (BMI)	8,642	**35.9**	5,610	**34.4**	3,861	**34.5**	2,583	**34.6**	1,866	**34.7**	1,329	**34.2**	907	**34.2**	656	**34.0**	512	**34.2**	352	**34.0**	209	**33.8**	84	**33.4**
Waist (inches)	8,435	**44.4**	5,474	**42.6**	3,711	**42.6**	2,456	**42.8**	1,769	**43.0**	1,260	**42.7**	863	**42.7**	628	**42.6**	457	**42.8**	320	**42.6**	179	**42.6**	76	**42.8**
Systolic BP (mm Hg)	8,590	**126.7**	5,527	**125.3**	3,826	**126.1**	2,548	**126.9**	1,850	**127.6**	1,318	**127.6**	905	**127.7**	650	**128.1**	508	**128.8**	353	**127.5**	206	**128.1**	84	**128.5**
Diastolic BP (mm Hg)	8,590	**78.5**	5,527	**77.5**	3,826	**77.6**	2,548	**77.8**	1,850	**77.9**	1,318	**77.9**	905	**77.8**	650	**77.6**	508	**77.3**	353	**76.0**	206	**75.7**	84	**74.2**
LDL (mg/dl)	8,479	**109.9**	5,417	**106.9**	3,787	**107.7**	2,535	**107.4**	1,820	**105.9**	1,312	**106.6**	894	**106.4**	645	**108.2**	505	**107.8**	344	**106.6**	199	**105.0**	82	**104.7**
HDL (mg/dl)	8,581	**46.1**	5,471	**46.8**	3,828	**48.2**	2,555	**48.6**	1,835	**48.6**	1,324	**49.7**	898	**49.7**	648	**50.3**	504	**49.7**	345	**50.7**	199	**50.3**	82	**52.7**
Triglycerides (mg/dl)	8,579	**156.2**	5,472	**146.4**	3,828	**149.1**	2,556	**150.5**	1,833	**149.2**	1,325	**147.5**	899	**143.0**	648	**144.8**	504	**142.5**	345	**138.9**	199	**139.1**	82	**133.9**
Total Cholesterol (mg/dl)	8,584	**183.9**	5,471	**180.0**	3,829	**183.1**	2,558	**183.2**	1,836	**181.6**	1,325	**183.1**	898	**182.3**	648	**184.8**	504	**182.4**	345	**181.0**	199	**179.7**	82	**180.8**
Fasting Blood Glucose (mg/dl)	6,436	**103.6**	4,172	**100.6**	2,963	**101.0**	1,943	**101.6**	1,331	**101.8**	928	**102.2**	615	**102.0**	463	**102.6**	357	**102.3**	248	**102.4**	138	**105.5**	53	**108.6**
A1c (%)	3,881	**5.8**	2,228	**5.7**	1,558	**5.7**	1,203	**5.8**	992	**5.8**	769	**5.8**	552	**5.8**	380	**5.8**	303	**5.8**	217	**5.7**	142	**5.8**	58	**5.8**

Table 3C.02: DP Clinical Measurements at Each Assessment by Gender (Unpaired Data)

	Female																					
	Baseline		Follow-up		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean
Weight (pounds)	6,458	**209.8**	4,229	**200.8**	2,935	**201.3**	1,941	**201.5**	1,409	**201.1**	1,011	**198.5**	697	**196.8**	515	**194.8**	399	**197.3**	274	**195.9**	169	**194.1**	61	**188.1**
Body Mass Index (BMI)	6,458	**36.0**	4,229	**34.5**	2,935	**34.7**	1,941	**34.8**	1,409	**34.8**	1,011	**34.3**	697	**34.1**	515	**33.9**	399	**34.1**	274	**34.0**	169	**33.8**	61	**32.7**
Waist (inches)	6,315	**44.1**	4,131	**42.2**	2,824	**42.2**	1,851	**42.4**	1,331	**42.7**	950	**42.4**	662	**42.3**	492	**42.1**	354	**42.2**	252	**42.1**	146	**42.2**	55	**41.8**
Systolic BP (mm Hg)	6,418	**125.6**	4,166	**124.6**	2,911	**125.2**	1,911	**126.3**	1,395	**127.2**	1,001	**126.9**	697	**127.1**	512	**127.5**	396	**128.7**	275	**127.1**	166	**127.5**	61	**129.5**
Diastolic BP (mm Hg)	6,418	**77.8**	4,166	**77.0**	2,911	**77.0**	1,911	**77.2**	1,395	**77.4**	1,001	**77.4**	697	**77.4**	512	**77.4**	396	**77.1**	275	**75.7**	166	**75.1**	61	**74.1**
LDL (mg/dl)	6,363	**109.8**	4,082	**107.4**	2,884	**108.1**	1,920	**107.9**	1,372	**106.5**	1,000	**107.4**	687	**107.7**	505	**108.7**	395	**109.6**	266	**107.3**	159	**105.4**	60	**102.3**
HDL (mg/dl)	6,414	**47.9**	4,112	**48.6**	2,909	**50.0**	1,928	**50.4**	1,383	**50.6**	1,007	**51.4**	690	**51.1**	507	**52.1**	394	**51.5**	267	**52.6**	159	**51.8**	60	**55.1**
Triglycerides (mg/dl)	6,412	**151.2**	4,113	**143.0**	2,909	**145.5**	1,929	**146.2**	1,381	**146.0**	1,007	**144.1**	691	**139.7**	507	**140.2**	394	**139.9**	267	**139.1**	159	**139.2**	60	**134.4**
Total Cholesterol (mg/dl)	6,415	**184.7**	4,112	**181.9**	2,910	**184.6**	1,930	**184.8**	1,383	**183.7**	1,007	**185.0**	691	**184.4**	507	**186.1**	394	**185.2**	267	**183.4**	159	**181.4**	60	**179.7**
Fasting Blood Glucose (mg/dl)	4,782	**103.1**	3,116	**99.9**	2,222	**100.5**	1,452	**101.0**	996	**101.2**	706	**101.3**	469	**101.3**	353	**101.6**	271	**101.3**	185	**101.3**	107	**104.3**	36	**109.4**
A1c (%)	2,944	**5.8**	1,707	**5.7**	1,212	**5.7**	910	**5.8**	753	**5.8**	577	**5.8**	414	**5.8**	301	**5.7**	243	**5.7**	173	**5.7**	115	**5.8**	43	**5.8**

Table 3C.02: DP Clinical Measurements at Each Assessment by Gender (Unpaired Data) (Continued)

	Male																					
	Baseline		Follow-up		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean	N	Mean
Weight (pounds)	2,184	**244.1**	1,381	**233.2**	926	**231.9**	642	**232.6**	457	**235.5**	318	**230.5**	210	**233.9**	141	**233.9**	113	**234.6**	78	**229.2**	40	**225.1**	23	**233.1**
Body Mass Index (BMI)	2,184	**35.5**	1,381	**34.0**	926	**33.9**	642	**33.9**	457	**34.5**	318	**33.8**	210	**34.4**	141	**34.4**	113	**34.5**	78	**34.0**	40	**33.5**	23	**35.0**
Waist (inches)	2,120	**45.5**	1,343	**43.7**	887	**43.8**	605	**43.9**	438	**44.1**	310	**43.8**	201	**44.2**	136	**44.5**	103	**45.1**	68	**44.5**	33	**44.7**	21	**45.7**
Systolic BP (mm Hg)	2,172	**130.2**	1,361	**127.6**	915	**128.9**	637	**128.8**	455	**128.9**	317	**129.8**	208	**129.9**	138	**130.2**	112	**129.3**	78	**128.9**	40	**130.8**	23	**126.0**
Diastolic BP (mm Hg)	2,172	**80.7**	1,361	**78.8**	915	**79.5**	637	**79.6**	455	**79.6**	317	**79.4**	208	**79.2**	138	**78.4**	112	**78.0**	78	**77.1**	40	**78.2**	23	**74.3**
LDL (mg/dl)	2,116	**110.3**	1,335	**105.3**	903	**106.4**	615	**105.8**	448	**104.0**	312	**104.1**	207	**102.1**	140	**106.3**	110	**101.5**	78	**104.1**	40	**103.3**	22	**111.2**
HDL (mg/dl)	2,167	**40.8**	1,359	**41.6**	919	**42.5**	627	**42.8**	452	**42.5**	317	**44.3**	208	**44.8**	141	**43.7**	110	**43.4**	78	**44.0**	40	**44.7**	22	**46.1**
Triglycerides (mg/dl)	2,167	**171.1**	1,359	**156.8**	919	**160.6**	627	**163.6**	452	**158.9**	318	**158.1**	208	**154.1**	141	**161.5**	110	**151.8**	78	**138.2**	40	**138.7**	22	**132.8**
Total Cholesterol (mg/dl)	2,169	**181.5**	1,359	**174.4**	919	**178.3**	628	**178.4**	453	**175.1**	318	**177.1**	207	**175.2**	141	**180.3**	110	**172.3**	78	**172.9**	40	**172.7**	22	**183.7**
Fasting Blood Glucose (mg/dl)	1,654	**104.9**	1,056	**102.7**	741	**102.5**	491	**103.4**	335	**103.7**	222	**105.2**	146	**104.1**	110	**105.7**	86	**105.5**	63	**105.5**	31	**109.6**	17	**106.9**
A1c (%)	937	**5.8**	521	**5.7**	346	**5.7**	293	**5.8**	239	**5.8**	192	**5.8**	138	**5.8**	79	**5.8**	60	**5.8**	44	**5.7**	27	**5.7**	15	**5.8**

Table 3C.03: DP Clinical Outcome Changes from Baseline (Paired Data)

Outcome	Follow-up (N=5639)	1st Annual (N=3903)	2nd Annual (N=2616)	3rd Annual (N=1885)	4th Annual (N=1343)	5th Annual (N= 918)	6th Annual (N= 661)	7th Annual (N= 518)	8th Annual (N= 357)	9th Annual (N= 212)	10th Annual (N= 86)
Mean Percent Weight Loss (pounds)*	-3.8	-2.8	-1.9	-1.5	-1.5	-1.1	-1.1	-1.3	-1.2	-0.7	0.1
Median Change in Body Mass Index (BMI)	-1.2	-0.7	-0.5	-0.3	-0.4	-0.2	-0.2	-0.3	-0.2	0.1	0.1
Median Change in Waist (inches)	-1.5	-1.0	-0.5	-0.3	0.0	0.0	0.5	0.5	0.3	1.0	1.0
Median Change in Systolic BP (mm Hg)	-2.0	0.0	0.0	0.0	0.0	2.0	2.0	1.0	2.0	3.0	0.0
Median Change in Diastolic BP (mm Hg)	-1.0	0.0	-1.0	0.0	0.0	0.0	0.0	-1.0	-2.0	-2.0	-5.5
Median Change in LDL (mg/dl)	-3.0	-2.0	-3.0	-4.0	-3.0	-4.0	-3.8	-5.0	-6.0	-6.0	-6.3
Median Change in HDL (mg/dl)	0.0	1.9	1.0	2.0	2.0	2.0	3.0	2.0	3.0	3.0	5.0
Median Change in Triglycerides (mg/dl)	-7.0	-6.0	-5.0	-3.0	-4.0	-8.0	-8.0	-6.0	-9.0	-3.5	0.0
Median Change in Total Cholesterol (mg/dl)	-4.0	-2.0	-3.0	-3.0	-3.0	-3.0	-4.0	-3.5	-6.0	-6.0	-3.0

* The change in weight is presented as the mean rather than the median because the weight loss goal is defined by percent change in weight, and reporting the mean percent change in weight facilitates comparisons with previous reports and other interventions.

Table 3C.04 : DP Clinical Outcome Changes from Baseline by Gender (Paired Data)

Female

Outcome	Follow-up (N=4250)	1st Annual (N=2967)	2nd Annual (N=1969)	3rd Annual (N=1420)	4th Annual (N=1020)	5th Annual (N= 704)	6th Annual (N= 517)	7th Annual (N= 404)	8th Annual (N= 277)	9th Annual (N= 171)	10th Annual (N= 63)
Mean Percent Weight Loss (pounds)*	-3.6	-2.8	-1.8	-1.6	-1.6	-1.4	-1.1	-1.4	-1.4	-0.8	-1.1
Median Change in Body Mass Index (BMI)	-1.1	-0.7	-0.5	-0.4	-0.4	-0.3	-0.2	-0.3	-0.2	0.1	-0.4
Median Change in Waist (inches)	-1.5	-1.0	-0.5	-0.3	0.0	0.0	0.5	0.5	0.3	1.0	0.8
Median Change in Systolic BP (mm Hg)	-1.0	0.0	0.0	0.0	0.0	2.0	2.0	2.0	2.0	4.0	1.0
Median Change in Diastolic BP (mm Hg)	0.0	0.0	0.0	-1.0	0.0	0.0	0.0	0.0	-2.0	-1.5	-3.0
Median Change in LDL (mg/dl)	-2.0	-1.5	-3.0	-4.0	-4.0	-4.0	-3.7	-4.0	-5.0	-6.0	-6.0
Median Change in HDL (mg/dl)	0.0	1.0	1.0	2.0	2.0	2.0	3.0	3.0	4.0	4.0	5.5
Median Change in Triglycerides (mg/dl)	-5.0	-5.0	-4.0	-3.0	-3.0	-7.0	-6.0	-6.0	-7.0	-3.5	-3.0
Median Change in Total Cholesterol (mg/dl)	-3.0	-1.0	-3.0	-2.0	-3.0	-3.0	-3.0	-2.5	-2.0	-5.0	-3.0

* The change in weight is presented as the mean rather than the median because the weight loss goal is defined by percent change in weight, and reporting the mean percent change in weight facilitates comparisons with previous reports and other interventions.

Table 3C.04: DP Clinical Outcome Changes from Baseline by Gender (Paired Data) (Continued)

Male

Outcome	Follow-up (N=1389)	1st Annual (N= 936)	2nd Annual (N= 647)	3rd Annual (N= 465)	4th Annual (N= 323)	5th Annual (N= 214)	6th Annual (N= 144)	7th Annual (N= 114)	8th Annual (N= 80)	9th Annual (N= 41)	10th Annual (N= 23)
Mean Percent Weight Loss (pounds)*	-4.2	-3.0	-2.2	-1.3	-1.2	-0.2	-1.2	-0.8	-0.6	-0.3	3.2
Median Change in Body Mass Index (BMI)	-1.3	-0.8	-0.6	-0.2	-0.3	-0.1	-0.3	-0.1	-0.3	-0.0	0.4
Median Change in Waist (inches)	-1.5	-1.0	-0.5	-0.3	-0.3	0.0	0.0	1.0	0.3	1.0	1.5
Median Change in Systolic BP (mm Hg)	-2.0	0.0	-2.0	0.0	0.0	1.0	2.0	-2.0	-1.0	0.0	-6.0
Median Change in Diastolic BP (mm Hg)	-2.0	0.0	-1.0	0.0	0.0	0.0	-2.0	-2.0	-4.0	-6.0	-8.0
Median Change in LDL (mg/dl)	-4.0	-4.0	-1.0	-3.0	-2.0	-3.6	-4.0	-7.0	-12.9	-15.0	-11.0
Median Change in HDL (mg/dl)	1.0	2.0	1.0	1.0	2.0	2.0	1.0	1.0	2.0	1.0	1.5
Median Change in Triglycerides (mg/dl)	-14.0	-9.0	-10.0	-5.0	-9.0	-15.0	-15.0	-11.5	-19.0	1.5	4.0
Median Change in Total Cholesterol (mg/dl)	-6.0	-4.0	-3.5	-4.0	-1.5	-4.0	-7.0	-8.0	-15.0	-17.0	-1.5

* The change in weight is presented as the mean rather than the median because the weight loss goal is defined by percent change in weight, and reporting the mean percent change in weight facilitates comparisons with previous reports and other interventions.

Table 3C.05: DP Percentage of Participants Achieving Goals for Primary Outcomes at Each Assessment (Unpaired Data)

% of Participants Achieving Goal	Baseline		Follow-up		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Weight Loss (7%)	8,642	**n/a**	5,610	**22**	3,861	**21**	2,583	**19**	1,866	**19**	1,329	**20**	907	**21**	656	**22**	512	**22**	352	**25**	209	**22**	84	**24**
Waist (men <= 40", women <= 35")	8,435	**11**	5,474	**18**	3,711	**18**	2,456	**17**	1,769	**16**	1,260	**16**	863	**15**	628	**13**	457	**14**	320	**11**	179	**11**	76	**18**

Table 3C.06: DP Percentage of Participants Meeting Recommended Targets for Secondary Outcomes at Each Assessment (Unpaired Data)

% of Participants Meeting Recommended Target	Baseline		Follow-up		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Systolic BP (< 130 mm Hg)	8,590	**60**	5,527	**63**	3,826	**62**	2,548	**60**	1,850	**58**	1,318	**59**	905	**56**	650	**56**	508	**56**	353	**59**	206	**55**	84	**55**
Diastolic BP (< 80 mm Hg)	8,590	**52**	5,527	**56**	3,826	**55**	2,548	**54**	1,850	**53**	1,318	**53**	905	**53**	650	**54**	508	**56**	353	**60**	206	**62**	84	**67**
LDL (< 100 mg/dl)	8,479	**39**	5,417	**43**	3,787	**41**	2,535	**41**	1,820	**45**	1,312	**44**	894	**43**	645	**42**	505	**44**	344	**43**	199	**45**	82	**45**
HDL (men > 40 mg/dl, women > 50 mg/dl)	8,581	**37**	5,471	**39**	3,828	**43**	2,555	**44**	1,835	**45**	1,324	**49**	898	**47**	648	**49**	504	**48**	345	**52**	199	**47**	82	**59**
Triglycerides (< 150 mg/dl)	8,579	**58**	5,472	**64**	3,828	**62**	2,556	**61**	1,833	**60**	1,325	**61**	899	**64**	648	**60**	504	**62**	345	**66**	199	**65**	82	**66**
Glycemic Measure in Normal Range	8,652	**16**	5,580	**43**	3,871	**39**	2,598	**38**	1,870	**35**	1,338	**34**	915	**34**	661	**36**	518	**37**	355	**37**	212	**27**	85	**25**
Non-Smoker	8,295	**77**	5,330	**79**	3,535	**80**	2,442	**82**	1,832	**83**	1,334	**84**	910	**84**	658	**84**	517	**88**	354	**89**	212	**85**	86	**88**

Table 3C.07: DP Percentage of Participants Achieving Goals for Primary Outcomes at Each Assessment by Gender (Unpaired Data)

% of Participants Achieving Goal	Female																					
	Baseline		Follow-up		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Weight Loss (7%)	6,458	**n/a**	4,229	**21**	2,935	**21**	1,941	**19**	1,409	**20**	1,011	**21**	697	**22**	515	**23**	399	**23**	274	**25**	169	**23**	61	**28**
Waist (men <= 40", women <= 35")	6,315	**7**	4,131	**13**	2,824	**13**	1,851	**12**	1,331	**12**	950	**11**	662	**10**	492	**9**	354	**11**	252	**8**	146	**8**	55	**20**

% of Participants Achieving Goal	Male																					
	Baseline		Follow-up		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Weight Loss (7%)	2,184	**n/a**	1,381	**25**	926	**21**	642	**20**	457	**16**	318	**17**	210	**19**	141	**21**	113	**19**	78	**26**	40	**15**	23	**13**
Waist (men <= 40", women <= 35")	2,120	**23**	1,343	**34**	887	**33**	605	**32**	438	**28**	310	**31**	201	**31**	136	**26**	103	**23**	68	**22**	33	**24**	21	**14**

Table 3C.08: DP Percentage of Participants Meeting Recommended Targets for Secondary Outcomes at Each Assessment by Gender (Unpaired Data)

% of Participants Meeting Recommended Target	Female																					
	Baseline		Follow-up		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Systolic BP (< 130 mm Hg)	6,418	**63**	4,166	**66**	2,911	**65**	1,911	**62**	1,395	**60**	1,001	**61**	697	**58**	512	**58**	396	**56**	275	**61**	166	**57**	61	**52**
Diastolic BP (< 80 mm Hg)	6,418	**55**	4,166	**58**	2,911	**58**	1,911	**57**	1,395	**56**	1,001	**55**	697	**56**	512	**56**	396	**58**	275	**61**	166	**64**	61	**69**
LDL (< 100 mg/dl)	6,363	**38**	4,082	**42**	2,884	**41**	1,920	**40**	1,372	**44**	1,000	**43**	687	**41**	505	**42**	395	**41**	266	**41**	159	**43**	60	**50**
HDL (men > 40 mg/dl, women > 50 mg/dl)	6,414	**35**	4,112	**37**	2,909	**41**	1,928	**42**	1,383	**43**	1,007	**46**	690	**46**	507	**48**	394	**48**	267	**49**	159	**44**	60	**57**
Triglycerides (< 150 mg/dl)	6,412	**60**	4,113	**64**	2,909	**63**	1,929	**63**	1,381	**61**	1,007	**62**	691	**65**	507	**62**	394	**63**	267	**65**	159	**66**	60	**65**
Glycemic Measure in Normal Range	6,467	**16**	4,200	**44**	2,942	**39**	1,958	**38**	1,409	**37**	1,015	**36**	701	**36**	517	**37**	404	**39**	276	**38**	171	**31**	62	**27**
Non-Smoker	6,210	**77**	4,039	**80**	2,691	**81**	1,827	**83**	1,383	**85**	1,014	**84**	698	**85**	515	**86**	403	**88**	275	**88**	171	**87**	63	**90**

% of Participants Meeting Recommended Target	Male																					
	Baseline		Follow-up		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Systolic BP (< 130 mm Hg)	2,172	**50**	1,361	**55**	915	**53**	637	**54**	455	**52**	317	**52**	208	**48**	138	**49**	112	**55**	78	**51**	40	**48**	23	**61**
Diastolic BP (< 80 mm Hg)	2,172	**42**	1,361	**49**	915	**46**	637	**46**	455	**46**	317	**45**	208	**42**	138	**47**	112	**50**	78	**56**	40	**55**	23	**61**
LDL (< 100 mg/dl)	2,116	**39**	1,335	**45**	903	**42**	615	**45**	448	**47**	312	**47**	207	**49**	140	**42**	110	**54**	78	**50**	40	**55**	22	**32**
HDL (men > 40 mg/dl, women > 50 mg/dl)	2,167	**45**	1,359	**48**	919	**50**	627	**51**	452	**50**	317	**58**	208	**52**	141	**52**	110	**49**	78	**62**	40	**60**	22	**64**
Triglycerides (< 150 mg/dl)	2,167	**54**	1,359	**63**	919	**59**	627	**58**	452	**55**	318	**59**	208	**61**	141	**54**	110	**57**	78	**68**	40	**60**	22	**68**
Glycemic Measure in Normal Range	2,185	**15**	1,380	**40**	929	**37**	640	**36**	461	**30**	323	**28**	214	**26**	144	**32**	114	**30**	79	**35**	41	**12**	23	**17**
Non-Smoker	2,085	**75**	1,291	**78**	844	**78**	615	**77**	449	**78**	320	**82**	212	**79**	143	**78**	114	**88**	79	**91**	41	**78**	23	**83**

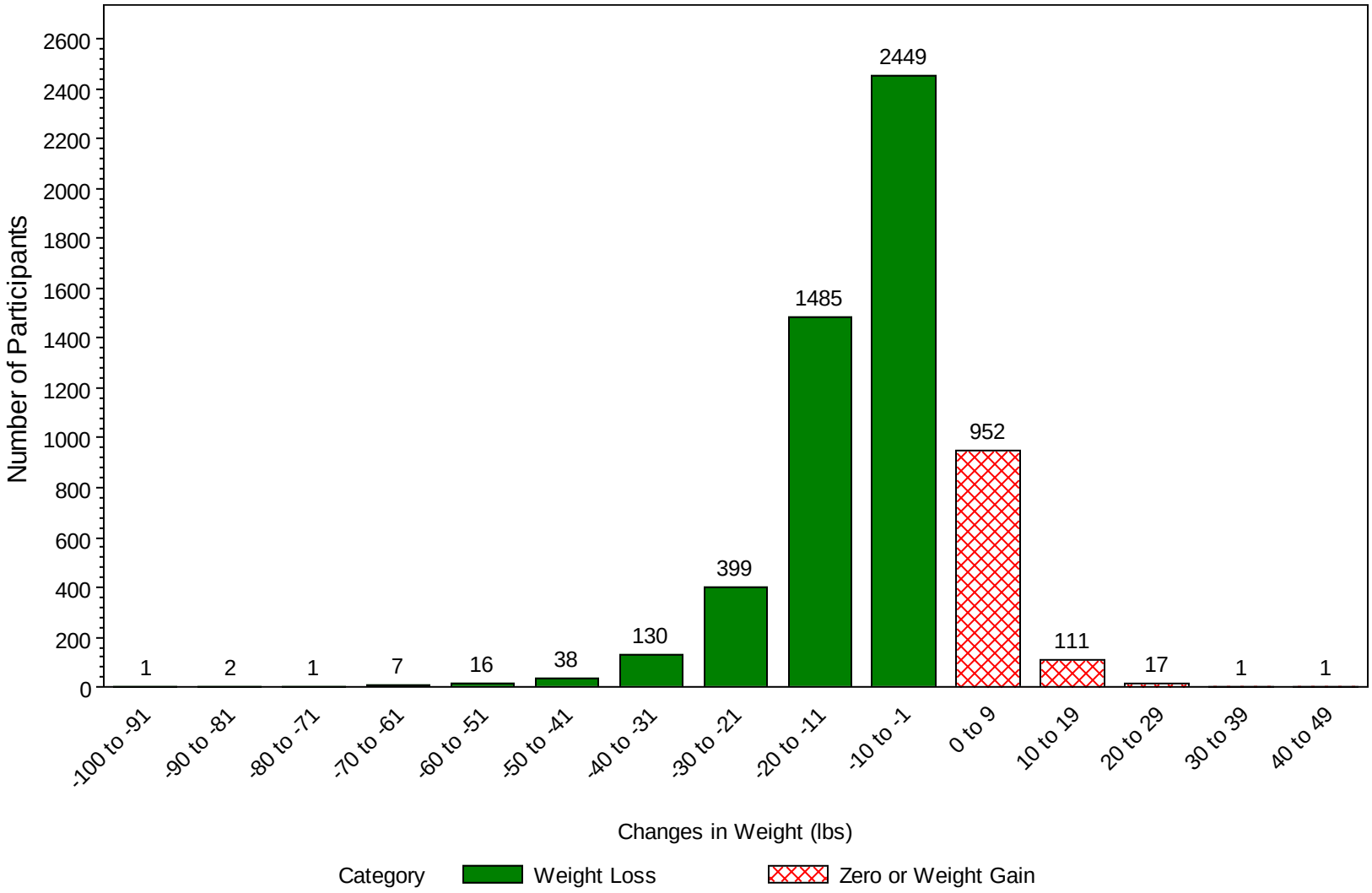


Figure 3C.01: DP Weight Changes from Baseline to Follow-up (Paired Data, Illustration)

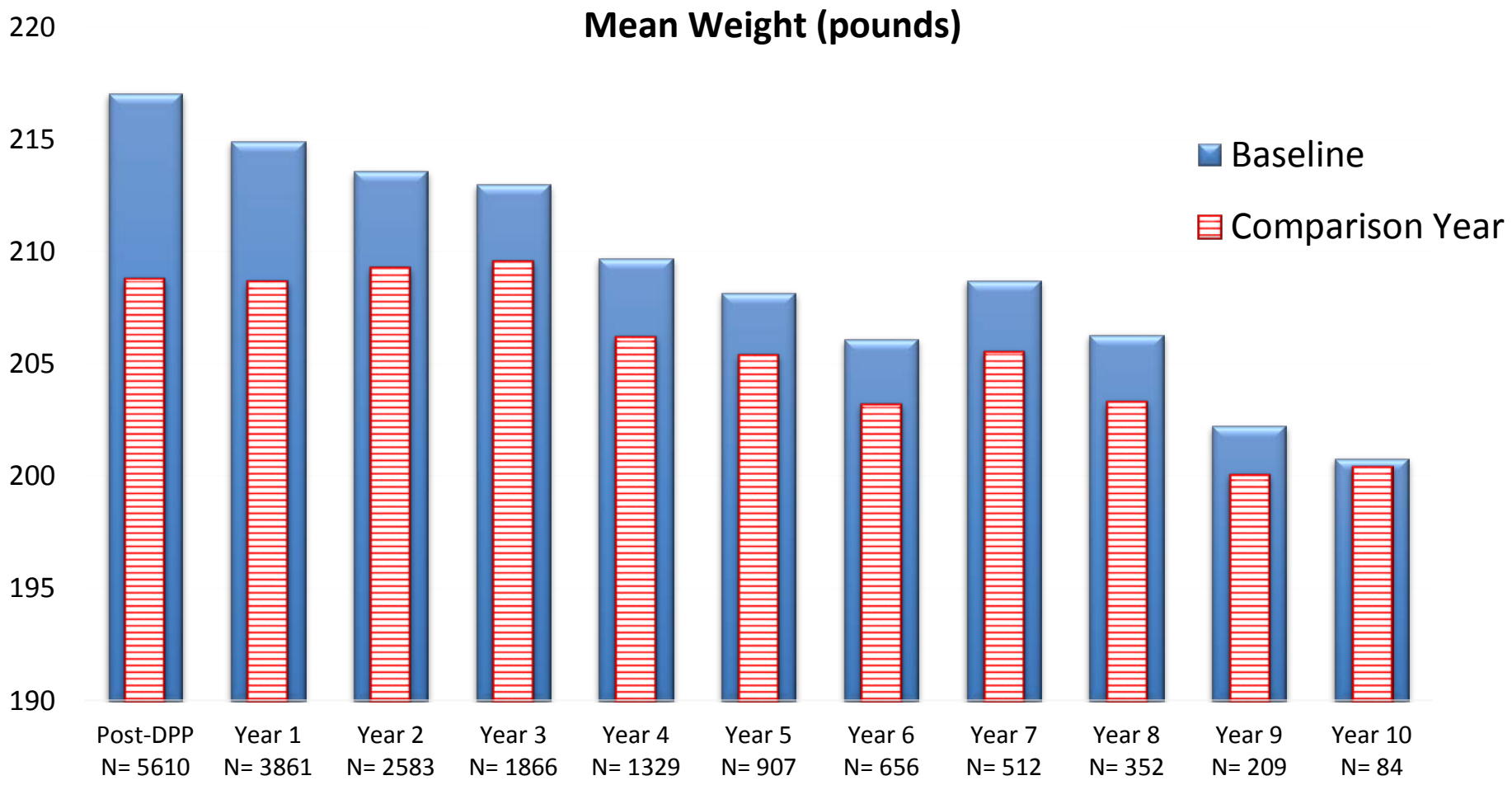


Figure 3C.02: DP Weight Changes from Baseline (Paired Data)

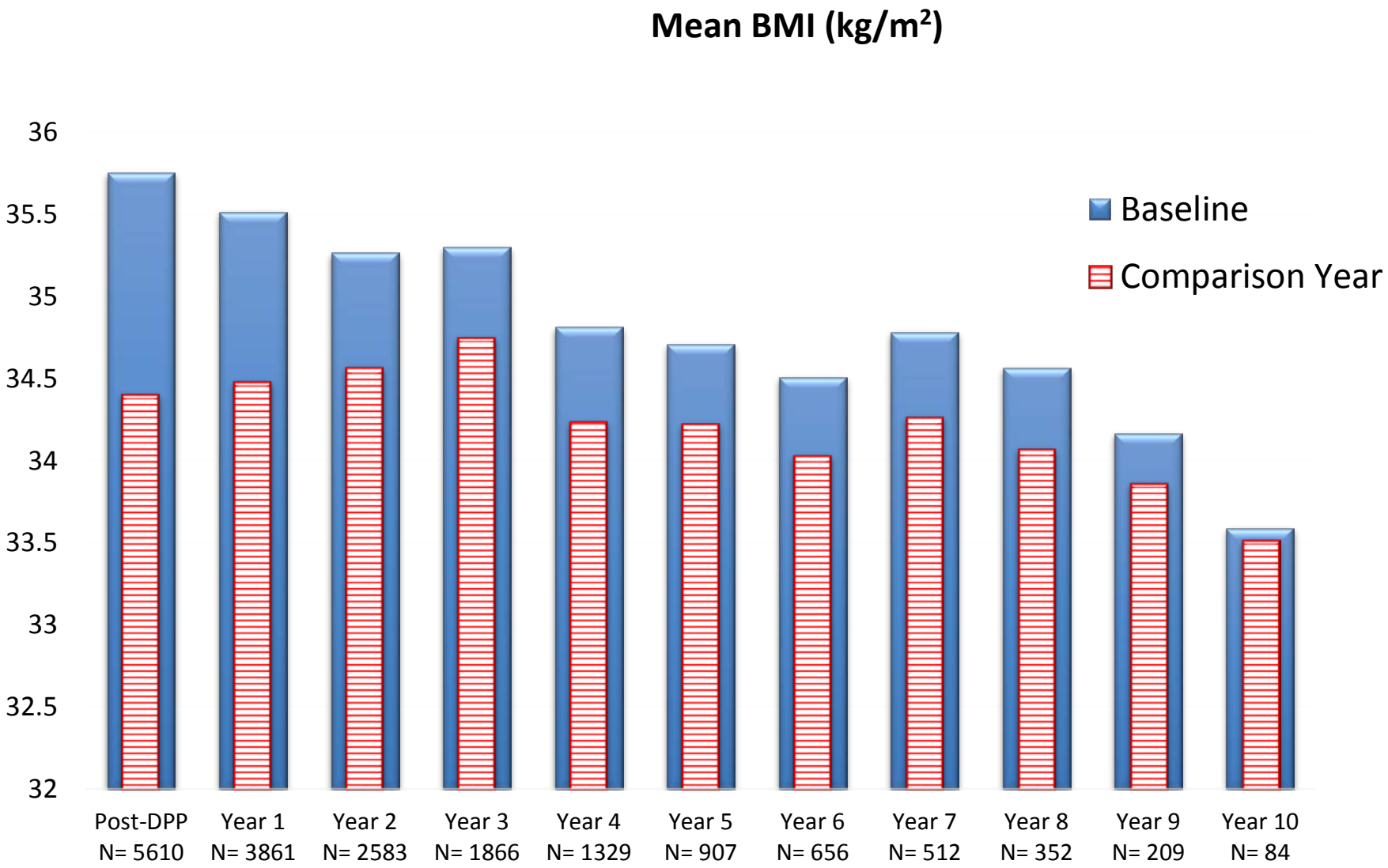


Figure 3C.03: DP BMI Changes from Baseline (Paired Data)

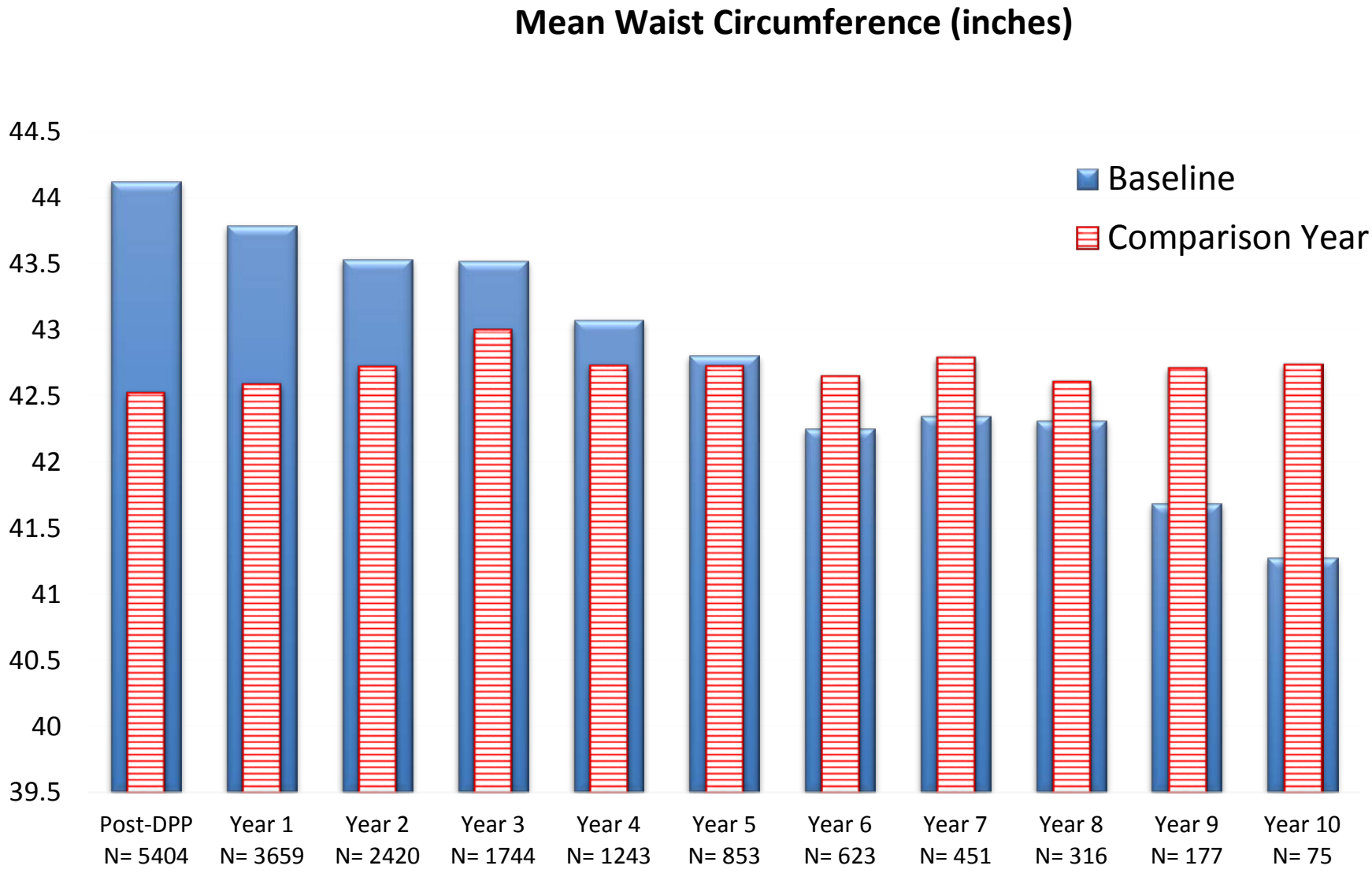


Figure 3C.04: DP Waist Circumference Changes from Baseline (Paired Data)

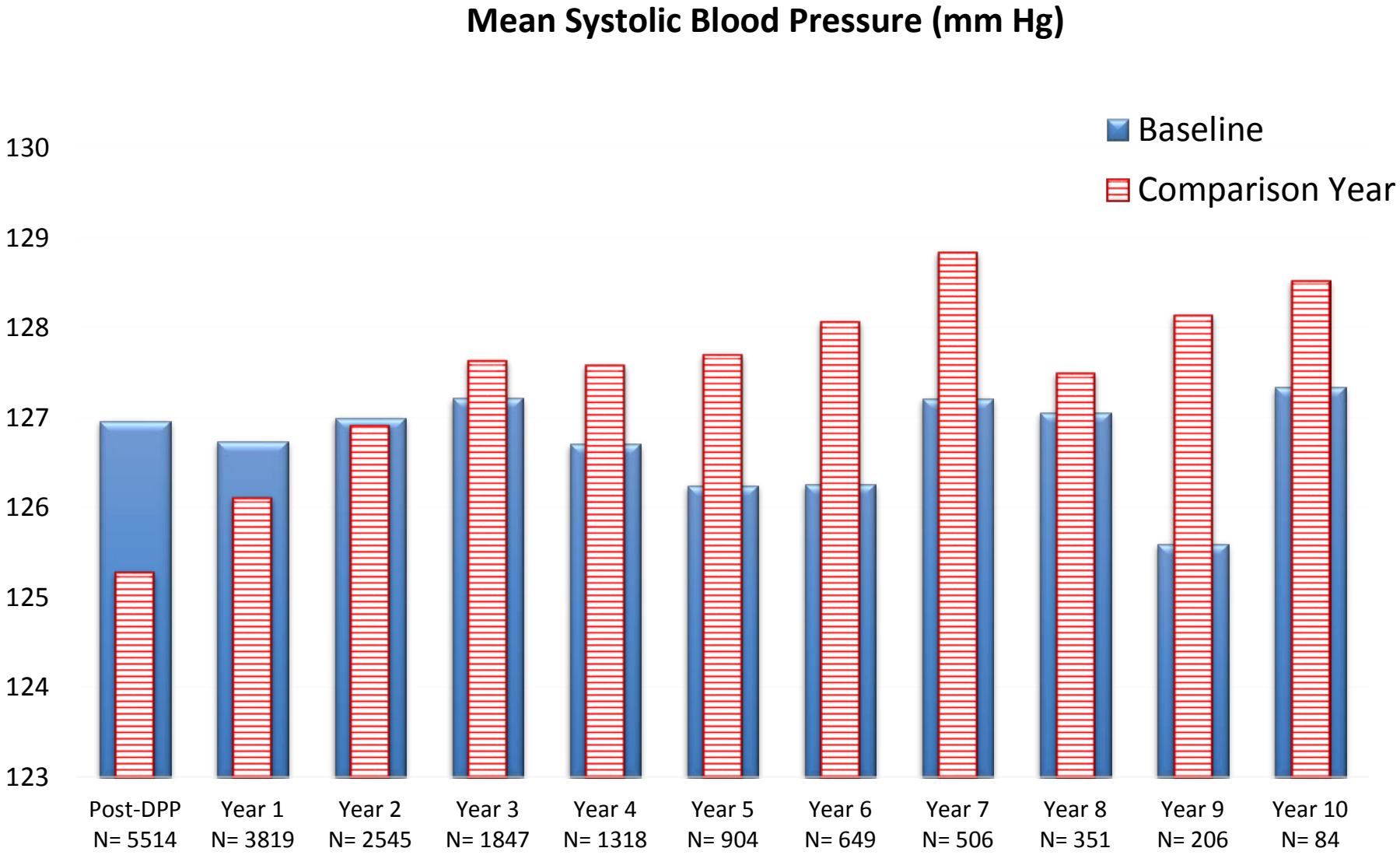


Figure 3C.05: DP Systolic Blood Pressure Changes from Baseline (Paired Data)

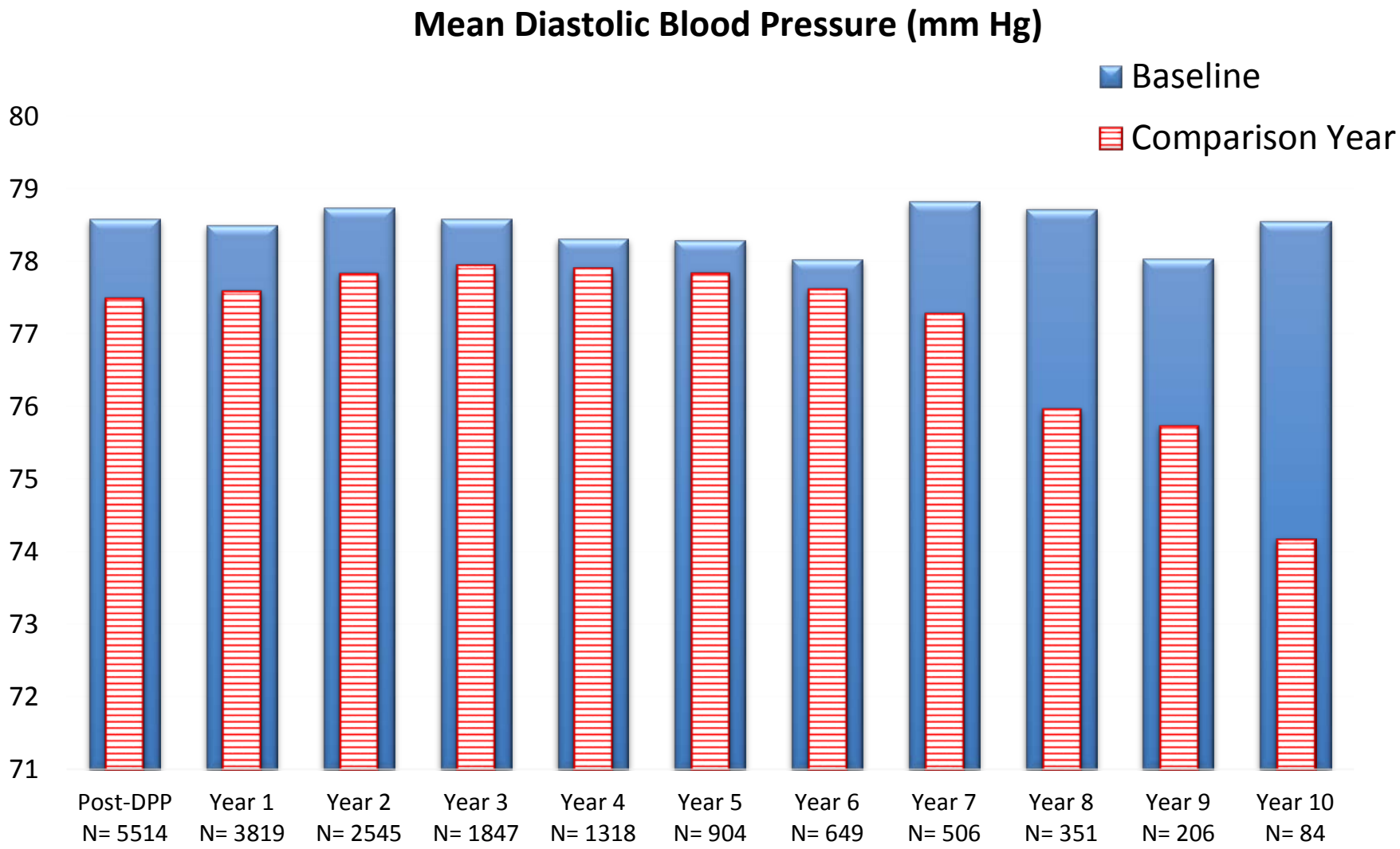


Figure 3C.06: DP Diastolic Blood Pressure Changes from Baseline (Paired Data)

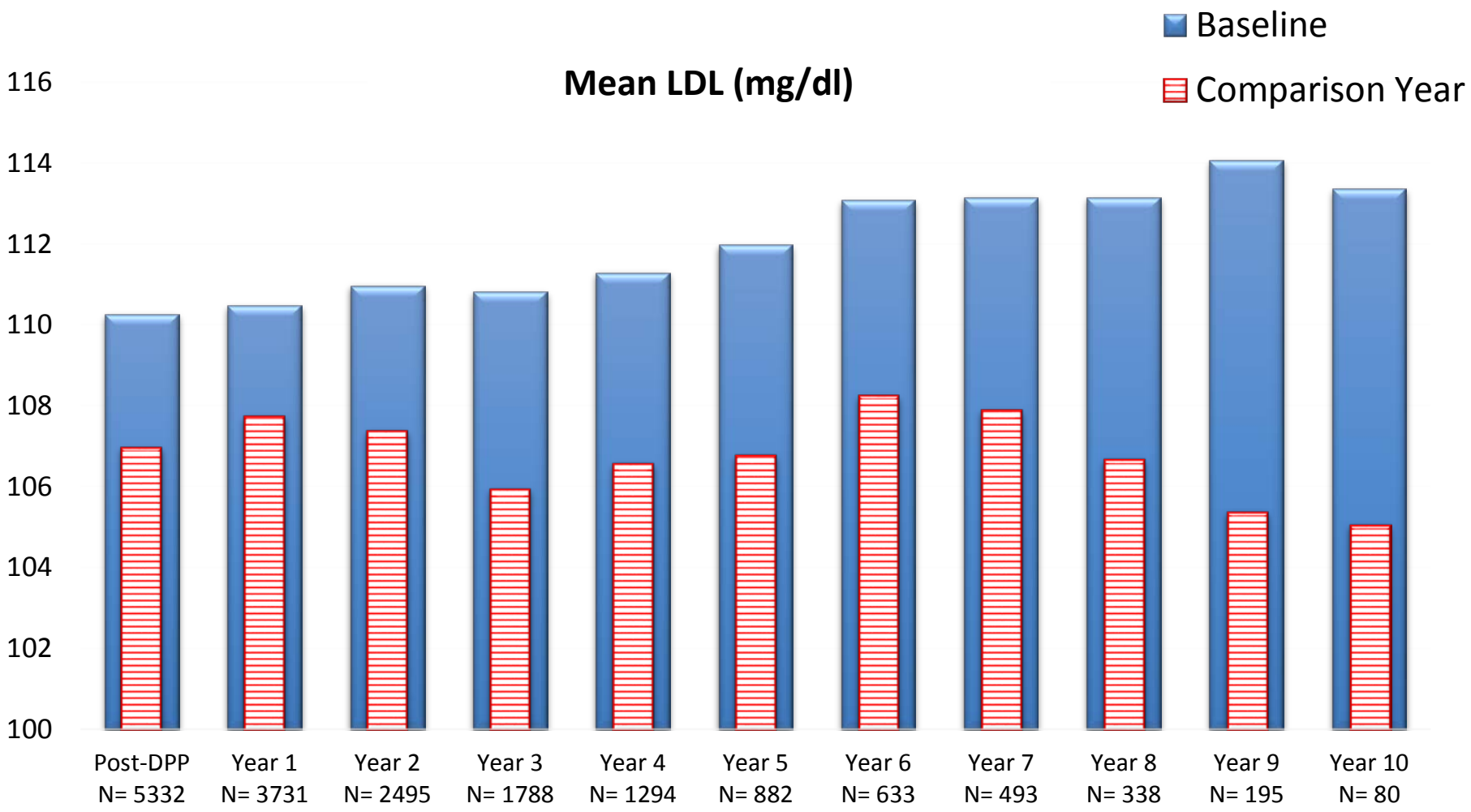
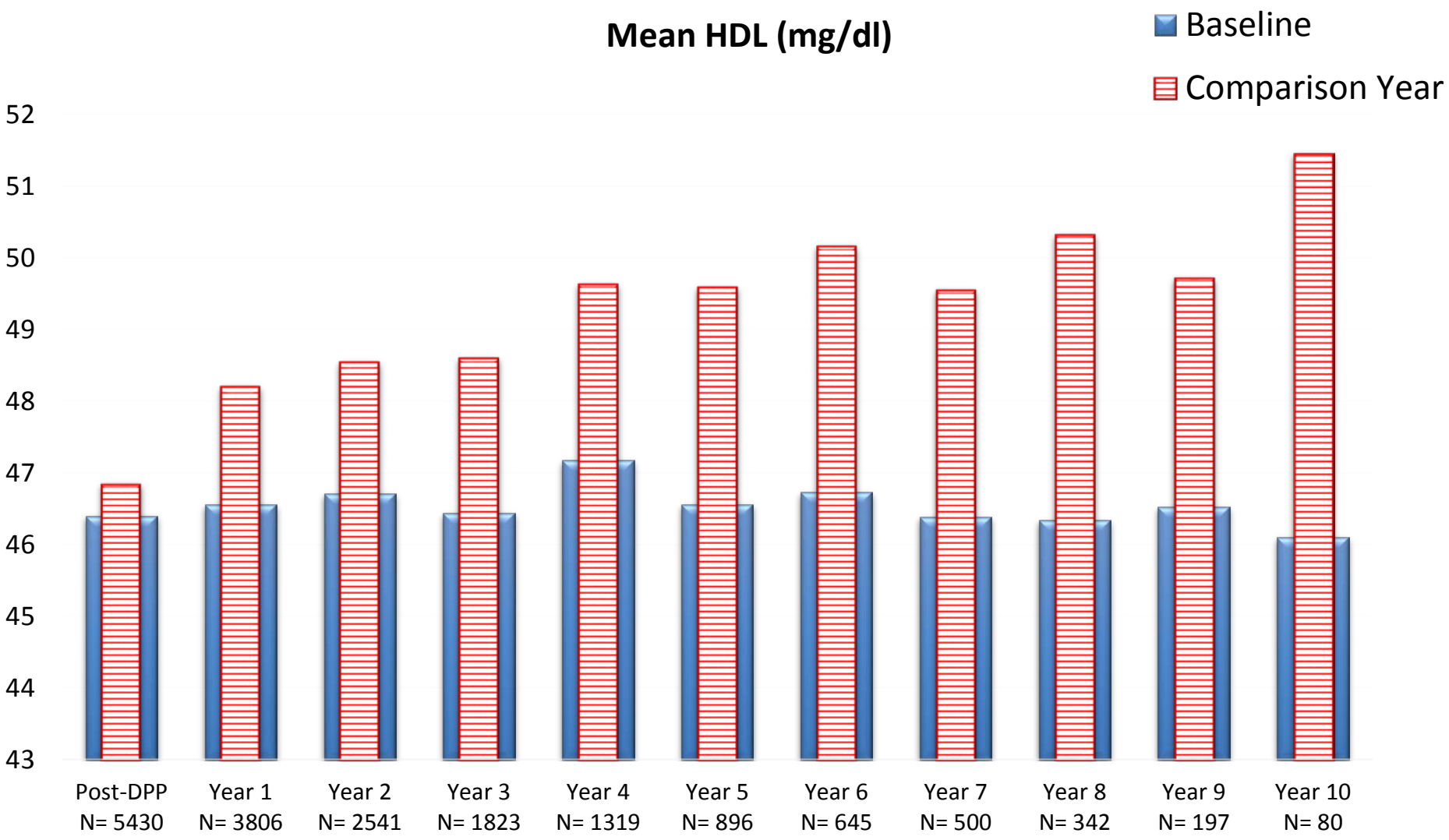


Figure 3C.07: DP LDL Changes from Baseline (Paired Data)



3C.08: DP HDL Changes from Baseline (Paired Data)

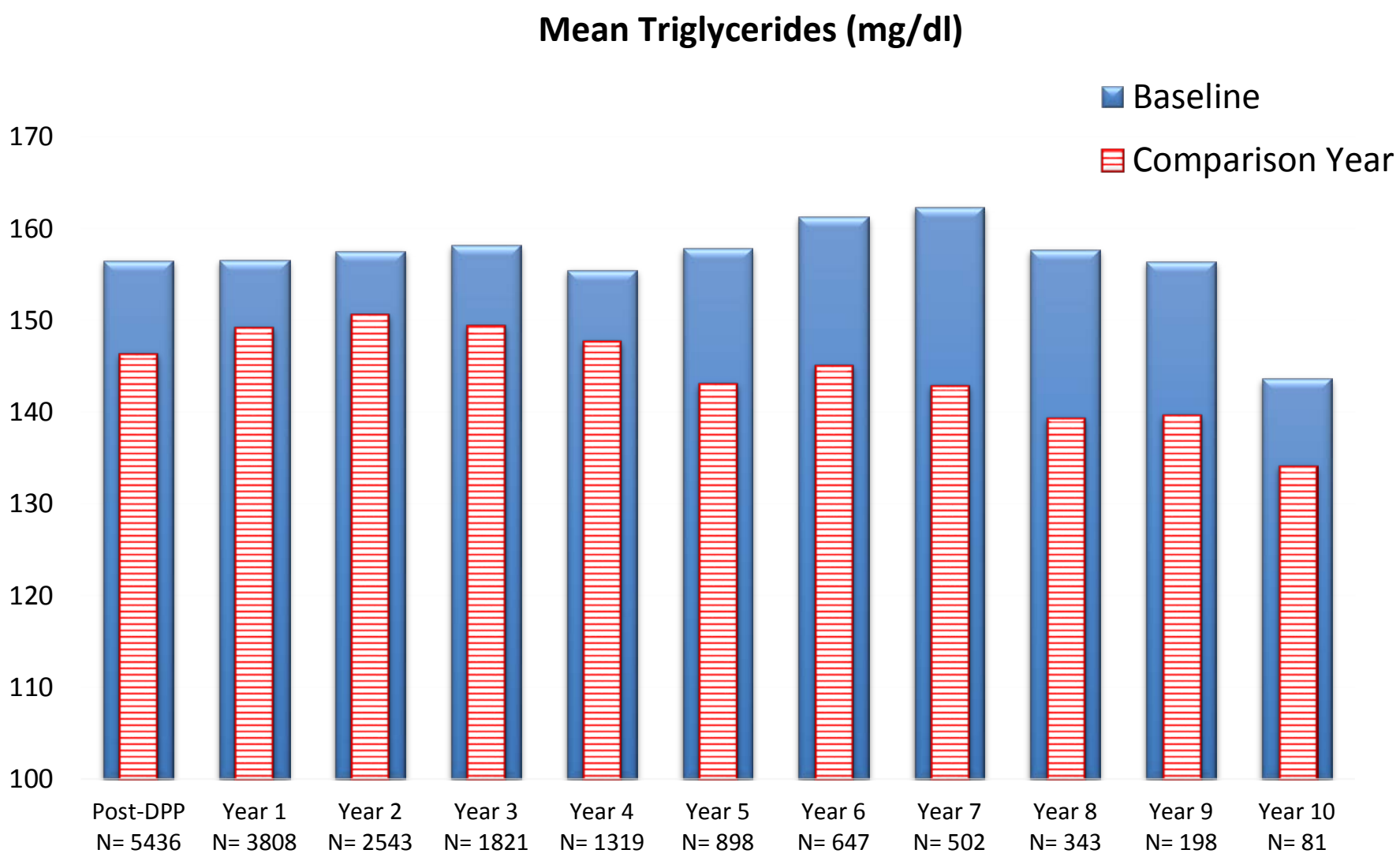


Figure 3C.09: DP Triglycerides Changes from Baseline (Paired Data)

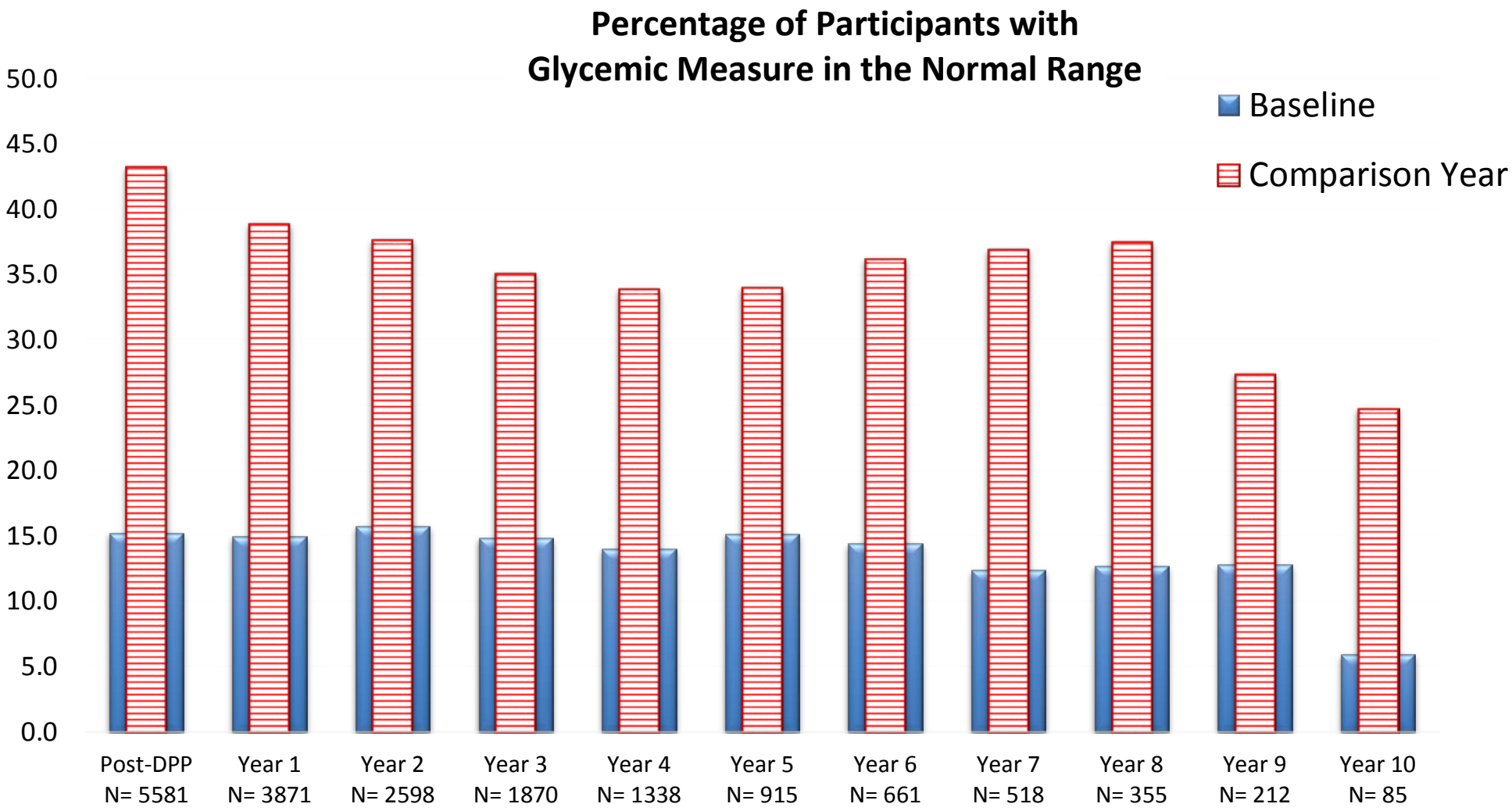


Figure 3C.10 DP Glycemic Measure in Normal Range (Paired Data)

D. Lifestyle Measurements:

Lifestyle measurements are reported in Tables 3D.01 (unpaired data) and 3D.02 (unpaired data by gender). These tables show that:

- Physical Activity (Aerobic): 30.3% of the participants reported active engagement in aerobic physical activity at baseline, while 7.2% reported a sedentary lifestyle. The percentage of participants reporting active physical activity was higher than baseline at the follow-up assessment and at each year except Year 10 (unpaired data). Examining paired data, the percentage of participants reporting active physical activity was higher than baseline at the follow-up assessment and at each year except Year 7 and Year 10 (Figure 3D.01).
  - An active level of physical activity was defined as engaging in:
    - 30 minutes or more per day of moderate physical activities 5 or more days a week **or**
    - 20 minutes or more per day of vigorous physical activities 3 or more days a week
  - An under-active regular level of physical activity was defined as engaging in:
    - moderate physical activities every week but less than 30 minutes a day for 5 days **or**
    - vigorous physical activities every week but less than 20 minutes a day for 3 days **or**
    - some light physical activity every week
  - An under-active level of physical activity was defined as engaging in some light or moderate physical activities less frequently than every week.
  - A sedentary lifestyle was defined as rarely or never engaging in physical activities.
- Strength and Flexibility: The percentage of participants reporting engaging in activities to improve flexibility or both strength and flexibility was up from baseline at the follow-up assessment and at each year (unpaired data).
- Healthy Diet Score: The Healthy Diet Score is constructed by taking the average of the scores from six questions (frequency of eating whole grain bread, fruit, lettuce or green leafy salad, cooked dried beans, fish/chicken/game, vegetables) from the participant questionnaire. Responses ranged from 1 (rarely eaten) to 6 (eaten daily), so a higher score indicates a greater frequency of eating healthy foods. The mean Healthy Diet Score was greater than the baseline mean at each subsequent time point (Figure 3D.02, paired data).
- Unhealthy Diet Score: The Unhealthy Diet Score is constructed by taking the average of the scores from twelve questions (frequency of eating bacon or sausage, processed meats, bread from processed flour, frybread, other baked goods, regular soft drinks/soda, 100% fruit juice, adding sugar or cream to coffee or tea, regular fat salad dressing or mayonnaise, French fries/fried potatoes/tater tots/hash brown potatoes, “red” meat, fast food) from the participant questionnaire. Responses ranged from 1 (rarely eaten) to 6 (eaten daily), so a higher score indicates a greater frequency of eating unhealthy foods. The mean Unhealthy Diet Score was less than the baseline mean at each subsequent time point (Figure 3D.03, paired data).

Table 3D.01: DP Lifestyle Measurements at Each Assessment (Unpaired Data)

Lifestyle Characteristic	Category	Baseline		Follow-Up		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
		N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean
Rapid Assessment of Physical Activity: Aerobic	Sedentary (%)	570	**7.2**	78	**1.6**	106	**3.2**	94	**4.2**	87	**5.4**	60	**5.2**	33	**4.2**	33	**5.7**	29	**6.7**	17	**5.6**	9	**5.0**	2	**3.1**
	Under-Active (%)	989	**12.5**	253	**5.0**	318	**9.6**	245	**11.0**	194	**11.9**	109	**9.4**	111	**14.2**	98	**17.0**	62	**14.2**	37	**12.2**	27	**15.1**	12	**18.8**
	Under-Active: Regular (%)	3956	**50.0**	2029	**40.3**	1494	**45.0**	1021	**45.9**	715	**44.0**	523	**45.2**	356	**45.6**	257	**44.7**	207	**47.5**	130	**42.9**	77	**43.0**	32	**50.0**
	Active (%)	2395	**30.3**	2669	**53.1**	1401	**42.2**	865	**38.9**	628	**38.7**	464	**40.1**	281	**36.0**	187	**32.5**	138	**31.7**	119	**39.3**	66	**36.9**	18	**28.1**
Rapid Assessment of Physical Activity: Strength and Flexibility	No Strength or Flexibility (%)	4743	**61.9**	1575	**32.7**	1461	**46.5**	972	**46.1**	717	**46.4**	457	**42.7**	305	**42.1**	246	**46.4**	173	**42.8**	132	**46.5**	63	**38.7**	23	**39.7**
	Strength (%)	768	**10.0**	672	**14.0**	503	**16.0**	296	**14.0**	185	**12.0**	114	**10.6**	80	**11.0**	53	**10.0**	42	**10.4**	33	**11.6**	15	**9.2**	8	**13.8**
	Flexibility (%)	1129	**14.7**	963	**20.0**	558	**17.8**	381	**18.1**	297	**19.2**	207	**19.3**	164	**22.6**	112	**21.1**	95	**23.5**	48	**16.9**	37	**22.7**	12	**20.7**
	Both Strength & Flexibility (%)	1026	**13.4**	1604	**33.3**	617	**19.7**	459	**21.8**	347	**22.4**	293	**27.4**	176	**24.3**	119	**22.5**	94	**23.3**	71	**25.0**	48	**29.4**	15	**25.9**
Food Consumption	Mean Healthy Diet Score	8014	**3.5**	5055	**3.8**	3349	**3.7**	2247	**3.7**	1642	**3.7**	1159	**3.7**	787	**3.7**	579	**3.7**	440	**3.8**	310	**3.7**	182	**3.6**	70	**3.7**
	Mean Unhealthy Diet Score	8023	**2.9**	5048	**2.4**	3350	**2.5**	2245	**2.6**	1642	**2.6**	1162	**2.6**	786	**2.7**	580	**2.7**	441	**2.7**	311	**2.7**	182	**2.6**	70	**2.8**

Table 3D.02: DP Lifestyle Measurements at Each Assessment by Gender (Unpaired Data)

Lifestyle Characteristic	Category	Female																					
		Baseline		Follow-Up		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
		N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean
Rapid Assessment of Physical Activity: Aerobic	Sedentary (%)	468	**7.9**	66	**1.7**	95	**3.8**	81	**4.9**	73	**6.0**	51	**5.8**	28	**4.7**	29	**6.5**	26	**7.8**	16	**6.8**	9	**6.3**	2	**4.5**
	Under-Active (%)	810	**13.7**	215	**5.6**	253	**10.1**	206	**12.3**	164	**13.4**	91	**10.4**	93	**15.6**	81	**18.2**	50	**15.0**	33	**14.1**	24	**16.8**	9	**20.5**
	Under-Active: Regular (%)	3084	**52.1**	1618	**42.4**	1200	**47.7**	801	**48.0**	550	**44.9**	393	**45.0**	276	**46.3**	200	**44.9**	162	**48.6**	101	**43.2**	58	**40.6**	20	**45.5**
	Active (%)	1556	**26.3**	1916	**50.2**	966	**38.4**	581	**34.8**	438	**35.8**	339	**38.8**	199	**33.4**	135	**30.3**	95	**28.5**	84	**35.9**	52	**36.4**	13	**29.5**
Rapid Assessment of Physical Activity: Strength and Flexibility	No Strength or Flexibility (%)	3757	**65.5**	1261	**34.6**	1163	**48.8**	768	**48.5**	575	**49.2**	363	**44.8**	257	**46.1**	208	**50.6**	139	**45.0**	106	**48.2**	53	**40.8**	19	**45.2**
	Strength (%)	436	**7.6**	434	**11.9**	325	**13.6**	192	**12.1**	109	**9.3**	73	**9.0**	44	**7.9**	37	**9.0**	22	**7.1**	18	**8.2**	9	**6.9**	3	**7.1**
	Flexibility (%)	883	**15.4**	772	**21.2**	461	**19.4**	302	**19.1**	237	**20.3**	166	**20.5**	135	**24.2**	85	**20.7**	82	**26.5**	44	**20.0**	29	**22.3**	10	**23.8**
	Both Strength & Flexibility (%)	663	**11.6**	1178	**32.3**	433	**18.2**	323	**20.4**	247	**21.1**	208	**25.7**	122	**21.9**	81	**19.7**	66	**21.4**	52	**23.6**	39	**30.0**	10	**23.8**
Food Consumption	Mean Healthy Diet Score	6003	**3.5**	3839	**3.8**	2540	**3.7**	1681	**3.7**	1236	**3.7**	875	**3.7**	602	**3.7**	448	**3.7**	336	**3.8**	240	**3.7**	145	**3.6**	50	**3.7**
	Mean Unhealthy Diet Score	6008	**2.9**	3830	**2.3**	2539	**2.5**	1680	**2.5**	1235	**2.6**	877	**2.5**	601	**2.6**	449	**2.6**	338	**2.7**	240	**2.6**	145	**2.5**	50	**2.8**

Table 3D.02: DP Lifestyle Measurements at Each Assessment by Gender (Unpaired Data) (Continued)

Lifestyle Characteristic	Category	Male																					
		Baseline		Follow-Up		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
		N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean
Rapid Assessment of Physical Activity: Aerobic	Sedentary (%)	102	**5.1**	12	**1.0**	11	**1.4**	13	**2.3**	14	**3.5**	9	**3.2**	5	**2.7**	4	**3.1**	3	**2.9**	1	**1.4**	**.**	.	**.**	.
	Under-Active (%)	179	**9.0**	38	**3.1**	65	**8.1**	39	**7.0**	30	**7.5**	18	**6.4**	18	**9.7**	17	**13.1**	12	**11.7**	4	**5.8**	3	**8.3**	3	**15.0**
	Under-Active: Regular (%)	872	**43.8**	411	**33.9**	294	**36.5**	220	**39.6**	165	**41.4**	130	**46.1**	80	**43.2**	57	**43.8**	45	**43.7**	29	**42.0**	19	**52.8**	12	**60.0**
	Active (%)	839	**42.1**	753	**62.0**	435	**54.0**	284	**51.1**	190	**47.6**	125	**44.3**	82	**44.3**	52	**40.0**	43	**41.7**	35	**50.7**	14	**38.9**	5	**25.0**
Rapid Assessment of Physical Activity: Strength and Flexibility	No Strength or Flexibility (%)	986	**51.2**	314	**26.9**	298	**39.4**	204	**39.0**	142	**37.6**	94	**36.0**	48	**28.7**	38	**31.9**	34	**35.8**	26	**40.6**	10	**30.3**	4	**25.0**
	Strength (%)	332	**17.2**	238	**20.4**	178	**23.5**	104	**19.9**	76	**20.1**	41	**15.7**	36	**21.6**	16	**13.4**	20	**21.1**	15	**23.4**	6	**18.2**	5	**31.3**
	Flexibility (%)	246	**12.8**	191	**16.3**	97	**12.8**	79	**15.1**	60	**15.9**	41	**15.7**	29	**17.4**	27	**22.7**	13	**13.7**	4	**6.3**	8	**24.2**	2	**12.5**
	Both Strength & Flexibility (%)	363	**18.8**	426	**36.4**	184	**24.3**	136	**26.0**	100	**26.5**	85	**32.6**	54	**32.3**	38	**31.9**	28	**29.5**	19	**29.7**	9	**27.3**	5	**31.3**
Food Consumption	Mean Healthy Diet Score	2011	**3.4**	1216	**3.8**	809	**3.7**	566	**3.7**	406	**3.7**	284	**3.7**	185	**3.7**	131	**3.7**	104	**3.7**	70	**3.7**	37	**3.6**	20	**3.5**
	Mean Unhealthy Diet Score	2015	**3.1**	1218	**2.5**	811	**2.7**	565	**2.8**	407	**2.8**	285	**2.8**	185	**2.8**	131	**2.8**	103	**3.0**	71	**2.9**	37	**2.9**	20	**3.0**

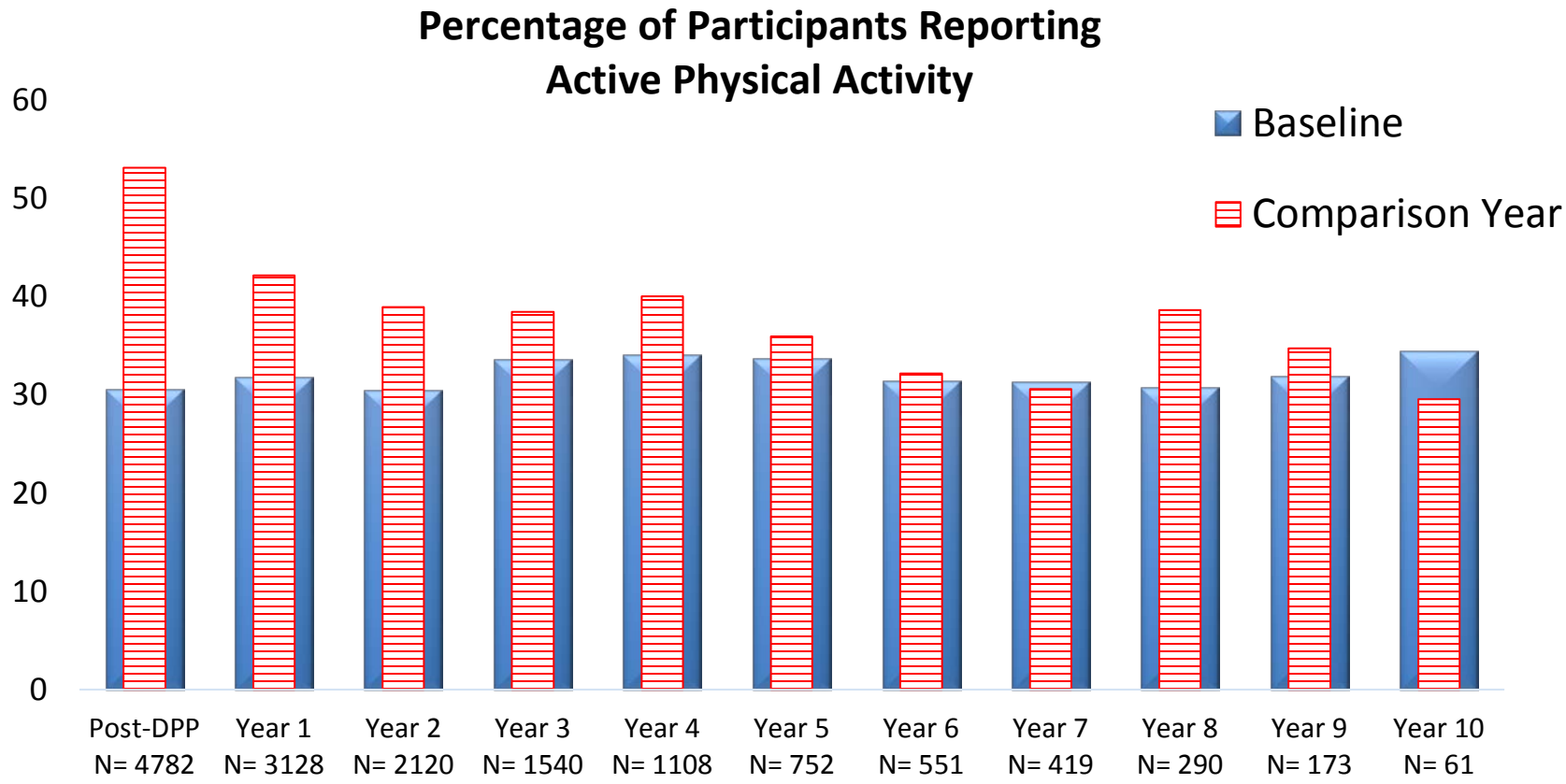


Figure 3D.01: DP Active Physical Activity (Paired Data)

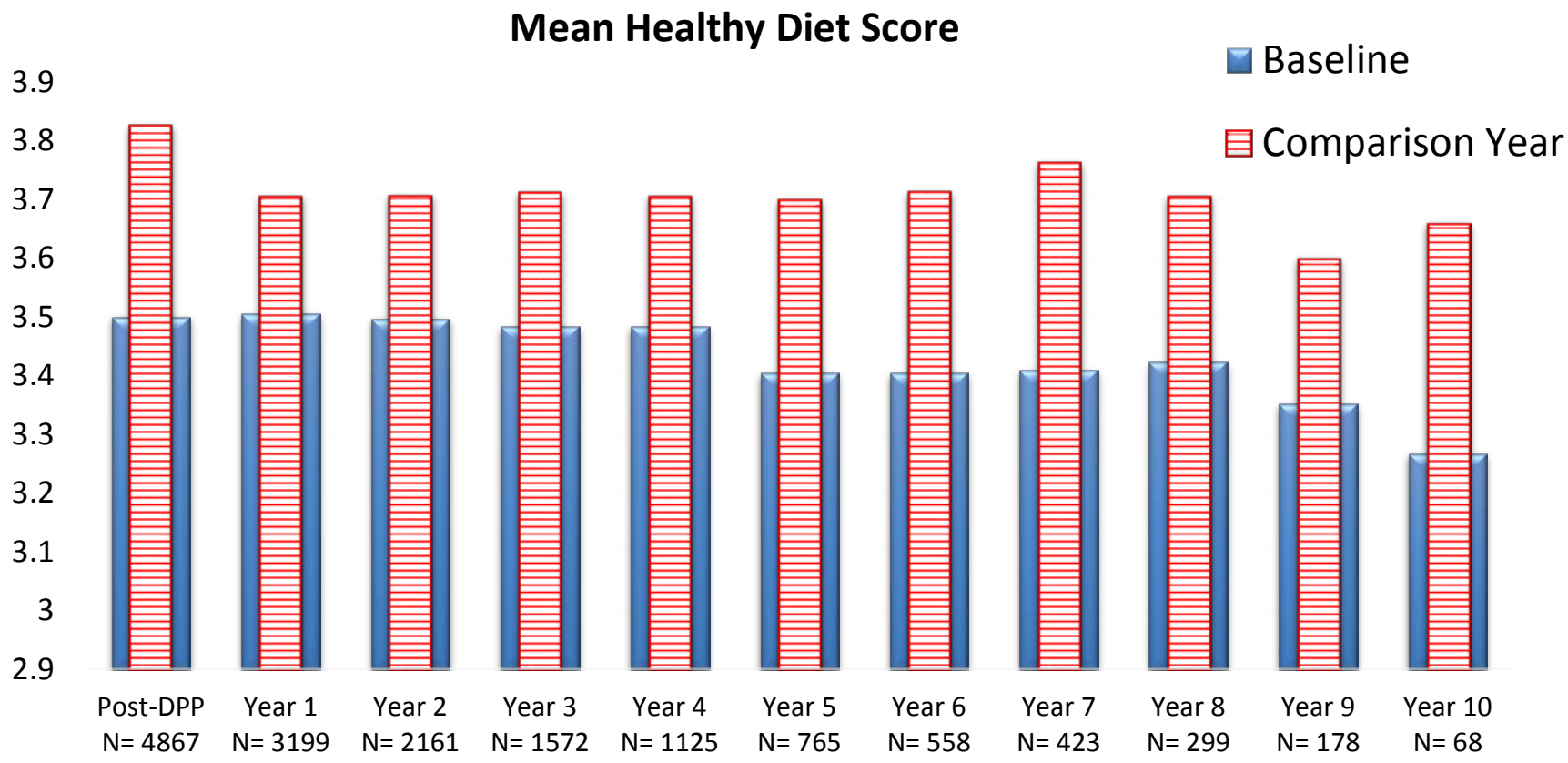


Figure 3D.02: DP Healthy Diet Score Changes from Baseline (Paired Data)

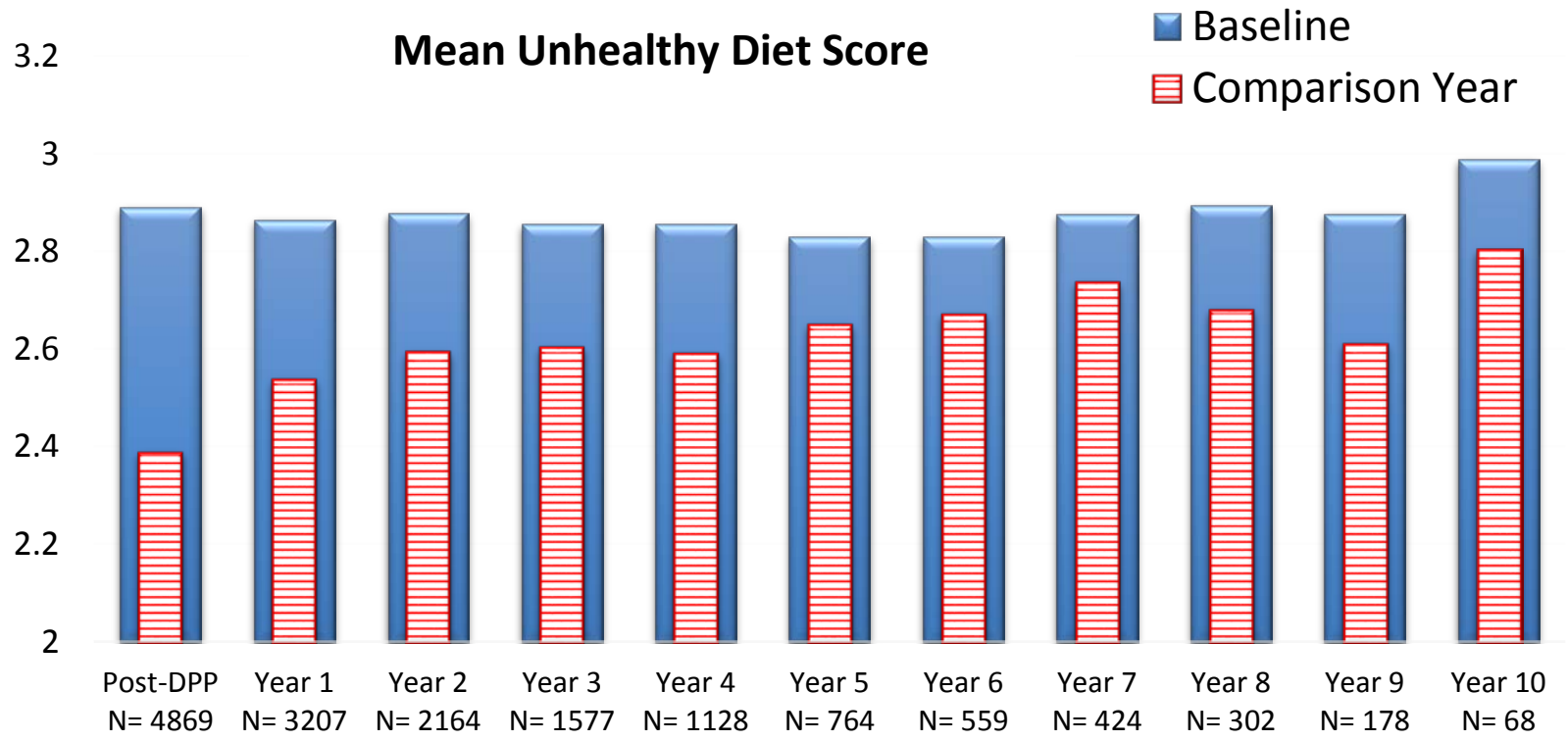


Figure 3D.03: DP Unhealthy Diet Score Changes from Baseline (Paired Data)

4. COMPARISON WITH NATIONAL DPP PROGRAMS

In 2015, the Centers for Disease Control (CDC) launched the Diabetes Prevention Recognition Program, referred to as the National DPP. Similarities between the SDPI DP Program and the National DPP include the use of an established lifestyle curriculum, an intervention of at least one year, and an initial six-month phase during which a minimum of 16 sessions are offered over a period lasting at least six weeks and not more than 26 weeks. Areas where the SDPI DP Program differed from the National DPP include the intervention intensity in months 7 through 12, which included individual lifestyle coaching and After-Core activities in the SDPI DP Program as opposed to curriculum sessions (although repeated curriculum sessions were optional as After-Core activities), and the fact that documentation of body weight and physical activity minutes were not reported the Coordinating Center at each session. (Most programs did document body weight at each session but did not report the weight to the Coordinating Center. It is unknown how many programs documented physical activity minutes at each session.) Table 4.01 compares the experiences of the SDPI DP Programs with the remaining five requirements of the CDC Diabetes Prevention Recognition Program. Taken as a whole, the SDPI DP Programs would easily have met the requirements for session attendance during months 1 through 6 and the program eligibility requirement. If attendance at lifestyle coaching visits and After-Core activities can be counted as 'sessions', the requirement for session attendance during months 7 through 12 would be met. The SDPI DP Programs come up short, however, on the average weight loss of the participants at six months and 12 months. The mean weight loss at six months was 3.8% of baseline weight, whereas the mean weight loss at 12 months was 3.1% of baseline weight (calculated using the National DPP guidelines). Participants age 65 and older were closer to the 5% weight loss goals, with a mean of 4.6% weight loss at six months and 4.2% weight loss at 12 months. Only a few of the individual DP Programs would have met the National DPP weight loss goals. Altogether, 36% of the SDPI Diabetes Prevention Program participants lost 5% or more of their baseline weight at follow-up and 31% lost 5% or more of their baseline weight at Year 1.

Table 4.01: DP Program and Select CDC Diabetes Prevention Recognition Program Standards

The CDC Diabetes Prevention Recognition Program has 11 requirments for recognition status. The 5444 DP participants with baseline BMI >= 24 who attended a minimum of 4 sessions and had weight reported at the follow-up assessment were evaluated for session attendance, weight loss, and program eligibility.		
Standard	**Requirement**	**SDPI DP Program**
Session attendance during months 1-6	Minimum of 9 sessions attended. Attendance averaged over all participants attending a minimum of 4 sessions	 Mean attendance = 15.7 sessions
Weight loss achieved at six months	Average weight loss achieved by participants attending a minimum of 4 sessions must be a minimum of 5% of "starting" body weight. *The first and last weights recorded for each participant during months 1-6 will be used to calculate this measure.*	Mean Weight loss = 3.8%
Session attendance during months 7-12	Minimum of 3 sessions in months 7-12. Attendance averaged over all participants attending a minimum of 4 sessions.	 Mean attendance = 3.6 (Lifestyle Coaching Visits = 2.3 After-Core Activities = 1.3)
Weight loss achieved at 12 months	Average weight loss achieved over the entire 12 month intervention period by participants attending a minimum of 4 sessions must be a minimum of 5% of "starting" body weight. *The first and last weights recorded for each participant during months 1-12 will be used to calculate this measure.*	Mean Weight loss = 3.1%
Program eligibility requirement	Minimum of 50% of participants must be eligible for the lifestyle intervention based on either a blood test indicating prediabetes or a history of GDM. The remainder (maximum of 50% of participants) must be eligible based on the CDC Prediabetes Screening Test, the American Diabetes Association Type 2 Diabetes Risk Test or a claims-based risk test.	 85% of participants were eligible based on blood test at baseline.

V. APPENDICES

APPENDIX 1. GLOSSARY

This glossary will serve the readers of this report as a "dictionary" of the terms within the report. Some glossary entries define terms, while others translate commonly used acronyms.

A1c
A test that measures a person's average blood glucose level over a 2-3 month period. Also called hemoglobin A1c, or HbA1c, the test shows the amount of glucose that sticks to red blood cells, which is proportional to the amount of glucose in the blood.

Accrual
The cumulative number of participants who began the program. In this report, a participant was counted in the accrual number when his/her baseline assessment form documenting eligibility was submitted to the Coordinating Center.

Attendance form
Form used to record participant attendance. During the full evaluation, attendance data included scheduled appointments, missed appointments, make-up appointments, etc. The minimum dataset attendance data includes only the dates of attended classes, visits and activities.

Assessment
In this report, assessment refers to the data items collected with respect to an individual participant at baseline and then again at subsequent time points. Assessments obtained at baseline and within one month of the yearly anniversary of the participant start date (and also after completing the DP curriculum for DP participants) contain both data recorded by program staff (clinical and laboratory values and body measurements) and data recorded by the participant on a questionnaire. Mid-year assessments containing only a glycemic measure were obtained six months after the annual assessments on DP participants. Assessments collected during the full evaluation phase were much more extensive than assessments collected during the minimum dataset phase.

Attrition
A reduction in numbers of participants. In this report, attrition means losing program participants, or the number of participants that had dropped out of the program for whatever reason. Attrition of staff members may also occur.

Baseline
Term used to identify a set of measures taken at the beginning of a study, just before the participant starts to receive any intervention (i.e., treatment or education). These first measures then serve as the reference point against which the outcome measures, taken after the activities are completed, are compared. It is very common for public health programs to collect baseline measurements to be able to evaluate whether participation in the program has resulted in the desired change in the health status of the participant. An individual's health status can change quickly, so it is very important that we know the health status of the participant just before they receive any intensive activities, and can then compare it to the same measures of health status taken after the participant completes the intensive activities.

Body Mass Index (BMI)
A measure of body weight relative to height. BMI can be used to determine if a person is under-weight, normal weight, over-weight, or obese. You calculate BMI with weight and height measurements according to a formula. An online calculator is available at: http://www.cdc.gov/nccdphp/dnpa/bmi/calc-bmi.htm

BP
Blood pressure

Cardiovascular disease (CVD)
In the Special Diabetes Program for Indians Demonstration Projects and Initiatives, cardiovascular disease is defined as coronary artery disease, cerebral vascular disease, peripheral vascular disease and aortic disease.

CC
Coordinating Center

Comorbidity
The coexistence of two or more pathologies, or disease processes, in the same individual.

Coordinating Center (CC)
The SDPI Demonstration Projects Coordinating Center is located at the University of Colorado Denver. It used to have two locations, one at the University of Colorado at Denver and Health Sciences Center (UCDHSC) and one at the University of Arizona, College of Public Health. The Coordinating Center is responsible for day-to-day coordination of data collection, evaluation and certain logistics related to the SDPI Demonstration Projects.

CVD
Cardiovascular Disease

DDTP
Division of Diabetes Treatment and Prevention of the Indian Health Service. Formerly called the National Diabetes Program (NDP).

Demonstration Projects Phase
The initial phase of the SDPI Diabetes Prevention Program and Healthy Heart Project, which occurred from October 2004 through September 2010. This phase involved an extensive data collection effort, also referred to as full evaluation data.

Diabetes
Diabetes is a disease in which the body does not produce or properly use insulin. Insulin is a hormone that is needed to convert sugar, starches and other food into energy needed for daily life. In the SDPI Demonstration Projects and Initiatives, diabetes refers to type 2 diabetes.

Diabetes Prevention Program (DP)
The diabetes prevention program of the IHS SDPI Demonstration Projects and Initiatives. In order to differentiate this from the original DPP research study, we use only the first 2 letters. Also referred to as the DP Program.

Diabetes Prevention Program (DPP) (Original)
The DPP was a major research study funded by the NIH aimed at discovering whether either diet and exercise or the diabetes drug Metformin could prevent or delay the onset of type 2 diabetes in people with impaired glucose tolerance. The Intensive Activities in the SDPI DP program are based on the activities from this research study.

Diabetic
This term is usually used to describe someone with diabetes or to refer to something related to diabetes. In general, diabetes educators do not like to use this term since it labels an individual. Therefore, we should use the phrase “individuals with diabetes.”

DP curriculum / DP classes
A series of 16 classes that aim to prevent diabetes through developing healthy behaviors and skills. During the Demonstration Projects phase, DP programs employed the curriculum originally developed by the NIH DPP research study. Beginning with the Initiatives phase, DP programs utilized the Native Lifestyle Balance (NLB) curriculum.

Enrollment
See Accrual.

Fasting Blood Glucose (FBG) Test
This test measures blood glucose levels after a minimum of 8 hours of fasting. It is used to detect diabetes or prediabetes.

Follow-up
In general, the term follow-up refers to outcomes measured after or during an intervention. In the DP Program, follow-up refers to the assessment and questionnaires administered immediately after the participant has completed the 16-session DP curriculum.

Framingham Cardiovascular Risk Score
The Framingham Cardiovascular Risk Score is a tool used to estimate the 10-year cardiovascular risk of an individual. The Framingham Risk Score was first developed based on data obtained from the Framingham Heart Study, to estimate the 10-year risk of developing coronary heart disease. Framingham Cardiovascular Risk Scores were calculated for participants in the Healthy Heart Project.

Full Evaluation Data
In this report, full evaluation data refers to the more extensive set of data collected during the Demonstration Projects phase.

Glycemic measure
A measurement of the concentration of glucose (a type of sugar) in the blood. Assessments obtained for the DP Program required at least one of these three measures: fasting blood glucose (FBG), an Oral Glucose Tolerance Test (OGTT, which includes an FBG and a 2-hour result), or an A1c. All of these measures involved an intravenous blood draw (finger sticks were not reported on the assessments) and appropriate laboratory capability. The A1c test was required on assessments obtained for HH Project participants with diabetes.

Glycemic measure in the normal range
An assessment was considered to have the glycemic measure in the normal range if at least one of these three glycemic measures was reported and all reported glycemic measures were in the normal range: fasting blood glucose < 100 mg/dl, 2-hour OGTT result < 140 mg/dl, A1c < 5.7%.

HDL (High Density Lipoprotein) cholesterol
A fat found in the blood that takes extra cholesterol from the blood to the liver for removal. Also known as “good” cholesterol.

Healthy foods
For the purposes of this report, healthy foods are considered to be: whole grain bread, fruit, lettuce or green leafy salad, cooked dried beans, fish/chicken/game, and vegetables.

Healthy Heart Project (HH)
The name given to the CVD risk reduction project of the IHS SDPI Demonstration Projects and Initiatives. Also referred to as the HH Project.

IHS
Indian Health Service

Impaired Fasting Glucose (IFG)
A form of prediabetes where fasting glucose levels are higher than normal but not high enough to be called diabetes. Individuals with IFG are at risk of developing diabetes but do not have it yet. Fasting glucose levels between 100 and 125 mg/dl indicate Impaired Fasting Glucose. The only way to diagnose IFG is to measure blood glucose while fasting.

Impaired Glucose Tolerance (IGT)
A form of prediabetes where blood glucose levels are higher than normal but not high enough to be called diabetes. Individuals with IGT are at risk of developing diabetes but do not have it yet. The only way to diagnose IGT is through a 2-hour Oral Glucose Tolerance Test (OGTT). Blood glucose levels at the 2-hour time between 140 and 199 mg/dl indicate Impaired Glucose Tolerance.

Inactive
A participant who is unable or unwilling to continue in a program. If possible, efforts should be made to encourage the participant to continue in or return to the program, following the guidelines in the Retention Policy.

Initiatives phase
The second phase of the SDPI Diabetes Prevention Program and Healthy Heart Project, as of October 2010. The DP and HH Initiatives are evidence-based public health initiatives, collecting and reporting a shorter, more focused set of data (minimum dataset).

Interquartile range
The interquartile range is the distance between the 25^{th} and the 75^{th} percentiles.

Intervention
A well-planned, structured process by which an identified crisis or problem is addressed. In the context of public health programs, the term intervention usually refers to the activities that a program implements to improve a particular health issue.

LDL (Low Density Lipoprotein) cholesterol
A fat found in the blood that carries cholesterol to areas of the body where it is needed for cell repair. LDLs also deposit cholesterol on the inside of artery walls. LDL is sometimes called "bad" cholesterol.

Lipids
The term lipids usually refers to certain fats found in the body. The lipids measured in the SDPI Demonstration Projects and Initiatives are LDL, HDL, triglycerides and total cholesterol.

Mean
The mean is the average of n numbers computed by adding all of the numbers and dividing by n.

Median
The median is the value below which 50% of the people or cases fall. If the median change in triglycerides is -5 mg/dl, then half of the participants had a decrease in triglycerides of at least 5 mg/dl, and the other half of the participants either had a smaller decrease in triglycerides, no change in triglycerides, or an increase in triglycerides. The median is often reported instead of the mean when there are extreme values that could make the mean misleading. For example, if one participant had an increase in triglycerides of 3457 mg/dl, that one value may result in a reported mean **increase** in triglycerides for the group, even if most of the participants had a **decrease** in triglycerides.

Metabolic Syndrome
To be diagnosed with Metabolic Syndrome, an individual must have three or more of the following conditions:

- Waist circumference > 40 inches (102 centimeters) for men, or > 35 inches (88 centimeters) for women.
- Triglycerides ≥ 150 mg/dl or on drug treatment for high triglycerides.
- HDL < 40 mg/dl for men and < 50 mg/dl for women, or on drug treatment for low HDL.
- Systolic blood pressure ≥ 130 mm Hg or diastolic blood pressure ≥ 85 mm Hg
- FBG ≥ 100 mg/dl.

For a short period of time, individuals with three of the first four conditions but without prediabetes or diabetes were considered eligible. Data from these individuals are not included in the Final Data Report.

Mid-year assessment
The mid-year assessment reports a glycemic measure on a participant six months after each annual assessment.

Minimum dataset
In this report, the minimum dataset refers to the shorter, more focused set of data collected as of August 1, 2009.

Missing data
In this report, missing data refers to required fields in a form or questionnaire that do not have a value. On the assessment forms, this includes measurements, dates of measurements, process questions, and the list of medications. It does not include fields that can be calculated from other fields, such as BMI.

Oral Glucose Tolerance Test (OGTT)
This test measures blood glucose levels after a minimum of 8 hours of fasting and again 2 hours after consuming a glucose-rich beverage. It is used to diagnose diabetes or prediabetes.

Paired data
In this report, paired data refers to reporting the changes in participants' measurement data over time or comparing participants' measurement data at different time points by restricting the analysis to the subset of participants who have data at the time points involved. For example, each participant's baseline systolic blood pressure can be subtracted from his/her systolic blood pressure at each time point, resulting in a change score that can be summarized for the participants completing each time point. Alternatively, for a given time point, the mean systolic blood pressure can be reported alongside the mean baseline systolic blood pressure for the subset of participants who have data at the given time point. See also unpaired data.

Participant
This term refers to a person who has officially agreed to be enrolled in the program.

Percentile
The p^{th} percentile of a list of numbers is the number such that p percent of the numbers in the list are less than that number. For example, if a student scores in the 75^{th} percentile on a standardized test, then 75% of those taking the test had lower scores.

Prediabetes
Lay term that is used to describe individuals who are at very high risk for diabetes. Clinically speaking, this term is used to classify people with blood glucose levels that are higher than normal but not yet in the diabetic range. Impaired Fasting Glucose (IFG) and Impaired Glucose Tolerance (IGT) are two forms of prediabetes, differing by the method used to diagnose the condition. In the DP Program, prediabetes is defined as either IFG, IGT, or an A1c in the prediabetes range.

Prevention
In the SDPI Demonstration Projects and Initiatives, it refers to trying to stop a medical condition from occurring in those at risk, i.e., prevention of diabetes in people with prediabetes or prevention of cardiovascular disease in people with diabetes.

Process evaluation
This type of evaluation focuses on the processes or steps taken to arrive at a specified outcome. Process evaluation involves documenting the programs' implementation of all activities and participation in those activities by individuals and communities. In other words, did we do what we said we would do?

Program ID
In this report, Program ID refers to a randomly-generated confidential ID number which was assigned to each program.

Questionnaire
In this report, 'questionnaire' usually refers to a form completed by the participant at each assessment time point (except the DP mid-year assessment). The questionnaire asks about the participant's physical activities, dietary habits and comorbidities. During the full evaluation, there were dozens of additional questions about psycho-social characteristics, diabetes knowledge, and lifestyle characteristics.

Recruitment
The process of adding new individuals to a program, organization or population, and the strategies used to secure participants.

Retention
The process of retaining individual participants in a program or organization; i.e., activities that encourage or motivate the participant to continue to participate in the program or organization.

Retention form
The retention form was used to inform the Coordinating Center when a participant changed from active to inactive status or from inactive to active status. The retention form in use during the full evaluation was more extensive than the minimum dataset retention form.

Scale
A scale summarizes the answers to a set of questions, which are designed to measure a specific aspect of a person's psycho-social characteristics or a program/organization's characteristics.

Screening
Activities that identify individuals who are at risk for a disease or condition. If the screening test is positive, the person needs to have further testing to make the diagnosis.

SDPI
Special Diabetes Program for Indians

Timeline compliance
Timeline compliance refers to whether evaluation measurements were obtained at the proper time in relation to the intervention, i.e., whether each clinical measure and questionnaire was collected within the required time period before, during, or after intervention activities, according to the timeline requirements (see below).

Timeline requirements
The timeline requirements clarify the time period during which each measurement must be collected to ensure accuracy of the baseline and follow-up results. Clinical and body measurements and questionnaires must be collected on a specific timeline in relation to the start and end of intervention activities. For example, in the SDPI Demonstration Projects and Initiatives, as with most program evaluations, all baseline measurements need to be obtained just before the start of the intervention, specifically within one month before the start of the intensive activities. For a few measures, this timeline is wider. For instance, lipids measures may be collected up to three months prior to the start of intensive activities.

Triglycerides (TG)
Triglycerides are the chemical form in which most fat exists in food as well as in the body. High triglyceride levels may occur when diabetes is out of control.

Type 2 diabetes
Sometimes referred to as type II diabetes, type 2 diabetes results from insulin resistance (i.e., a condition in which the body fails to properly use insulin), combined with relative insulin deficiency. Most Americans who are diagnosed with diabetes have type 2 diabetes. In the past, type 2 diabetes was sometimes called non-insulin dependent diabetes mellitus (NIDDM).

UCD
University of Colorado Denver, previously known as University of Colorado at Denver and Health Sciences Center (UCDHSC).

Unhealthy foods

For the purposes of this analysis, unhealthy foods are considered to be: bacon or sausage, processed meats, bread from processed flour, frybread, other baked goods, regular soft drinks/soda, 100% fruit juice, adding sugar or cream to coffee or tea, regular fat salad dressing or mayonnaise, French fries/fried potatoes/tater tots/hash brown potatoes, "red" meat, fast food.

Unpaired data

In this report, unpaired data refers to reporting means and percentages for all participants with a data value at any time point. These means and percentages are not directly comparable, because different individuals have contributed data at each time point. For example, the number of participants who have completed the 2nd annual assessment is less than half of those with baseline assessments. These participants' baseline values may be very different from the baseline values of the participants who became inactive before the 2nd annual assessment, or from the participants who have recently enrolled and are not yet due for the 2nd annual assessment. See also paired data.

APPENDIX 2. MISSING DATA AND TIMELINE COMPLIANCE

Missing Data:

The percentages of assessments missing key data items are shown in Table APP2.01. Missing rates for most of the key clinical variables are low, less than 5%. Lifestyle variables self-reported by the participant on the questionnaire are missing more frequently than variables reported by program staff, often because the participant failed to fill out the questionnaire at all. The minimum dataset questionnaire asks questions about physical activity, diet, and comorbidities; these variables are missing more frequently than the clinical variables. Smoking status was reported on the questionnaire during the full evaluation phase but on the staff-completed assessment form for the minimum dataset, hence the percentage of assessments missing smoking data is lower for the minimum dataset.

Timeline Compliance:

The baseline timeline requirements mandate that the baseline data be collected within one month before each individual's first DP class. This is necessary in order to ensure true baseline data. Many programs struggled to meet these timeline requirements. On average, 45% of the full evaluation baseline assessments and 24% of the minimum dataset baseline assessments did not meet all the timeline requirements for the baseline assessment (Figure APP2.01).

The follow-up timeline requirements mandate that the follow-up data be collected within one month after each individual's last DP class. On average, 17% of the full evaluation follow-up assessments did not meet all the timeline requirements. However, difficulty meeting timeline requirements at follow-up increased after implementation of the minimum dataset. On average, 29% of the minimum dataset follow-up assessments did not meet all of the follow-up timeline requirements (Figure APP2.02).

According to the annual timeline requirements, the annual data are to be collected within one month of the yearly anniversary of each individual's first DP class. DP programs also had difficulty meeting the annual assessment timeline requirements. On average, 53% of the full evaluation annual assessments and 38% of the minimum dataset annual assessments did not meet all of the annual timeline requirements (Figure APP2.02)), even after widening the window to two months before or after the anniversary date.

The mid-year assessment (glycemic measure) is to be collected 5 to 7 months after the yearly anniversary of each individual's first DP class. DP programs also had difficulty meeting the mid-year assessment timeline requirements. On average, 53% of the full evaluation mid-year assessments and 38% of the minimum dataset mid-year assessments did not meet the timeline requirements (Figure APP2.02), even after widening the window to two months before or after the anniversary date.

Table APP2.01: DP Rates of Missing Data – Key Variables

% of Assessments with Missing Variable						
	Baseline Assessment		Follow-up Assessment		Annual Assessment	
Variable (Range)	Full Evaluation (N=3314)	Minimum Dataset (N=5338)	Full Evaluation (N=2373)	Minimum Dataset (N=3266)	Full Evaluation (N=2865)	Minimum Dataset (N=9634)
Height (53-80.5 inches)	0	0.1	0	0	0	0
Weight (70-570 pounds)	0	0.2	0.5	0.5	1.3	1.1
Waist (22-83 inches)	1.0	3.4	2.2	3.4	3.2	7.1
SBP (72-231 mm Hg)	0.4	0.9	2.5	1.6	2.5	1.9
DBP (34-133 mm Hg)	0.4	0.9	2.5	1.6	2.5	1.9
HDL (8-161 mg/dl)	0.7	1.4	3.8	2.8	2.1	2.3
LDL* (11.2-350 mg/dl)	1.9	2.5	4.8	3.6	3.2	3.0
Triglycerides (19-5480 mg/dl)	0.7	1.4	3.8	2.7	2.1	2.3
Total Cholesterol (55-534 mg/dl)	0.6	1.4	3.8	2.8	2.1	2.2
FBG or A1c (FBG range 46 – 346 mg/dl, A1c range 3.1 – 13.6%)	0	< 0.1	1.8	0.7	1.8	0.8
Smoking Status** (Y/N)	10.6	0.1	13.5	0.4	21.6	0.4
Questionnaire? (Y/N)	7.5	5.6	12.0	8.2	18.0	12.1
Physical Activity – Aerobic (Scale 1-7)	9.4	8.1	13.5	9.6	19.8	13.6
Strength Activities (Y/N)	10.0	10.7	14.3	13.2	20.6	17.4
Flexibility Activities (Y/N)	9.4	10.8	14.5	13.1	21.1	17.2
Healthy Diet Score (Scale 1-6)	9.0	6.4	13.6	8.7	19.3	12.7
Unhealthy Diet Score (Scale 1-6)	9.0	6.2	14.0	8.7	19.4	12.6

* LDL was usually calculated from HDL, triglycerides, and Total Cholesterol. Most laboratories did not report LDL when triglycerides were greater than 400 mg/dl; some laboratories obtained a direct LDL when triglycerides were greater than 400 mg/dl.

** In the full evaluation phase smoking status was asked on the questionnaire; in the minimum dataset phase smoking status was reported on the assessment form recorded by program staff.

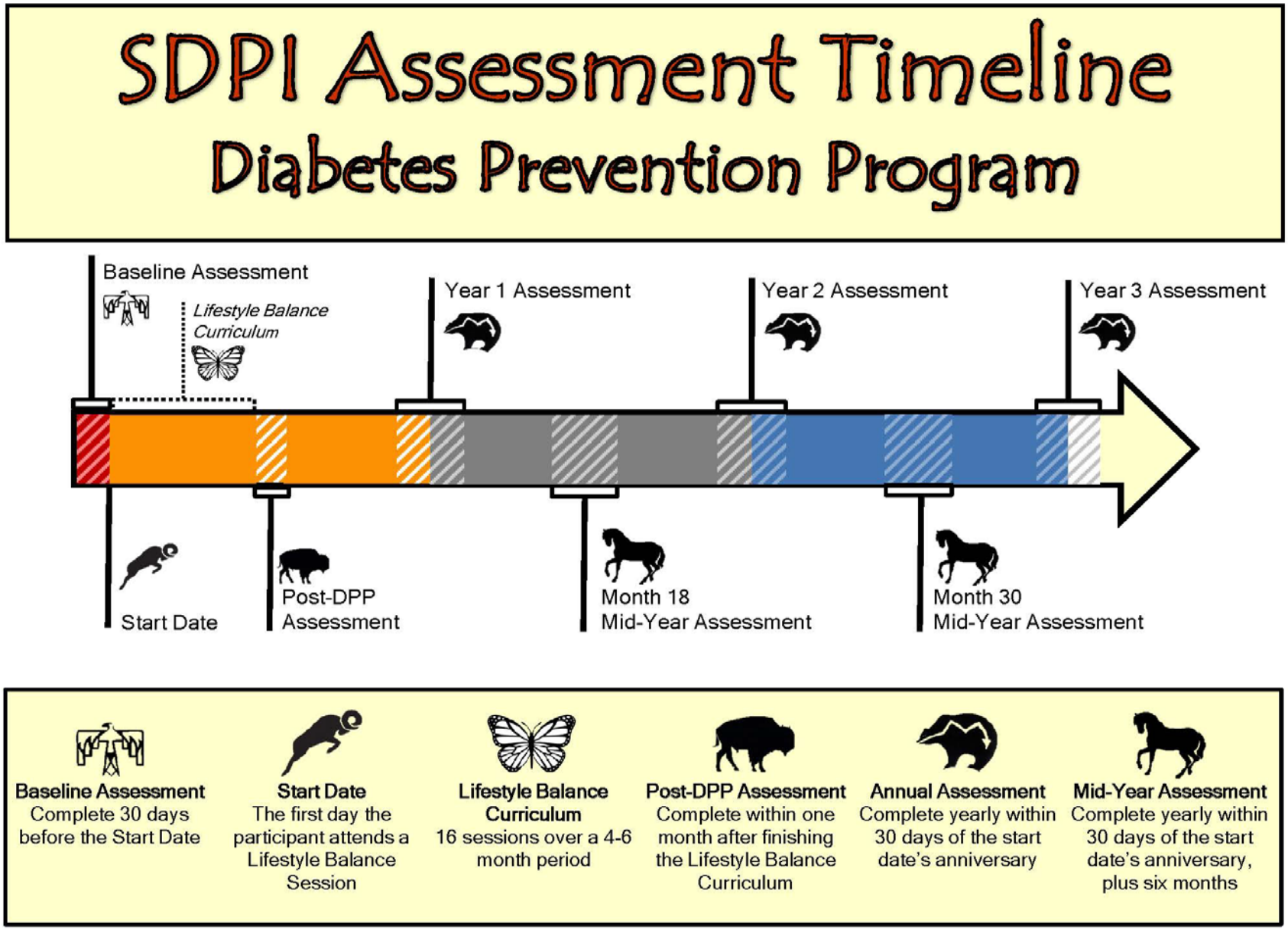


Figure APP2.01: DP Assessment Timeline Diagram

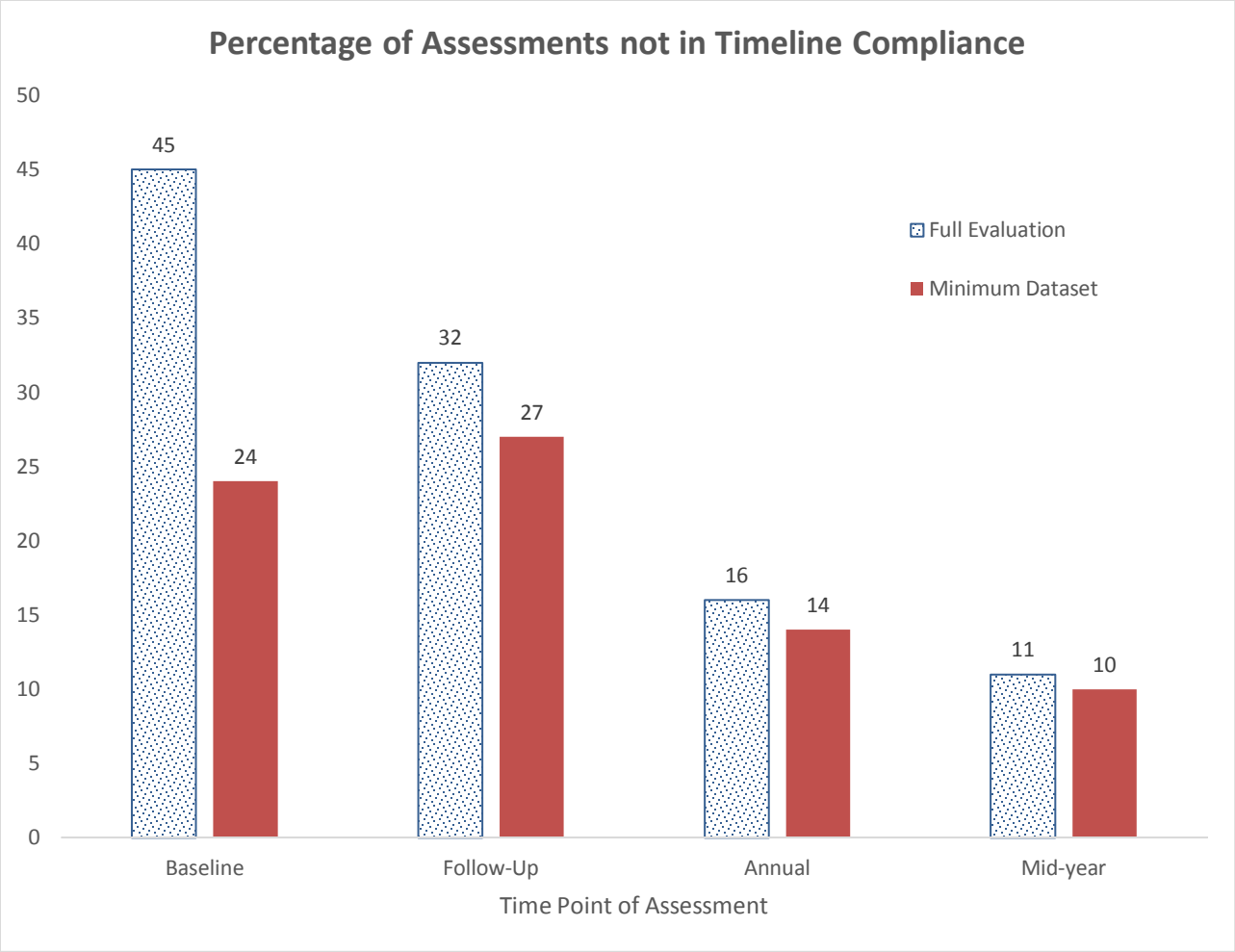


Figure APP2.02: DP Rates of Timeline Non-Compliance

APPENDIX 3. SDPI DP PROGRAM ADDITIONAL DATA ITEMS

The SDPI Diabetes Prevention Program Final Data Report details several important outcome variables and basic demographic data such as gender and age. Many additional data items were collected and reported by the DP Programs. Table APP3.01 lists additional data items found on participant assessments; some of these variables were collected for both the full evaluation and the minimum dataset (although not always in the same manner) and some were collected in only one of the phases. This is not an exhaustive list – omitted items include control items (for example, confirming that the participant was not on dialysis) and ancillary items (for example, details on cardiovascular disease history). The designated scale variables were derived from published scales and are comprised of multiple individual questions; the individual question responses are also available.

Table APP3.02 summarizes the non-assessment data which were collected during the full evaluation phase only.

Table APP3.01: DP Additional Data Items on Assessments

Variables obtained similarly on full evaluation and minimum dataset		
Variable	**Range**	**Notes**
Oral glucose tolerance test	34 – 537 mg/dl (2 hour result)	Full evaluation: Baseline and annual only; Minimum dataset: Optional
History of gestational diabetes?	Y/N	Women only
Delivered a baby > 9 pounds?	Y/N	Women only
Heart disease?	Y/N	On questionnaire
High blood pressure?	Y/N	On questionnaire
Lung disease?	Y/N	On questionnaire
Ulcer/stomach disease?	Y/N	On questionnaire
Kidney disease?	Y/N	On questionnaire
Liver disease?	Y/N	On questionnaire
Anemia or other blood disease?	Y/N	On questionnaire
Cancer?	Y/N	On questionnaire
Depression?	Y/N	On questionnaire
Arthritis?	Y/N	On questionnaire
Back Pain?	Y/N	On questionnaire

Table APP3.01: DP Additional Data Items on Assessments (Continued)

Variables obtained differently on full evaluation and minimum dataset		
Variable	**Range**	**Notes**
Previous diagnosis of hypertension?	Y/N	Full evaluation: Baseline only
Year of diagnosis of hypertension	1955 to 2016	Those with hypertension only
Family history of diabetes?	Y/N	Full evaluation: family history in general; Minimum dataset: parental history/sibling history
On diabetes or diabetes prevention therapy?	Full evaluation: Program staff obtained a complete list of medications, doses, purposes, and any known non-compliance issues; Minimum dataset: Yes/No responses with options to report refusal, adverse reaction, contraindication	
On an angiotensin converting enzyme or angiotensin receptor blocker (ACE/ARB)?		
On other anti-hypertensive medication (not ACE/ARB)?		
On daily aspirin or other anti-platelet or anti-coagulant therapy?		
On a statin or other prescribed lipid lowering agent?		
Variables obtained on minimum dataset only		
Variable	**Range**	**Notes**
Referred for tobacco cessation counseling?	Y/N	Smokers only
Casual sugar	78 - 625 mg/dl	Optional
Albumin to creatinine ratio	0 – 2480.5 mg/g	Not required after October 21, 2013
Date clinical history obtained	4/10/2009 – 8/1/2016	
Date of first glycemic measure in the pre-diabetes range	1984 – 7/19/2016	
History of proteinuria?	Y/N	
History of cardiovascular disease?	Y/N	
Date medication history obtained	4/10/2009 – 8/1/2016	

Table APP3.01: DP Additional Data Items on Assessments (Continued)

Variables obtained on full evaluation only		
Variable	**Range**	**Notes**
Hip circumference	25-78.5 inches	
History of polycystic ovary syndrome?	Y/N	Baseline only; Women only
Education	22 categories	On questionnaire
Employment	8 categories	On questionnaire
Marital status	5 categories	On questionnaire
Income	12 categories	On questionnaire; more missing data than other variables
Sleep (number of hours per night)	10 categories	On questionnaire
TV/sedentary activity (number of hours per day)	10 categories	On questionnaire
Physical activity in prior month	0-4200 minutes per week	On questionnaire
Self-administered comorbidity questionnaire	0-26	On questionnaire; Includes comorbidities listed previously plus information on treatment and limitation of activities
Tribal affiliation	Open-ended	On questionnaire
How well do you speak your tribal language?	4 categories	On questionnaire
How important is spirituality in your life?	4 categories	On questionnaire
Are you able to buy or grow low cost vegetables?	Y/N	On questionnaire
Stages of change for weight control	4 categories	On questionnaire
Stages of change for exercise	5 categories	On questionnaire
Stages of change for diet	5 categories	On questionnaire
Stages of change for alcohol use	4 categories	On questionnaire
Stages of change for smoking	6 categories	On questionnaire
Poverty scale	1-5	On questionnaire
AUDIT scale (Alcohol Use Disorders Identification Test Score)	0-40	On questionnaire
Diabetes knowledge scale	1-5	On questionnaire

Table APP3.01: DP Additional Data Items on Assessments (Continued)

Variables obtained on full evaluation only		
Variable	**Range**	**Notes**
Health literacy scale – print	1-5	On questionnaire
Health literacy scale – numeracy	0-1	On questionnaire
Perceived health competence scale	1.25-5	On questionnaire
Brief resilient coping scale	1-5	On questionnaire
Positive family support scale	1-5	On questionnaire
Negative family support scale	1-5	On questionnaire
Post-traumatic stress disorder	Y/N	On questionnaire
Kessler distress scale	1-5	On questionnaire
Expressed anger scale	0-1	On questionnaire
Suppressed hostility scale	0-1	On questionnaire
Pain disability index scale	1-10	On questionnaire
Pain visual assessment scale	1-10	On questionnaire
Orthogonal ethnic identity scale	4 categories	On questionnaire
Everyday discrimination scale	1-4	On questionnaire
Cultural spirituality scale	1-5	On questionnaire
Health-related quality of life (SF-12): Physical Component Summary	12.5 – 64.7	On questionnaire
Health-related quality of life (SF-12): Mental Component Summary	9.6 – 70.4	On questionnaire

Table APP3.02: DP Non-Assessment Full Evaluation Data Summary

Form	Completed By	Frequency of Completion	Number Received	Notes
Family Baseline Questionnaire	Support person (family member or friend of participant)	Once, at baseline	1923	Demographics, the family's participation in community-based activities, and how support person envisions the program working in their family and community
Family Follow-Up Questionnaire	Support person (family member or friend of participant)	Once, at follow-Up	1221	Similar to the family baseline questionnaire, plus questions about the family's experience in the DP Program
Family Annual Questionnaire	Support person (family member or friend of participant)	At each annual assessment (participant years 1, 2, 3)	1358	Similar to the family baseline questionnaire, plus questions about the family's experience in the DP Program
Community Annual Questionnaire	Community member, up to 10 per program	Once a year (December 2006, 2007, 2008)	1205	Attitudes and perspectives about the DP Program
Provider Annual Questionnaire	Program staff members and care providers, up to 10 per program	Once a year (December 2006, 2007, 2008)	847	Demographics, plus questions about the how the DP Program is working in their setting
Organization Annual Questionnaire	Program staff members, up to 10 per program	Once a year (December 2006, 2007, 2008)	1008	Questions concerning organizational culture, effectiveness, and whether these factors are associated with successful performance by grantee programs
Recruitment Team Meetings Form	Program staff	Ongoing but submitted once a year (December 2006, 2007, 2008)	114	Descriptions of 1310 recruitment team meetings attended by 547 program staff members

Table APP3.02: DP Non-Assessment Full Evaluation Data Summary (Continued)

Form	Completed By	Frequency of Completion	Number Received	Notes
DP Team Meetings Form	Program staff	Ongoing but submitted once a year (December 2006, 2007, 2008)	133	Descriptions of 1427 DP team meetings attended by 696 program staff members
Recruitment Activities Annual Report	Program staff	Once a year (December 2006, 2007, 2008)	173	Descriptions of 3602 recruitment activities. Programs could also send brochures, flyers, etc.
Retention Activities Annual Report	Program staff	Once a year (December 2006, 2007, 2008)	141	Descriptions of 1477 retention activities. Programs could also send brochures, flyers, etc.
After-Core Activities Annual Report	Program staff	Once a year (December 2006, 2007, 2008)	139	Descriptions of 1057 After-Core activities. Programs could also send brochures, flyers, etc.
Participant Attendance Form	Program staff	Ongoing but submitted once a year (December 2006, 2007, 2008)	3497	Full evaluation attendance information included date scheduled, whether attended, make-up date, whether trying for monthly or quarterly lifestyle coaching, type of After-Core activity, etc. The minimum dataset attendance data consisted only of actual dates attended for each type of activity (DP class, lifestyle coaching visit, After-Core activity).
Individual (Participant) Retention Form	Program staff	Ongoing but submitted once a year (December 2006, 2007, 2008)	3497	Full evaluation retention information included reasons for missing specific appointments, attempts to contact, barriers to participation, multiple reasons for inactivity, etc. The minimum dataset retention data consisted only of the primary reason for inactivity (if known).
Community Screening Worksheet	Program staff	Optional	3656	Screening worksheets for potential participants.

Table APP3.02: DP Non-Assessment Full Evaluation Data Summary (Continued)

Form	Completed By	Frequency of Completion	Number Received	Notes
Serious Adverse Event Form	Program staff	As needed	158	During the full evaluation phase, programs submitted a Serious Adverse Event form if a participant was hospitalized, had an emergency room visit, passed away, or had another serious adverse event. These forms were not required by the Indian Health Service National Institutional Review Board.

APPENDIX 4. SDPI DP PROGRAM PUBLICATIONS

Latent class analysis of stages of change for multiple health behaviors: results from the Special Diabetes Program for Indians Diabetes Prevention Program (Jiang, Beals, Zhang, et al.) *Prevention Science.* 2012, 13:449-461.

- Latent class analysis was used to identify subgroups of people based on their answers to stages of change questions. Three classes were identified: Contemplation, Preparation, and Action/Maintenance classes.
- Male and retired participants were more likely to be in more advanced stages.
- Participants who exercised more, ate healthier diets, and weighed less were significantly more likely to be in the Action/Maintenance class. Further, the participants who had higher self-efficacy, stronger family support, and better health-related quality of life had higher odds of being in the Action/ Maintenance class.
- Stages of change for multiple behaviors can be summarized by a three-class model in this sample.

Translating the Diabetes Prevention Program into American Indian and Alaska Native communities: results from the Special Diabetes Program for Indians Diabetes Prevention Demonstration Project (Jiang, Manson, Beals, et al.) *Diabetes Care*, 2013, 36:2027-2034.

- The completion rates of SDPI-DP were 74, 59, 42, and 33% for the follow-up and Year 1, 2, and 3 assessments, respectively.
- The crude incidence of diabetes among SDPI-DP participants was 4.0% per year.
- Significant improvements in weight, blood pressure, and lipid levels were observed immediately after the intervention and annually thereafter for 3 years.
- Class attendance strongly correlated with diabetes incidence rate, weight loss, and change in systolic blood pressure.
- Our findings demonstrate the feasibility and potential of translating the lifestyle intervention in diverse American Indian and Alaska Native communities.
- Knowler and Ackermann provided a commentary on the article (*Diabetes Care*, 2013, 36:1820-1822), and Jiang at al. responded (*Diabetes Care*, 2014, 37:e-35-e36).

Participant and site characteristics related to participant retention in a diabetes prevention translational project (Jiang, Manson, Dill, et al.) *Prevention Science*, 2014, 16:41-52.

- Participants who were younger, male, with lower household income, no family support person, and more baseline chronic pain were at higher risk for not completing all 16 DP sessions and for dropping out.
- Sites with large user populations and younger staff had lower likelihood of retaining participants successfully. Other site characteristics related to higher risk for retention

failure included staff rating of participant disinterest in the DP program and barriers to participant transportation and child/elder care.

- Future translational initiatives need to pay attention to both participant- and site level factors in order to maximize participant retention.

Demographic characteristics and food choices of participants in the Special Diabetes Program for American Indians Diabetes Prevention Demonstration Project (Teufel-Shone, Jiang, Beals, et al.) *Ethnicity and Health,* 2015, 20:327-340.

- Retired participants, those living in urban areas and with high income and education selected healthy foods most frequently.
- Young males, those with low income and education consumed unhealthy foods most frequently.
- Selection of unhealthy foods did not differ by urban and rural setting.

Socioeconomic disparities in weight and behavioral outcomes among American Indian and Alaska Native participants of a translational lifestyle intervention project (Jiang, Huang, Johnson, et al.) *Diabetes Care,* 2015, 38:2090-2099.

- Lower household income was strongly related to less reduction in BMI, and weakly related to less improvement in physical activity and unhealthy food consumption.
- Sites with fewer professionally prepared staff were less successful at improving participant BI and healthy food consumption.

Changes in food choices of participants in the Special Diabetes Program for Indians–Diabetes Prevention Demonstration Project, 2006–2010 (Teufel-Shone, Jiang, Beals, et al.) *Preventing Chronic Disease,* 2015;12:E193, 150266, 13 pages.

- An increase in healthy food choices was associated with reduced weight, BMI, fasting blood glucose and LDL and with increased physical activity at the follow-up assessment.
- At the Year 1 assessment, the associations persisted between healthy food and reduced weight and BMI, and with increased physical activity.

Longitudinal patterns of stages of change for exercise and lifestyle intervention outcomes: An application of latent class analysis with distal outcomes (Jiang, Chen, Zhang, et al.) *Prevention Science,* 2016, 17:398-409.

- Based on many questionnaire responses regarding plans for exercise, participants were divided into one of three groups: Pre-Action, Transition, and Maintenance.
- Females in the Transition group had the greatest improvements in physical activity and weight at follow-up and Year 1, and males in the Transition group had the greatest improvements in weight at follow-up and Year 1
- This article demonstrated that latent class analysis can be used to consolidate questionnaire responses to create meaningful categories to examine factors affecting outcomes.

Psychosocial predictors of weight loss among American Indian and Alaska Native participants in a diabetes prevention translational project (Dill, Manson, Jiang, et al.) *Journal of Diabetes Research*, 2016;Article ID 1546939, 10 pages.

- At baseline, psychological distress and negative family support were linked to greater weight, whereas cultural spirituality was correlated with lower weight.
- Psychological distress and negative family support predicted less weight loss, and positive family support predicted greater weight loss.

Derivation and evaluation of a risk-scoring tool to predict participant attrition in a lifestyle intervention project (Jiang, Yang, Huang, et al.) *Prevention Science, 2016, 17:461-471.*

- Seven factors were related to not finishing the DP curriculum: male gender, younger participant age, lower household income, fewer comorbidities, chronic pain, site user population size (<5,000 or > 10,000 not optimal), and average age of site staff being under age 40.
- Six factors were related to dropping out in general: male gender, younger participant age, marital status (separated, divorced or widowed), chronic pain, site user population size (<5,000 or > 10,000 not optimal), and average age of site staff being under age 40.
- Scoring systems were created to identify whether a participant was at high risk for attrition.

Sleep duration and diabetes risk in American Indian and Alaska Native participants of a lifestyle intervention project (Nuyujukian, Beals, Huang, et al.) *Sleep*, 2016, 39:1919-1926.

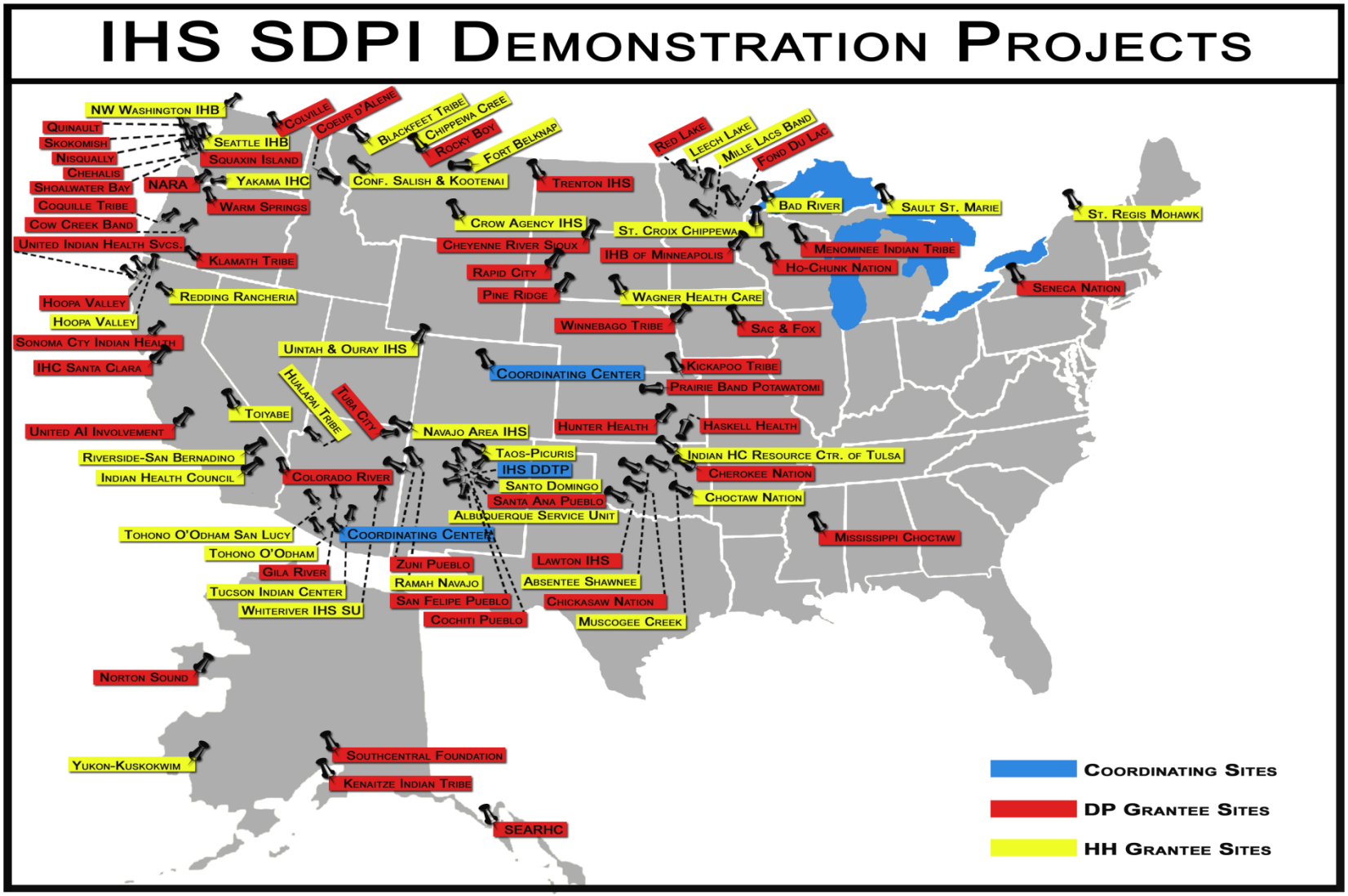
- Short sleep duration, but not long duration, was significantly associated with increased diabetes risk and less weight loss

[In Progress] **Health-related Quality of Life in American Indian and Alaska Native participants of a diabetes prevention translational project** (Dill, Manson, Jiang, et al.)

[In Progress] **Evaluating community-based translational interventions using historical controls** (Jiang, Hollingsworth, Chen, et al.)

[In Progress] **Neighborhood characteristics and lifestyle intervention outcomes: Results from the Special Diabetes Program for Indians** (Jiang, Chang, Beals, et al.)

APPENDIX 5. SDPI PROGRAM MAP – DEMONSTRATION PROJECTS



APPENDIX 6. SDPI PROGRAM MAP – INITIATIVES