



**SPECIAL DIABETES PROGRAM FOR INDIANS**

**DEMONSTRATION PROJECTS / INITIATIVES**

**HEALTHY HEART PROJECT**

# FINAL DATA REPORT

Prepared by the SDPI Initiatives Coordinating Center

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## I. EXECUTIVE SUMMARY

**Participant Accrual and Data Submission:** The Special Diabetes Program for Indians (SDPI) Healthy Heart (DP) Projects began enrolling American Indian and Alaska native adults with diabetes in November 2005 (although most projects began in January 2006) and submitted data to the Coordinating Center through July 2016. Assessments were completed at baseline and annually on approximately the yearly anniversary of the first case management visit. Since recruitment was ongoing, the Coordinating Center received up to 10 years of data on participants who enrolled early in the project and remained active, whereas data received from participants who enrolled later in the project may only include the baseline assessment. The Coordinating Center received baseline assessments for 7663 eligible participants. There were 19,342 submitted annual assessments for years 1 through 10. Not surprisingly, projects with a larger user population size recruited more participants on average than projects with smaller user populations.

**Attendance and Retention:** The 7663 HH participants attended a combined total of 143,386 case management visits. In addition to case management, projects offered their participants a wide variety of supplemental group activities; combined attendance at these activities was 15,097. Participant retention was a struggle for most projects, with 38% of participants not returning for the Year 1 assessment and 52% attrition of enrolled participants by Year 5. The most common reasons given for becoming inactive were being unable to contact and scheduling difficulties.

**Assessment Data:** The projects enrolled more female (63.5%) than male (36.5%) participants, and the average age of participants was 53.5 years old. At baseline, the average Body Mass Index (BMI) was 36.3, and 32% 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.

A summary of important HH outcomes at the baseline 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 HH outcomes from baseline to annual years 1 through 10 (paired data). Participants for whom change cannot be calculated due to a missing assessment or data item are excluded. Median changes are reported (rather than mean changes) due to the potential for misleading effects of extreme changes. **The majority of participants had small but consistent improvements in weight, BMI, diastolic blood pressure, LDL, HDL, triglycerides, total cholesterol, dietary habits, smoking status, and daily use of aspirin or other anti-coagulant/anti-platelet therapy at most time points. Waist did not show consistent improvement, and systolic blood pressure, A1c, and physical activity all became worse over time.** A fact sheet summarizing the SDPI Healthy Heart Project follows Table E.02.

**Table E.01 Summary of HH Outcomes at Each Assessment (Unpaired Data)**

<b>Outcome</b>	<b>Baseline (N=7663)</b>	<b>1st Annual (N=4744)</b>	<b>2nd Annual (N=3611)</b>	<b>3rd Annual (N=2936)</b>	<b>4th Annual (N=2330)</b>	<b>5th Annual (N=1758)</b>	<b>6th Annual (N=1380)</b>	<b>7th Annual (N=1052)</b>	<b>8th Annual (N= 815)</b>	<b>9th Annual (N= 503)</b>	<b>10th Annual (N= 195)</b>
Weight (pounds)	222.2	221.1	220.1	218.8	217.7	215.6	214.0	212.5	212.8	208.3	205.1
Body Mass Index (BMI)	36.3	36.2	36.1	36.0	35.9	35.7	35.4	35.2	35.2	34.6	34.1
Waist (inches)	45.6	45.3	45.2	45.1	45.0	44.8	44.6	44.8	45.0	44.8	43.9
Systolic BP (mm Hg)	129.0	127.6	127.8	127.9	127.4	128.2	129.0	128.1	129.4	129.8	128.4
Diastolic BP (mm Hg)	77.0	75.7	75.3	74.8	74.2	74.3	74.3	73.9	74.3	73.6	72.6
LDL (mg/dl)	97.1	91.8	90.3	88.2	87.2	87.3	85.3	84.5	82.4	78.1	77.6
HDL (mg/dl)	43.5	43.9	44.3	44.4	45.0	45.2	45.5	46.0	46.4	47.2	48.8
Triglycerides (mg/dl)	199.9	185.2	183.3	184.3	179.3	179.2	175.1	178.0	175.6	175.7	168.6
Total Cholesterol (mg/dl)	176.2	169.0	167.7	165.5	164.6	164.7	162.2	161.5	158.9	156.3	156.9
A1C (%)	8.1	7.7	7.7	7.8	7.9	8.0	8.0	8.0	8.1	8.0	8.0
Healthy Diet Score	3.6	3.7	3.7	3.7	3.7	3.7	3.7	3.7	3.6	3.6	3.7
Unhealthy Diet Score	2.7	2.6	2.6	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
Percentage of Participants Reporting Active Physical Activity*	32%	37%	37%	36%	34%	29%	29%	25%	26%	23%	24%
Non-Smoker (%)	78%	82%	83%	83%	84%	86%	86%	87%	86%	86%	89%
Aspirin use (%)	66%	75%	77%	80%	81%	81%	78%	80%	83%	80%	79%

\* 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 HH Outcome Changes from Baseline (Paired Data)**

<b>Outcome</b>	<b>1st Annual (N=4744)</b>	<b>2nd Annual (N=3611)</b>	<b>3rd Annual (N=2936)</b>	<b>4th Annual (N=2330)</b>	<b>5th Annual (N=1758)</b>	<b>6th Annual (N=1380)</b>	<b>7th Annual (N=1052)</b>	<b>8th Annual (N= 815)</b>	<b>9th Annual (N= 503)</b>	<b>10th Annual (N= 195)</b>
Median Change in Weight (pounds)	-1.0	-1.8	-2.3	-3.0	-5.0	-6.6	-7.9	-9.0	-9.8	-11.8
Median Change in Body Mass Index (BMI)	-0.2	-0.3	-0.4	-0.5	-0.8	-1.1	-1.3	-1.5	-1.7	-2.0
Median Change in Waist (inches)	0.0	-0.3	0.0	0.0	0.0	-0.5	-0.6	-0.5	-0.5	0.0
Median Change in Systolic BP (mm Hg)	-1.0	-1.0	0.0	-1.0	0.0	1.0	0.0	2.0	2.0	1.5
Median Change in Diastolic BP (mm Hg)	-1.0	-1.0	-1.0	-2.0	-2.0	-2.0	-2.0	-2.0	-2.0	-3.0
Median Change in LDL (mg/dl)	-3.0	-4.0	-5.6	-6.0	-7.0	-9.0	-11.0	-12.0	-16.0	-17.0
Median Change in HDL (mg/dl)	0.0	0.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	2.3
Median Change in Triglycerides (mg/dl)	-3.0	-4.0	-4.0	-4.0	-4.5	-4.0	-3.0	-3.0	-3.5	-15.5
Median Change in Total Cholesterol (mg/dl)	-4.0	-5.0	-7.0	-7.0	-10.0	-10.0	-12.0	-13.5	-17.0	-23.0
Median Change in A1C (%)	-0.1	-0.1	0.1	0.1	0.2	0.3	0.3	0.4	0.4	0.7
Change in % physically active	4.4	3.3	1.4	-1.6	-8.4	-9.6	-15.0	-14.2	-16.5	-15.1
Change in % non-smoker	3.1	2.7	3.1	2.9	3.6	3.9	4.2	2.8	2.0	2.6
Change in % aspirin use	5.6	6.2	7.3	7.4	4.9	2.0	4.0	6.5	3.4	3.6





# Special Diabetes Program for Indians

## Healthy Heart Project



### GOAL:

Reduce the risk of cardiovascular disease in American Indians and Alaska Natives with diabetes

**7,663**



Participants enrolled:

American Indian and Alaska Native adults with diabetes (at high risk for developing cardiovascular disease)

**15.9%**



of American Indian/Alaska Native adults suffer from Type 2 Diabetes – the highest rate of any racial/ethnic group in the nation.<sup>1</sup>

Type 2 diabetes greatly increases the risk of having a heart attack or stroke. Managing risk factors can prevent or delay the development of heart or blood vessel disease.<sup>2</sup>

Did You Know?

### 143,386 Individual Case Management Visits:



- Needs assessment
- Care plan
- Diabetes self-management education
- Goal setting/review (ADA/IHS Standards of Care)
  - \* Smoking cessation
  - \* Lifestyle changes and/or medication to control:
    - Blood pressure
    - Lipids
    - Weight
    - Blood sugar
- Encouragement and support



### Group & Community Activities:



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



.....and much more!



38 programs serving over 130 tribes across the U.S.

### Participant Successes:



- Lipid improvements
- Healthier diets
- Increased use of daily low-dose aspirin
- Less tobacco use
- Slight but consistent weight loss



### Participant Challenges:



- Motivation
- Making time for the program
- Staying physically active
- Blood sugar control
- Blood pressure control\*

\*Diastolic blood pressures improved; systolic blood pressures did not



### 26,987 Submitted Assessments



■ Baseline ■ Year 1 ■ Year 2 ■ Year 3 ■ Year 4  
■ Year 5 ■ Year 6 ■ Year 7 ■ Year 8 ■ Year 9  
■ Year 10

Program Challenges: Recruitment, retention, and **no comparison group**



The SDPI HH Project was a unique translational, community-based intervention because it lasted over **10½ years**,

enrolled over **7,500 participants**, and

**1,989 individuals** remained in the program for **5 years or more**

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

<sup>2</sup>[http://www.heart.org/HEARTORG/Conditions/More/Diabetes/WhyDiabetesMatters/Cardiovascular-Disease-Diabetes\\_UCM\\_313865\\_Article.jsp/#](http://www.heart.org/HEARTORG/Conditions/More/Diabetes/WhyDiabetesMatters/Cardiovascular-Disease-Diabetes_UCM_313865_Article.jsp/#)

## II. INTRODUCTION

This is the final data report for the Special Diabetes Program for Indians (SDPI) Healthy Heart (HH) Project. The goal of the HH Project was to reduce the risk of cardiovascular disease in American Indian and Alaska Natives with diabetes through intensive case management. This report summarizes a small fraction of the data which were collected on over 7,500 participants over 10½ years. The HH Project began with 30 Demonstration Projects in a formal collaborative planning process starting in October 2004, and the majority of projects began recruiting participants, implementing project activities, and submitting data to the Coordinating Center (CC) in January 2006. The HH Demonstration Projects not only implemented intensive case management but also collected and submitted data gathered on and from participants, potential participants, project staff, support persons, and community members. There were 17 categories of forms, 12 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 intensive case management) and annually thereafter. Beginning on August 1, 2009, in order to allow the project staff to focus their energies on providing services rather than on a costly and labor-intensive data collection effort, 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. Project funding changed on September 29, 2010, and the 7 new projects who joined the effort and the 23 projects with continued funding became the HH Initiatives. At the same time, most of the 7 original projects 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.



### **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 (36) 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 project include recruitment of individuals with 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 project 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

Table 1.01 presents the number of participants enrolled (also referred to as accrual) by each project, the total number of participants enrolled, and the user population size of each project (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 7663 participants who met the following eligibility criteria: American Indian or Alaska Native, at least 18 years of age, previous diagnosis of diabetes or diagnosed with diabetes at baseline, 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. This report excludes data from 36 participants who did not meet (or document) these eligibility criteria sufficiently, including 10 participants who were enrolled based on Metabolic Syndrome rather than diabetes. (Metabolic Syndrome was added as an inclusion criterion for a short period of time.) Each project was expected to work towards an enrollment goal of 50 participants per year. The final accrual of 7663 participants represents 49.6% of the overall enrollment goal (15,463) for up to 126 months of recruitment. Table 1.01 lists each project's cumulative enrollment goal, which is dependent upon when each project received funding. Projects that were part of both the Demonstration Projects and Initiatives phases were expected to enroll 50 participants per year beginning in January 2006 and ending in July 2016. Projects that were part of the Demonstration Projects only were expected to enroll 50 participants per year beginning in January 2006 and ending in September 2010. Projects that were part of the Initiatives phase only were expected to enroll 50 participants per year beginning in April 2011 and ending in July. Two projects listed in Table 1.01 have different enrollment goals from all the other projects, due to a differing consortium composition for these particular projects between the Demonstration Projects and Initiatives phases. The last project listed started in November of 2015 and exceeded their enrollment goal in the first 8 months.

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

Figure 1.02 shows the percentage of the enrollment goal attained for each project, listed from highest to lowest, excluding the project starting in November 2015. The bars are shaded based on the user population size of the project. Recruitment goal attainment ranged from 114% (598 enrolled participants out of a target number of 525 participants) to 22% (58 enrolled participants out of a

target number of 262 participants). Figure 1.03 compares the ranges and averages of the enrollment goal percentages attained according to the user population size of the projects.

Table 1.02 reports the number of assessments submitted at each time point. For each time point, Table 1.02 also reports the percentage of participants with a submitted assessment of those who began the project early enough to have completed the given assessment. For example, there were 719 participants who started the HH project who could have completed the Year 10 assessment but only 195 Year 10 assessments were received, for a 27% 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 moves, passes away, leaves the project, or misses an assessment. Submission totals and rates are also presented by project user population size. These submissions represent a total of 21,855 person-years of participation in the HH project.

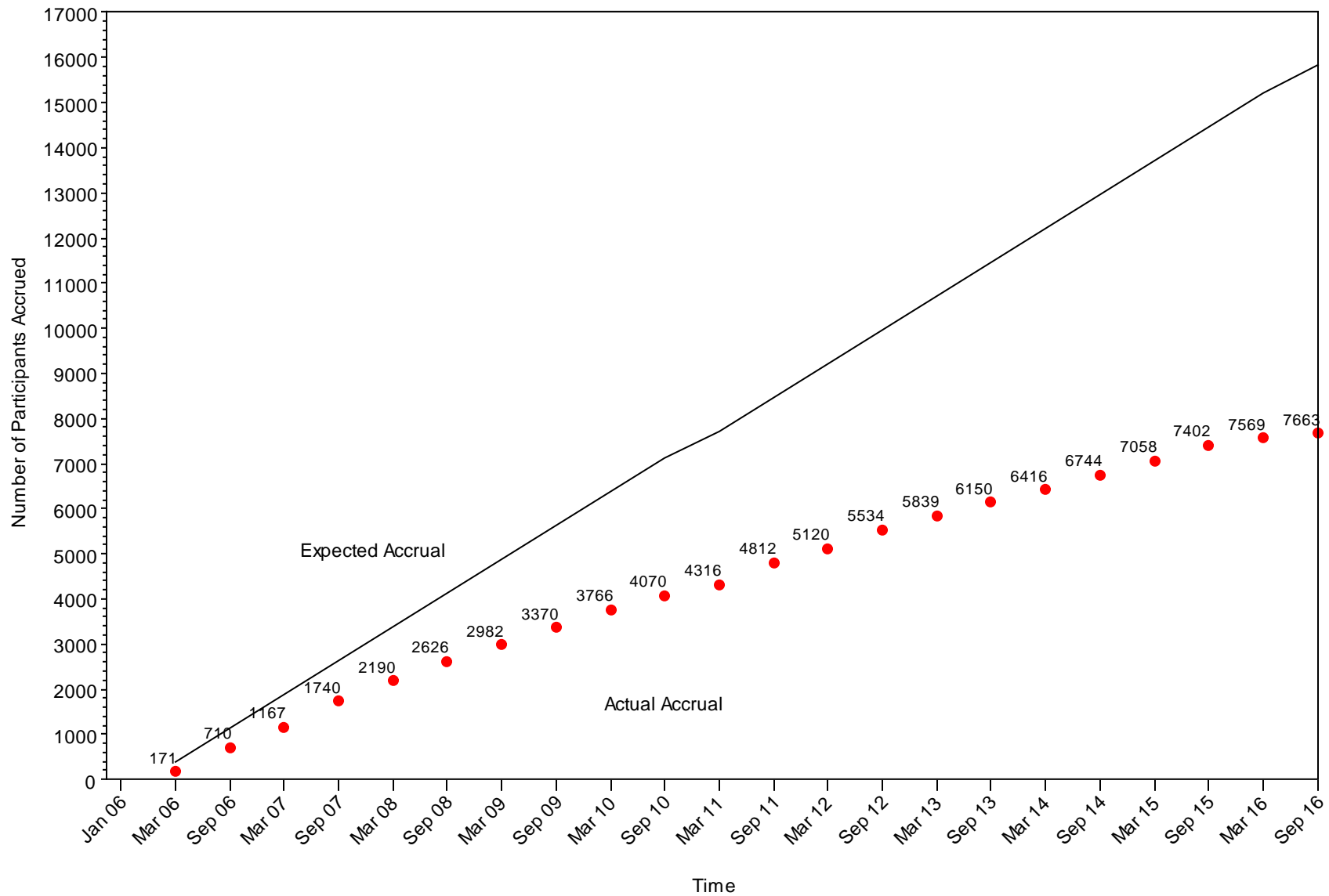
**Table 1.01: HH Participant Accrual**

	Baseline Assessment Received			Population Size *
ID	N	Goal	% of Goal	
1	304	525	57.9	Small
2	350	525	66.7	Small
3	290	525	55.2	Medium
4	111	237	46.8	Large
5	598	525	113.9	Large
6	361	525	68.8	Large
7	215	525	41.0	Small
8	138	525	26.3	Small
9	69	237	29.1	Small
10	195	525	37.1	Medium
11	142	525	27.0	Large
12	421	525	80.2	Large
13	86	237	36.3	Medium
14	161	525	30.7	Small
15	356	525	67.8	Large
16	132	237	55.7	Large
17	125	237	52.7	Medium
18	223	525	42.5	Medium
19	120	237	50.6	Large
20	302	525	57.5	Medium
21	91	237	38.4	Large
22	90	387	23.3	Small
23	133	525	25.3	Medium
24	189	525	36.0	Large
25	256	525	48.8	Large
26	273	525	52.0	Medium
27	243	525	46.3	Large
28	185	525	35.2	Medium

**Table 1.01: HH Participant Accrual (Continued)**

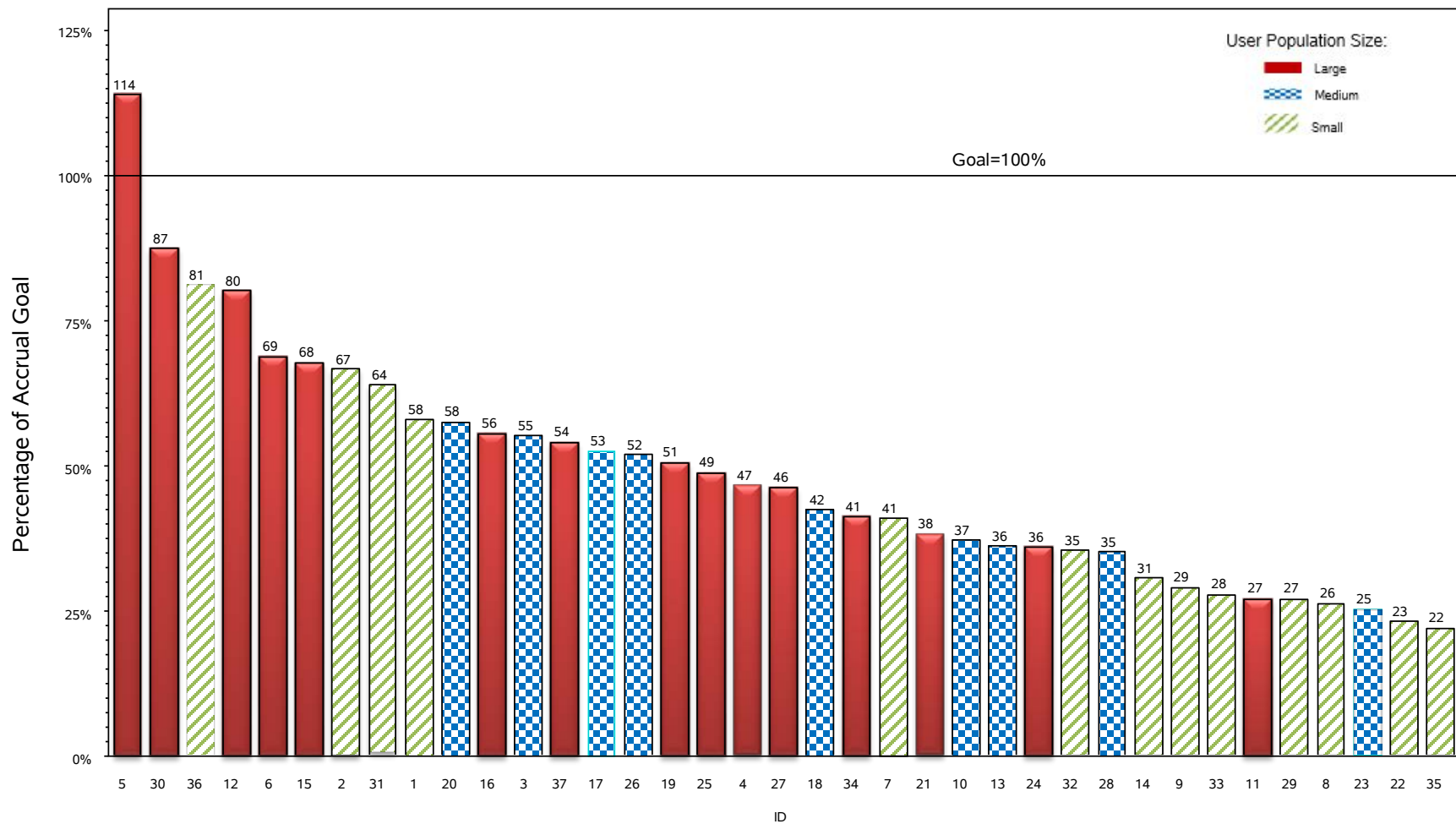
	Baseline Assessment Received			Population Size *
ID	N	Goal	% of Goal	
29	142	525	27.0	Small
30	459	525	87.4	Large
31	168	262	64.1	Small
32	93	262	35.5	Small
33	73	262	27.9	Small
34	108	262	41.2	Large
35	58	262	22.1	Small
36	213	262	81.3	Small
37	142	262	54.2	Large
38	48	33	145.5	Small
TOTAL	7663	15463		
MIN	48		22.1	
MAX	598		145.5	
MEAN	202		50.9	

\*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.

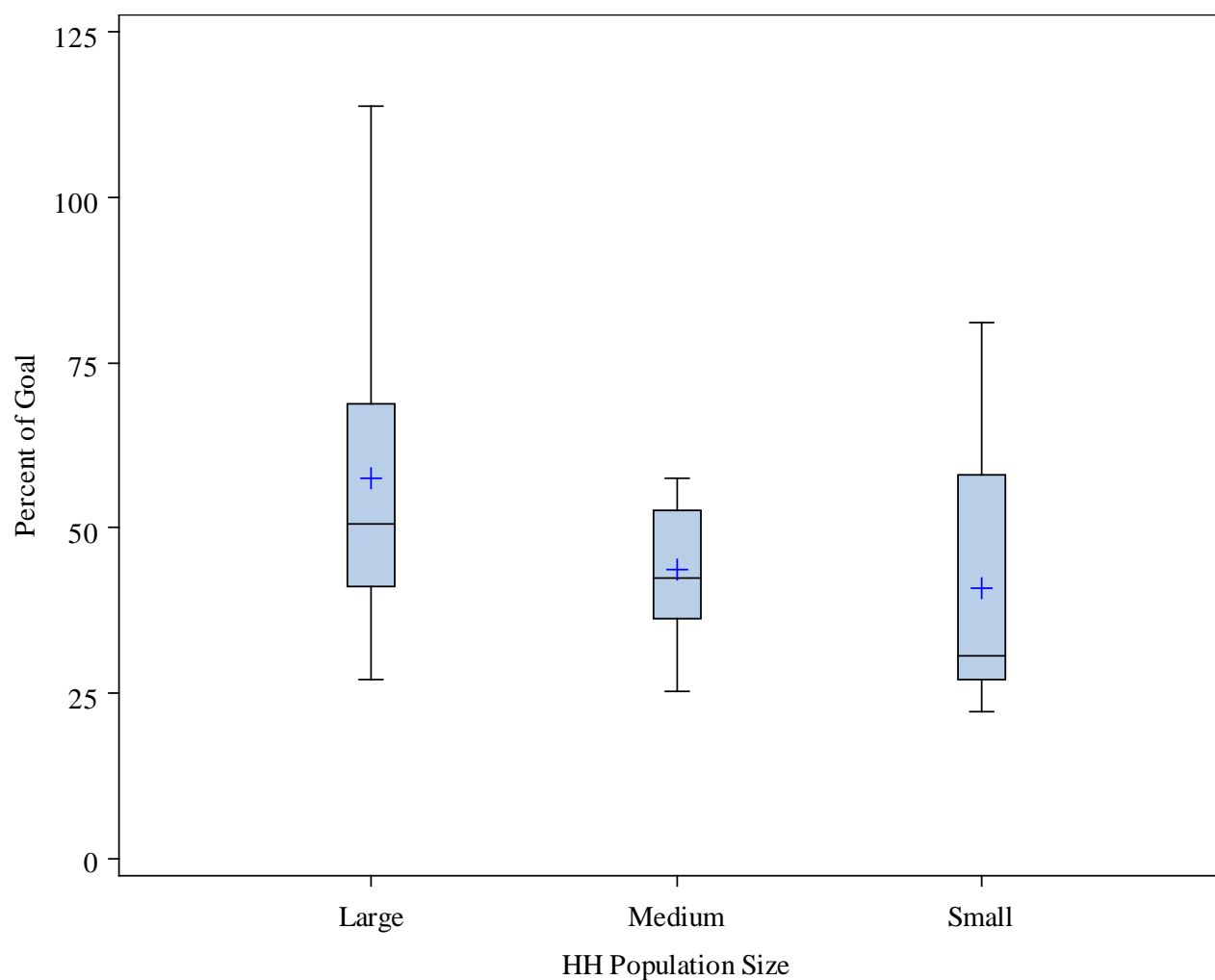


**Figure 1.01: HH Participant Accrual over Time**





**Figure 1.02: HH Percentage of Accrual Goal Achieved**



**Figure 1.03: HH Percentage of Accrual Goal Achieved by Project 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: HH Assessment Forms Submitted**

Time Point	All Projects		By Project User Population Size					
	Number Submitted	Submission Rate (%)	Small (N = 14)		Medium (N = 9)		Large (N = 15)	
			#	%	#	%	#	%
Baseline	7663	.	2122	.	1812	.	3729	.
Year 1	4744	65%	1023	53%	1301	73%	2420	67%
Year 2	3611	54%	761	45%	1008	59%	1842	56%
Year 3	2936	48%	546	37%	822	51%	1568	53%
Year 4	2330	43%	456	35%	680	45%	1194	45%
Year 5	1758	37%	305	29%	560	41%	893	39%
Year 6	1380	34%	239	28%	461	37%	680	34%
Year 7	1052	31%	173	25%	376	35%	503	32%
Year 8	815	31%	144	27%	270	31%	401	33%
Year 9	503	29%	84	26%	176	29%	243	30%
Year 10	195	27%	30	24%	69	28%	96	27%
Total Annual Assessments	19,324	.	3761	.	5723	.	9840	.
Total Assessments	26,987	.	5883	.	7535	.	13,569	.

308 participants started in the last year and did not have time to complete the Year 1 assessment before close-out.

## 2. ATTENDANCE AND RETENTION

### Attendance:

HH attendance data are shown in Table 2.01. The 7663 HH participants attended a combined total of 143,386 individual case management visits (CMVs). In addition to case management, projects offered their participants a wide variety of supplemental group activities; combined HH attendance at these group activities was 15,097. Attendance at group activities was not recorded during the full evaluation phase, so this total reflects group activities during the minimum dataset phase only. The attendance data are also reported by project user population size.

Table 2.01 also includes the mean number of CMV per participant per year in project. Case managers ideally meet one-to-one with each participant monthly at the start of the intervention and at least quarterly if the participant is meeting their individual treatment goals. The mean number of CMV per participant per year in project was calculated by first summing the number of CMV for each participant and then dividing by the total length of time (in years) that the participant was active in the project. Adjustments were made for CMVs close together in time and for short periods of enrollment. The resultant number of CMVs per participant per year in project ranges between 0 and 12 visits for each participant (0 to 12 CMVs per year). The mean for all participants was 5.5 case management visits per year in the project. The mean was slightly higher (5.8 case management visits per year) for participants in projects with a larger user population size.

### Retention:

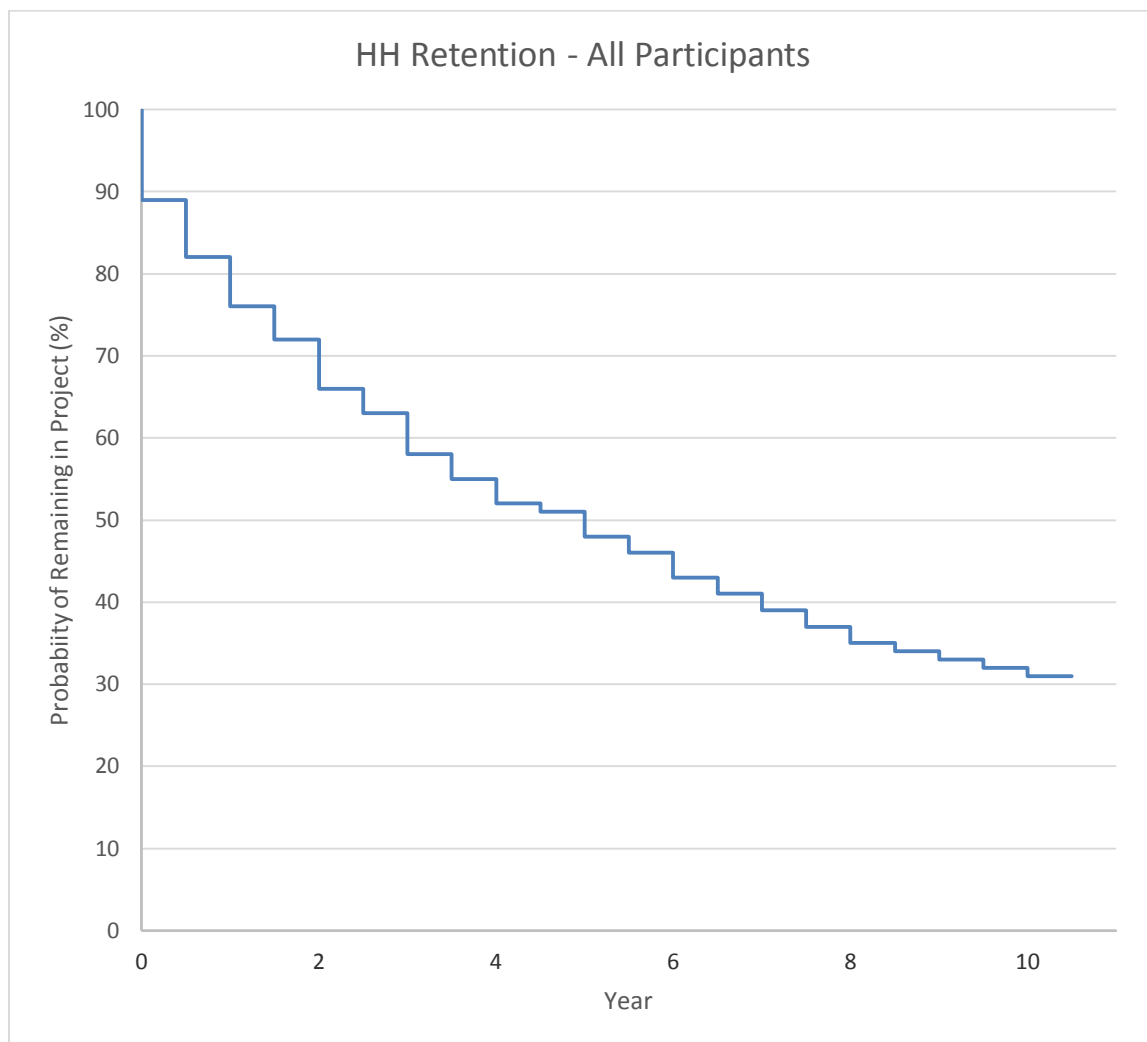
Participant retention was a struggle for most projects, with only 65% of participants returning for the Year 1 assessment and 48% returning for the Year 3 assessment (see Table 1.02, previous chapter). Figure 2.01 shows the probability of remaining in the HH project over the 10 years of implementation. There is a steep drop-off in the first few months 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 project user population size, showing that projects with a larger user population size had worse retention rates overall, and projects with a smaller user population size had the best retention rate after two years.

Figure 2.04 depicts the reasons participants became inactive as reported by project 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.” Five percent of HH participants were made inactive prior to July 31, 2016 due to loss of funding; it is unknown how many of the HH participants who were active as of July 31, 2016 (N = 3413) will become inactive due to loss of funding or will transition to another diabetes program within the community. Currently, many HH projects are continuing to offer the intervention to their participants without centralized data submission.

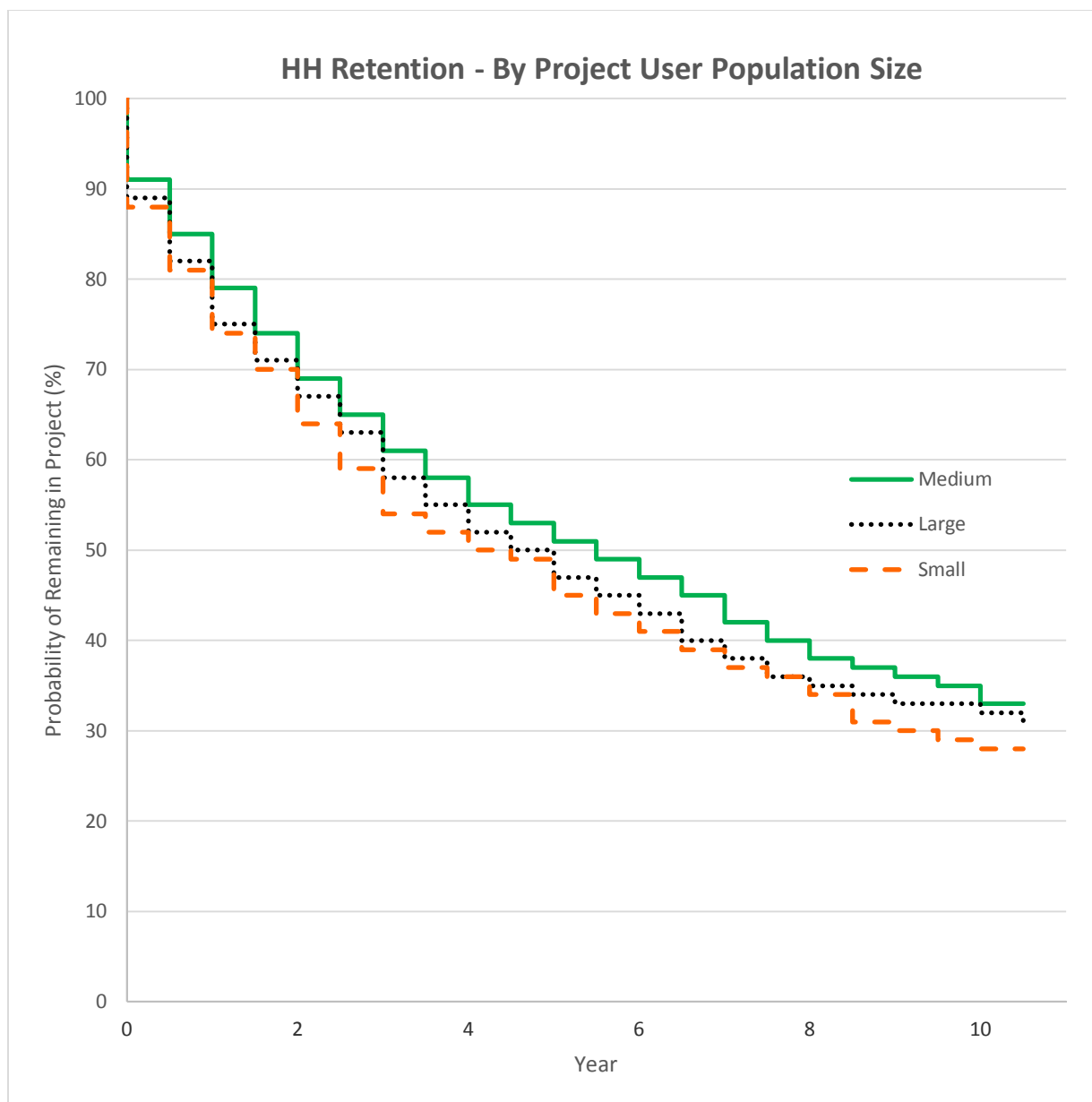
**Table 2.01: HH Attendance**

Type of Attendance		All Projects	By Project User Population Size		
			Small (N = 14 projects, 2122 participants)	Medium (N = 9 projects, 1812 participants)	Large (N = 15 projects, 3729 participants)
Case Management Visits	Total attendance	143,386	28,375	35,880	79,131
	Mean per participant per year in project (0.2 to 12)	5.5	5.0	5.2	5.8
HH Group Activities (after July 31, 2009)	Total attendance (0 to 224)	15,097	7685	3129	4283

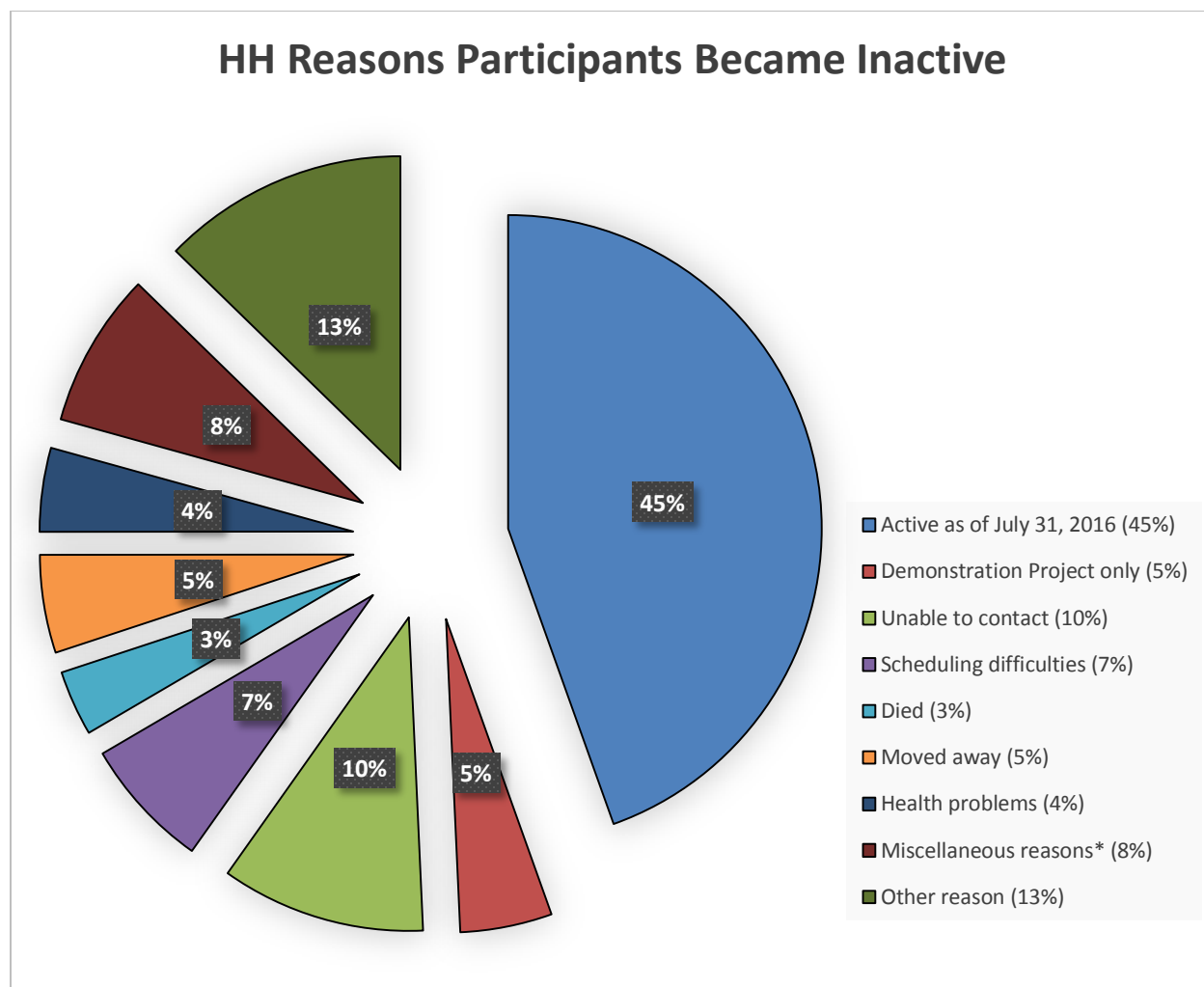


**Figure 2.01 HH Retention (Probability of Remaining Active in the HH Project)**





**Figure 2.02 HH Retention by Project User Population Size (Probability of Remaining Active in the HH Project)**



**Figure 2.03 HH Reasons Participants Became Inactive**

\*Miscellaneous reasons: Did not like project (4%), Family problems (1%), No reason given (2%), Transportation (0.8%), Pregnancy (0.4%)

### **3. ASSESSMENT DATA**

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

#### **A. Baseline Data:**

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

- There are more female participants (63.5%) than male participants (36.5%).
- The average age of the HH participants was 53 years old, with 1% being younger than age 25 and 19% 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 HH participants at baseline are shown in Table 3A.02. The most common conditions, in addition to diabetes, were high blood pressure (66.2%), back pain (44.4%), arthritis (34.4%), and depression (26.8%). Females had higher rates of arthritis, depression, ulcer/stomach disease, anemia or other blood disease, and lung disease. Males had higher rates of high blood pressure and heart disease, and a slightly higher rate of kidney disease.

Table 3A.03 compares the baseline characteristics of HH participants who returned for any annual assessment with those participants having only a baseline assessment. The majority of the participants who did not return for any annual assessment became inactive during the first year; 642 participants returned for a later annual assessment after missing the Year 1 assessment. Table 3A.03 indicates that the participants who continued in the project past baseline were more likely to be female, were older, were less likely to smoke, and ate unhealthy foods less frequently than participants having only a baseline assessment. The participants who continued in the project past baseline also had higher BMI, lower diastolic blood pressure, and lower LDL and total cholesterol levels.

**Table 3A.01 HH Gender and Baseline Age**

<b>Baseline age (years)</b>	<b>Female</b>		<b>Male</b>		<b>All</b>	
	<b>N</b>	<b>Mean</b>	<b>N</b>	<b>Mean</b>	<b>N</b>	<b>Mean</b>
	4867	53.5	2796	53.5	7663	<b>53.5</b>
<b>Age category:</b>	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>
<b>18 – 24 years</b>	49	1%	16	1%	65	<b>1%</b>
<b>25 – 34 years</b>	288	6%	184	7%	472	<b>6%</b>
<b>35 – 44 years</b>	774	16%	488	17%	1262	<b>16%</b>
<b>45 – 54 years</b>	1409	29%	755	27%	2164	<b>28%</b>
<b>55 – 64 years</b>	1424	29%	814	29%	2238	<b>29%</b>
<b>65 years and older</b>	923	19%	539	19%	1462	<b>19%</b>

**Table 3A.02 HH Baseline Rates of Comorbidities**

<b>Comorbidity</b>	<b>Female</b>		<b>Male</b>		<b>All</b>	
	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>	<b>N</b>	<b>%</b>
<b>Heart Disease</b>	4,393	12.6%	2,499	20.0%	6,892	<b>15.3%</b>
<b>High Blood Pressure</b>	4,457	63.0%	2,548	71.9%	7,005	<b>66.2%</b>
<b>Lung Disease</b>	4,450	7.5%	2,521	5.2%	6,971	<b>6.7%</b>
<b>Ulcer/Stomach Disease</b>	4,432	10.9%	2,526	7.1%	6,958	<b>9.6%</b>
<b>Kidney Disease</b>	4,445	4.1%	2,521	5.4%	6,966	<b>4.6%</b>
<b>Liver Disease</b>	4,441	3.3%	2,511	3.6%	6,952	<b>3.4%</b>
<b>Anemia or Other Blood Disease</b>	4,443	9.3%	2,515	3.5%	6,958	<b>7.2%</b>
<b>Cancer</b>	4,452	2.4%	2,527	2.0%	6,979	<b>2.2%</b>
<b>Depression</b>	4,433	30.3%	2,510	20.8%	6,943	<b>26.8%</b>
<b>Back Pain</b>	4,448	44.8%	2,525	43.7%	6,973	<b>44.4%</b>
<b>Arthritis</b>	4,384	36.8%	2,498	30.0%	6,882	<b>34.4%</b>

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

Baseline Variable	Baseline Assessment Only			At Least One Annual Assessment		
	Female (N = 1214)	Male (N = 761)	All (N = 1975)	Female (N = 3476)	Male (N = 1910)	All (N = 5386)
<b>Gender (% male)</b>	--	--	38.5%	--	--	35.5%
<b>Age (years)</b>	51.7	50.6	51.3	54.1	54.6	54.3
<b>Weight (pounds)</b>	211.1	237.4	221.2	211.7	242.9	222.8
<b>BMI (kg/m<sup>2</sup>)</b>	36.5	34.6	35.8	37.0	35.6	36.5
<b>Waist (inches)</b>	45.4	45.4	45.4	45.3	46.3	45.6
<b>Systolic BP (mm Hg)</b>	127.9	130.3	128.9	127.7	130.8	128.9
<b>Diastolic BP (mm Hg)</b>	76.3	79.4	77.5	75.7	78.4	76.6
<b>HDL (mg/dl)</b>	45.3	40.7	43.5	45.6	39.7	43.5
<b>LDL (mg/dl)</b>	102.0	97.1	100.1	97.4	93.8	96.2
<b>Triglycerides (mg/dl)</b>	197.2	234.0	211.3	187.4	210.1	195.4
<b>Total Cholesterol (mg/dl)</b>	182.9	176.1	180.3	177.2	170.7	174.9
<b>Non-Smoker (%)</b>	79%	71%	76%	80%	77%	79%
<b>Questionnaire returned? (%)</b>	94%	93%	94%	94%	93%	94%
<b>Physically Active (%)</b>	26%	39%	31%	28%	43%	33%
<b>Healthy Diet Score</b>	3.6	3.5	3.5	3.6	3.6	3.6
<b>Unhealthy Diet Score</b>	2.7	2.9	2.8	2.6	2.8	2.7

Values reported are means or percentages.

302 participants who started the project after July 2015 and did not complete a Year 1 assessment were excluded.

642 participants did not complete a Year 1 assessment but returned for at least one annual assessment.

## B. Clinical Measurements:

Table 3B.01 summarizes the clinical measurements for the participants at each assessment (unpaired data), and Table 3B.02 summarizes the same measurements by gender (unpaired data).

Tables 3B.03 and 3B.04 present changes in clinical measurements from baseline to later time-points using paired data. Tables 3B.05 and 3B.06 summarize the percentages of HH participants achieving goals at each assessment (unpaired data). The percentage of participants achieving goals is greater than or equal to the baseline percentage for most outcomes at most time points, with the exception of waist, systolic blood pressure, and A1c (Table 3B.05).

Please note that there was a wide range of changes in the clinical variables among HH participants. Figure 3B.01 shows such an example. The change in LDL of HH participants from baseline to Year 1 ranged from a decrease of 225 mg/dl to an increase of 162 mg/dl. The mean 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 most of the clinical outcome measurements reported, so both median changes (Table 3B.03 and 3B.04) and changes in means (Figures 3B.02 through 3B.11) are reported.

Figures 3B.02 through 3B.09 depict the means of clinical measurements at baseline and at each annual assessment 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 3B.07: HH LDL Changes from Baseline (Paired Data), there were 174 participants who had LDL measured at baseline and at Year 10. The mean baseline LDL for these 174 participants was 95 mg/dl and the mean LDL at Year 10 was 78 mg/dl. **The majority of participants had small but consistent improvements in weight, BMI, diastolic blood pressure, LDL, HDL, triglycerides, total cholesterol, smoking status, and daily use of aspirin or other anti-coagulant/anti-platelet therapy at most time points. Waist did not show consistent improvement, and systolic blood pressure and A1c became worse over time.**



**Table 3B.01 HH Clinical Measurements at Each Assessment (Unpaired Data)**

	Baseline		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
<b>Weight (pounds)</b>	7,659	<b>222.2</b>	4,733	<b>221.1</b>	3,600	<b>220.1</b>	2,930	<b>218.8</b>	2,320	<b>217.7</b>	1,754	<b>215.6</b>	1,375	<b>214.0</b>	1,048	<b>212.5</b>	814	<b>212.8</b>	498	<b>208.3</b>	192	<b>205.2</b>
<b>Body Mass Index (BMI)</b>	7,659	<b>36.3</b>	4,732	<b>36.2</b>	3,599	<b>36.1</b>	2,929	<b>36.0</b>	2,319	<b>35.9</b>	1,753	<b>35.7</b>	1,374	<b>35.4</b>	1,048	<b>35.2</b>	814	<b>35.2</b>	498	<b>34.6</b>	192	<b>34.1</b>
<b>Waist (inches)</b>	7,361	<b>45.6</b>	4,411	<b>45.3</b>	3,361	<b>45.2</b>	2,689	<b>45.1</b>	2,144	<b>45.0</b>	1,561	<b>44.8</b>	1,225	<b>44.6</b>	920	<b>44.8</b>	703	<b>45.0</b>	431	<b>44.8</b>	161	<b>43.9</b>
<b>Systolic BP (mm Hg)</b>	7,657	<b>129.0</b>	4,730	<b>127.6</b>	3,604	<b>127.8</b>	2,935	<b>127.9</b>	2,322	<b>127.4</b>	1,755	<b>128.2</b>	1,376	<b>129.0</b>	1,051	<b>128.1</b>	814	<b>129.4</b>	503	<b>129.8</b>	194	<b>128.4</b>
<b>Diastolic BP (mm Hg)</b>	7,657	<b>77.0</b>	4,730	<b>75.7</b>	3,604	<b>75.3</b>	2,935	<b>74.8</b>	2,322	<b>74.2</b>	1,755	<b>74.3</b>	1,376	<b>74.3</b>	1,051	<b>73.9</b>	814	<b>74.3</b>	503	<b>73.6</b>	194	<b>72.6</b>
<b>LDL (mg/dl)</b>	7,393	<b>97.1</b>	4,525	<b>91.8</b>	3,458	<b>90.3</b>	2,814	<b>88.2</b>	2,225	<b>87.2</b>	1,678	<b>87.3</b>	1,321	<b>85.3</b>	1,006	<b>84.5</b>	773	<b>82.4</b>	478	<b>78.1</b>	177	<b>77.6</b>
<b>HDL (mg/dl)</b>	7,595	<b>43.5</b>	4,620	<b>43.9</b>	3,532	<b>44.3</b>	2,862	<b>44.4</b>	2,263	<b>45.0</b>	1,687	<b>45.2</b>	1,318	<b>45.5</b>	1,014	<b>46.0</b>	782	<b>46.4</b>	480	<b>47.2</b>	181	<b>48.8</b>
<b>Triglycerides (mg/dl)</b>	7,598	<b>199.9</b>	4,615	<b>185.2</b>	3,526	<b>183.3</b>	2,853	<b>184.3</b>	2,257	<b>179.3</b>	1,680	<b>179.2</b>	1,315	<b>175.1</b>	1,010	<b>178.0</b>	771	<b>175.6</b>	470	<b>175.7</b>	176	<b>168.6</b>
<b>Total Cholesterol (mg/dl)</b>	7,626	<b>176.2</b>	4,645	<b>169.0</b>	3,542	<b>167.7</b>	2,880	<b>165.5</b>	2,278	<b>164.6</b>	1,709	<b>164.7</b>	1,346	<b>162.2</b>	1,021	<b>161.5</b>	788	<b>158.9</b>	483	<b>156.3</b>	181	<b>156.9</b>
<b>A1C (%)</b>	7,636	<b>8.1</b>	4,731	<b>7.7</b>	3,606	<b>7.7</b>	2,929	<b>7.8</b>	2,328	<b>7.9</b>	1,757	<b>8.0</b>	1,379	<b>8.0</b>	1,048	<b>8.0</b>	814	<b>8.1</b>	503	<b>8.0</b>	195	<b>8.0</b>

**Table 3B.02 HH Clinical Measurements at Each Assessment by Gender (Unpaired Data)**

	Female																					
	Baseline		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
<b>Weight (pounds)</b>	4,864	<b>211.4</b>	3,054	<b>209.8</b>	2,332	<b>207.6</b>	1,888	<b>207.3</b>	1,512	<b>206.8</b>	1,156	<b>203.9</b>	909	<b>202.5</b>	706	<b>200.4</b>	531	<b>199.4</b>	336	<b>194.6</b>	133	<b>192.3</b>
<b>Body Mass Index (BMI)</b>	4,864	<b>36.8</b>	3,054	<b>36.6</b>	2,332	<b>36.3</b>	1,888	<b>36.3</b>	1,512	<b>36.3</b>	1,156	<b>35.9</b>	909	<b>35.6</b>	706	<b>35.4</b>	531	<b>35.3</b>	336	<b>34.6</b>	133	<b>34.0</b>
<b>Waist (inches)</b>	4,690	<b>45.3</b>	2,862	<b>44.9</b>	2,189	<b>44.7</b>	1,746	<b>44.6</b>	1,402	<b>44.6</b>	1,050	<b>44.3</b>	823	<b>44.1</b>	624	<b>44.1</b>	461	<b>44.2</b>	295	<b>43.9</b>	116	<b>43.1</b>
<b>Systolic BP (mm Hg)</b>	4,863	<b>127.9</b>	3,052	<b>126.7</b>	2,335	<b>126.7</b>	1,891	<b>127.1</b>	1,512	<b>126.8</b>	1,156	<b>127.6</b>	909	<b>128.6</b>	707	<b>127.3</b>	531	<b>128.7</b>	340	<b>129.5</b>	135	<b>128.8</b>
<b>Diastolic BP (mm Hg)</b>	4,863	<b>75.9</b>	3,052	<b>74.9</b>	2,335	<b>74.5</b>	1,891	<b>74.3</b>	1,512	<b>73.6</b>	1,156	<b>73.9</b>	909	<b>73.9</b>	707	<b>73.3</b>	531	<b>73.9</b>	340	<b>73.4</b>	135	<b>72.9</b>
<b>LDL (mg/dl)</b>	4,733	<b>98.5</b>	2,924	<b>93.4</b>	2,243	<b>91.8</b>	1,826	<b>90.0</b>	1,456	<b>89.2</b>	1,111	<b>89.4</b>	880	<b>87.7</b>	685	<b>87.6</b>	508	<b>84.5</b>	327	<b>79.8</b>	121	<b>79.1</b>
<b>HDL (mg/dl)</b>	4,828	<b>45.5</b>	2,976	<b>46.0</b>	2,284	<b>46.6</b>	1,848	<b>46.9</b>	1,477	<b>47.4</b>	1,110	<b>47.5</b>	873	<b>47.8</b>	687	<b>48.5</b>	513	<b>49.1</b>	329	<b>49.2</b>	126	<b>50.5</b>
<b>Triglycerides (mg/dl)</b>	4,830	<b>189.8</b>	2,973	<b>181.2</b>	2,282	<b>184.2</b>	1,839	<b>179.9</b>	1,474	<b>176.0</b>	1,104	<b>171.8</b>	871	<b>169.9</b>	686	<b>171.5</b>	508	<b>173.1</b>	324	<b>178.4</b>	124	<b>174.8</b>
<b>Total Cholesterol (mg/dl)</b>	4,843	<b>178.6</b>	2,992	<b>172.5</b>	2,289	<b>171.6</b>	1,857	<b>169.6</b>	1,487	<b>169.0</b>	1,124	<b>168.8</b>	892	<b>166.7</b>	691	<b>166.6</b>	516	<b>163.3</b>	330	<b>160.4</b>	126	<b>162.6</b>
<b>A1C (%)</b>	4,849	<b>8.1</b>	3,052	<b>7.7</b>	2,336	<b>7.8</b>	1,887	<b>7.9</b>	1,516	<b>7.9</b>	1,159	<b>8.0</b>	911	<b>8.0</b>	704	<b>8.0</b>	532	<b>8.1</b>	340	<b>8.0</b>	136	<b>7.9</b>

**Table 3B.02 HH Clinical Measurements at Each Assessment by Gender (Unpaired Data) (Continued)**

	Male																					
	Baseline		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
<b>Weight (pounds)</b>	2,795	<b>241.2</b>	1,679	<b>241.8</b>	1,268	<b>243.1</b>	1,042	<b>239.6</b>	808	<b>238.0</b>	598	<b>238.2</b>	466	<b>236.3</b>	342	<b>237.5</b>	283	<b>238.0</b>	162	<b>236.7</b>	59	<b>234.2</b>
<b>Body Mass Index (BMI)</b>	2,795	<b>35.3</b>	1,678	<b>35.5</b>	1,267	<b>35.6</b>	1,041	<b>35.3</b>	807	<b>35.1</b>	597	<b>35.2</b>	465	<b>34.9</b>	342	<b>34.9</b>	283	<b>35.0</b>	162	<b>34.6</b>	59	<b>34.3</b>
<b>Waist (inches)</b>	2,671	<b>46.1</b>	1,549	<b>46.1</b>	1,172	<b>46.1</b>	943	<b>45.9</b>	742	<b>45.8</b>	511	<b>46.0</b>	402	<b>45.8</b>	296	<b>46.1</b>	242	<b>46.4</b>	136	<b>46.6</b>	45	<b>46.1</b>
<b>Systolic BP (mm Hg)</b>	2,794	<b>130.9</b>	1,678	<b>129.3</b>	1,269	<b>129.7</b>	1,044	<b>129.2</b>	810	<b>128.7</b>	599	<b>129.5</b>	467	<b>129.9</b>	344	<b>129.7</b>	283	<b>130.7</b>	163	<b>130.5</b>	59	<b>127.4</b>
<b>Diastolic BP (mm Hg)</b>	2,794	<b>78.8</b>	1,678	<b>77.1</b>	1,269	<b>76.8</b>	1,044	<b>75.8</b>	810	<b>75.2</b>	599	<b>75.1</b>	467	<b>75.2</b>	344	<b>75.3</b>	283	<b>74.9</b>	163	<b>74.1</b>	59	<b>71.9</b>
<b>LDL (mg/dl)</b>	2,660	<b>94.6</b>	1,601	<b>88.9</b>	1,215	<b>87.5</b>	988	<b>84.8</b>	769	<b>83.5</b>	567	<b>83.3</b>	441	<b>80.5</b>	321	<b>77.9</b>	265	<b>78.6</b>	151	<b>74.4</b>	56	<b>74.3</b>
<b>HDL (mg/dl)</b>	2,767	<b>40.0</b>	1,644	<b>40.0</b>	1,248	<b>40.2</b>	1,014	<b>40.0</b>	786	<b>40.4</b>	577	<b>40.7</b>	445	<b>40.9</b>	327	<b>41.0</b>	269	<b>41.3</b>	151	<b>42.8</b>	55	<b>44.9</b>
<b>Triglycerides (mg/dl)</b>	2,768	<b>217.4</b>	1,642	<b>192.3</b>	1,244	<b>181.5</b>	1,014	<b>192.3</b>	783	<b>185.4</b>	576	<b>193.3</b>	444	<b>185.2</b>	324	<b>191.6</b>	263	<b>180.3</b>	146	<b>169.8</b>	52	<b>153.7</b>
<b>Total Cholesterol (mg/dl)</b>	2,783	<b>172.2</b>	1,653	<b>162.8</b>	1,253	<b>160.5</b>	1,023	<b>158.0</b>	791	<b>156.3</b>	585	<b>156.7</b>	454	<b>153.4</b>	330	<b>151.0</b>	272	<b>150.5</b>	153	<b>147.6</b>	55	<b>143.9</b>
<b>A1C (%)</b>	2,787	<b>8.3</b>	1,679	<b>7.7</b>	1,270	<b>7.7</b>	1,042	<b>7.8</b>	812	<b>7.9</b>	598	<b>8.0</b>	468	<b>8.0</b>	344	<b>8.0</b>	282	<b>8.1</b>	163	<b>8.0</b>	59	<b>8.1</b>

**Table 3B.03 HH Clinical Outcome Changes from Baseline (Paired Data)**

<b>Outcome</b>	<b>1st Annual (N=4744)</b>	<b>2nd Annual (N=3611)</b>	<b>3rd Annual (N=2936)</b>	<b>4rd Annual (N=2330)</b>	<b>5th Annual (N=1758)</b>	<b>6th Annual (N=1380)</b>	<b>7th Annual (N=1052)</b>	<b>8th Annual (N= 815)</b>	<b>9th Annual (N= 503)</b>	<b>10th Annual (N= 195)</b>
<b>Median Change in Weight (pounds)*</b>	-1.0	-1.8	-2.3	-3.0	-5.0	-6.6	-7.9	-9.0	-9.8	-11.8
<b>Median Change in Body Mass Index (BMI)</b>	-0.2	-0.3	-0.4	-0.5	-0.8	-1.1	-1.3	-1.5	-1.7	-2.0
<b>Median Change in Waist (inches)</b>	0.0	-0.3	0.0	0.0	0.0	-0.5	-0.6	-0.5	-0.5	0.0
<b>Median Change in Systolic BP (mm Hg)</b>	-1.0	-1.0	0.0	-1.0	0.0	1.0	0.0	2.0	2.0	1.5
<b>Median Change in Diastolic BP (mm Hg)</b>	-1.0	-1.0	-1.0	-2.0	-2.0	-2.0	-2.0	-2.0	-2.0	-3.0
<b>Median Change in LDL (mg/dl)</b>	-3.0	-4.0	-5.6	-6.0	-7.0	-9.0	-11.0	-12.0	-16.0	-17.0
<b>Median Change in HDL (mg/dl)</b>	0.0	0.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	2.3
<b>Median Change in Triglycerides (mg/dl)</b>	-3.0	-4.0	-4.0	-4.0	-4.5	-4.0	-3.0	-3.0	-3.5	-15.5
<b>Median Change in Total Cholesterol (mg/dl)</b>	-4.0	-5.0	-7.0	-7.0	-10.0	-10.0	-12.0	-13.5	-17.0	-23.0
<b>Median Change in A1C (%)</b>	-0.1	-0.1	0.1	0.1	0.2	0.3	0.3	0.4	0.4	0.7

**Table 3B.03 HH Clinical Outcome Changes from Baseline by Gender (Paired Data)**

**Female**

<b>Outcome</b>	<b>1st Annual (N=3059)</b>	<b>2nd Annual (N=2339)</b>	<b>3rd Annual (N=1892)</b>	<b>4rd Annual (N=1518)</b>	<b>5th Annual (N=1159)</b>	<b>6th Annual (N= 912)</b>	<b>7th Annual (N= 707)</b>	<b>8th Annual (N= 532)</b>	<b>9th Annual (N= 340)</b>	<b>10th Annual (N= 136)</b>
<b>Median Change in Weight (pounds)</b>	-1.0	-2.0	-2.9	-3.2	-5.5	-8.0	-8.5	-9.4	-11.4	-12.0
<b>Median Change in Body Mass Index (BMI)</b>	-0.2	-0.4	-0.5	-0.6	-1.0	-1.4	-1.5	-1.7	-2.0	-2.2
<b>Median Change in Waist (inches)</b>	0.0	0.0	0.0	0.0	-0.3	-0.8	-0.5	-0.5	0.0	0.0
<b>Median Change in Systolic BP (mm Hg)</b>	-1.0	-1.0	0.0	0.0	0.0	2.0	0.0	4.0	2.5	3.0
<b>Median Change in Diastolic BP (mm Hg)</b>	0.0	-1.0	-1.0	-2.0	-1.0	-1.0	-2.0	-1.0	-2.0	-2.0
<b>Median Change in LDL (mg/dl)</b>	-2.0	-4.0	-5.0	-6.9	-6.4	-7.0	-8.0	-11.0	-16.0	-17.0
<b>Median Change in HDL (mg/dl)</b>	0.0	0.0	1.0	1.0	1.0	1.9	1.0	1.0	0.0	2.3
<b>Median Change in Triglycerides (mg/dl)</b>	-1.0	-2.0	-4.0	-4.0	-2.0	-4.0	-1.0	-2.0	-1.0	-8.0
<b>Median Change in Total Cholesterol (mg/dl)</b>	-2.0	-3.0	-4.0	-7.0	-8.0	-8.0	-9.0	-12.0	-17.0	-16.5
<b>Median Change in A1C (%)</b>	-0.1	0.0	0.1	0.1	0.2	0.3	0.3	0.4	0.4	0.7

**Table 3B.03 HH Clinical Outcome Changes from Baseline by Gender (Paired Data) (Continued)**

**Male**

<b>Outcome</b>	<b>1st Annual (N=1685)</b>	<b>2nd Annual (N=1272)</b>	<b>3rd Annual (N=1044)</b>	<b>4rd Annual (N= 812)</b>	<b>5th Annual (N= 599)</b>	<b>6th Annual (N= 468)</b>	<b>7th Annual (N= 345)</b>	<b>8th Annual (N= 283)</b>	<b>9th Annual (N= 163)</b>	<b>10th Annual (N= 59)</b>
<b>Median Change in Weight (pounds)</b>	-0.8	-1.0	-1.6	-1.8	-3.0	-4.8	-6.7	-8.4	-8.0	-11.7
<b>Median Change in Body Mass Index (BMI)</b>	-0.1	-0.1	-0.2	-0.3	-0.4	-0.6	-1.0	-1.3	-1.2	-1.9
<b>Median Change in Waist (inches)</b>	0.0	-0.3	0.0	0.0	0.0	0.0	-1.0	-1.0	-1.1	-1.5
<b>Median Change in Systolic BP (mm Hg)</b>	-2.0	-2.0	0.0	-2.0	1.0	0.0	0.0	0.0	0.0	-3.0
<b>Median Change in Diastolic BP (mm Hg)</b>	-1.0	-1.0	-2.0	-2.0	-2.0	-2.0	-1.0	-4.0	-3.0	-4.0
<b>Median Change in LDL (mg/dl)</b>	-3.0	-5.0	-6.5	-6.0	-9.0	-11.0	-16.0	-13.0	-14.0	-17.0
<b>Median Change in HDL (mg/dl)</b>	0.0	0.0	0.0	0.0	0.7	1.0	1.0	1.0	1.6	2.0
<b>Median Change in Triglycerides (mg/dl)</b>	-7.0	-8.0	-4.0	-4.0	-11.0	-4.0	-9.0	-5.0	-7.0	-31.0
<b>Median Change in Total Cholesterol (mg/dl)</b>	-5.0	-7.0	-10.0	-9.0	-12.0	-16.0	-19.0	-18.0	-16.0	-28.0
<b>Median Change in A1C (%)</b>	-0.2	-0.1	0.0	0.1	0.2	0.3	0.2	0.4	0.5	0.6

**Table 3B.05 HH Percentage of Participants Achieving Goals at Each Assessment (Unpaired Data)**

% of Participants Achieving Goal	Baseline		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	%
<b>Weight Loss (7%)</b>	7,659	<b>n/a</b>	4,732	<b>10</b>	3,599	<b>15</b>	2,929	<b>18</b>	2,319	<b>21</b>	1,753	<b>27</b>	1,374	<b>32</b>	1,048	<b>37</b>	814	<b>38</b>	498	<b>43</b>	192	<b>45</b>
<b>Waist (men &lt;=40", women &lt;=35")</b>	7,361	<b>11</b>	4,411	<b>11</b>	3,361	<b>11</b>	2,689	<b>11</b>	2,144	<b>11</b>	1,561	<b>11</b>	1,225	<b>10</b>	920	<b>10</b>	703	<b>10</b>	431	<b>10</b>	161	<b>12</b>
<b>Systolic BP (&lt; 130 mm Hg)</b>	7,657	<b>54</b>	4,730	<b>58</b>	3,604	<b>58</b>	2,935	<b>57</b>	2,322	<b>58</b>	1,755	<b>55</b>	1,376	<b>54</b>	1,051	<b>56</b>	814	<b>52</b>	503	<b>49</b>	194	<b>55</b>
<b>Diastolic BP (&lt; 80 mm Hg)</b>	7,657	<b>58</b>	4,730	<b>64</b>	3,604	<b>66</b>	2,935	<b>67</b>	2,322	<b>69</b>	1,755	<b>69</b>	1,376	<b>71</b>	1,051	<b>70</b>	814	<b>70</b>	503	<b>72</b>	194	<b>74</b>
<b>LDL (&lt; 100 mg/dl)</b>	7,393	<b>57</b>	4,525	<b>65</b>	3,458	<b>66</b>	2,814	<b>70</b>	2,225	<b>70</b>	1,678	<b>70</b>	1,321	<b>73</b>	1,006	<b>74</b>	773	<b>76</b>	478	<b>79</b>	177	<b>79</b>
<b>HDL (men &gt; 40 mg/dl, women &gt; 50 mg/dl)</b>	7,595	<b>33</b>	4,620	<b>34</b>	3,532	<b>35</b>	2,862	<b>36</b>	2,263	<b>37</b>	1,687	<b>37</b>	1,318	<b>38</b>	1,014	<b>40</b>	782	<b>40</b>	480	<b>44</b>	181	<b>50</b>
<b>Triglycerides (&lt; 150 mg/dl)</b>	7,598	<b>46</b>	4,615	<b>50</b>	3,526	<b>50</b>	2,853	<b>51</b>	2,257	<b>52</b>	1,680	<b>51</b>	1,315	<b>52</b>	1,010	<b>52</b>	771	<b>52</b>	470	<b>51</b>	176	<b>53</b>
<b>A1C (&lt; 7%)</b>	7,636	<b>36</b>	4,731	<b>45</b>	3,606	<b>43</b>	2,929	<b>41</b>	2,328	<b>39</b>	1,757	<b>36</b>	1,379	<b>35</b>	1,048	<b>33</b>	814	<b>35</b>	503	<b>35</b>	195	<b>31</b>
<b>Non-Smoker</b>	7,145	<b>78</b>	4,020	<b>82</b>	3,295	<b>83</b>	2,807	<b>83</b>	2,330	<b>84</b>	1,757	<b>86</b>	1,380	<b>86</b>	1,052	<b>87</b>	815	<b>86</b>	502	<b>86</b>	195	<b>89</b>
<b>Aspirin Use</b>	7,595	<b>66</b>	4,710	<b>75</b>	3,556	<b>77</b>	2,892	<b>80</b>	2,307	<b>81</b>	1,728	<b>81</b>	1,361	<b>78</b>	1,046	<b>80</b>	811	<b>83</b>	503	<b>80</b>	195	<b>79</b>

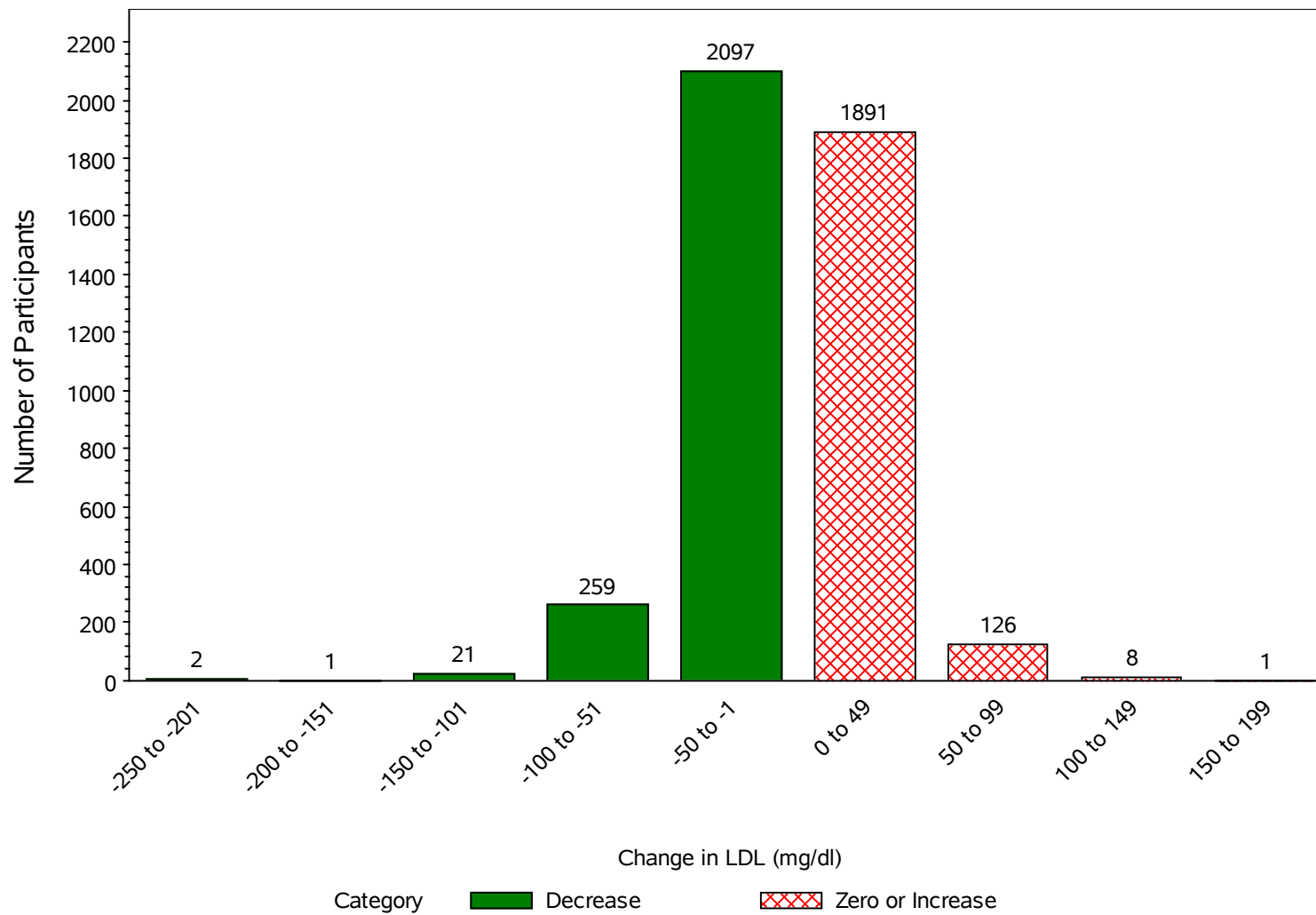


**Table 3B.06 HH Percentage of Participants Achieving Goals at Each Assessment by Gender (Unpaired Data)**

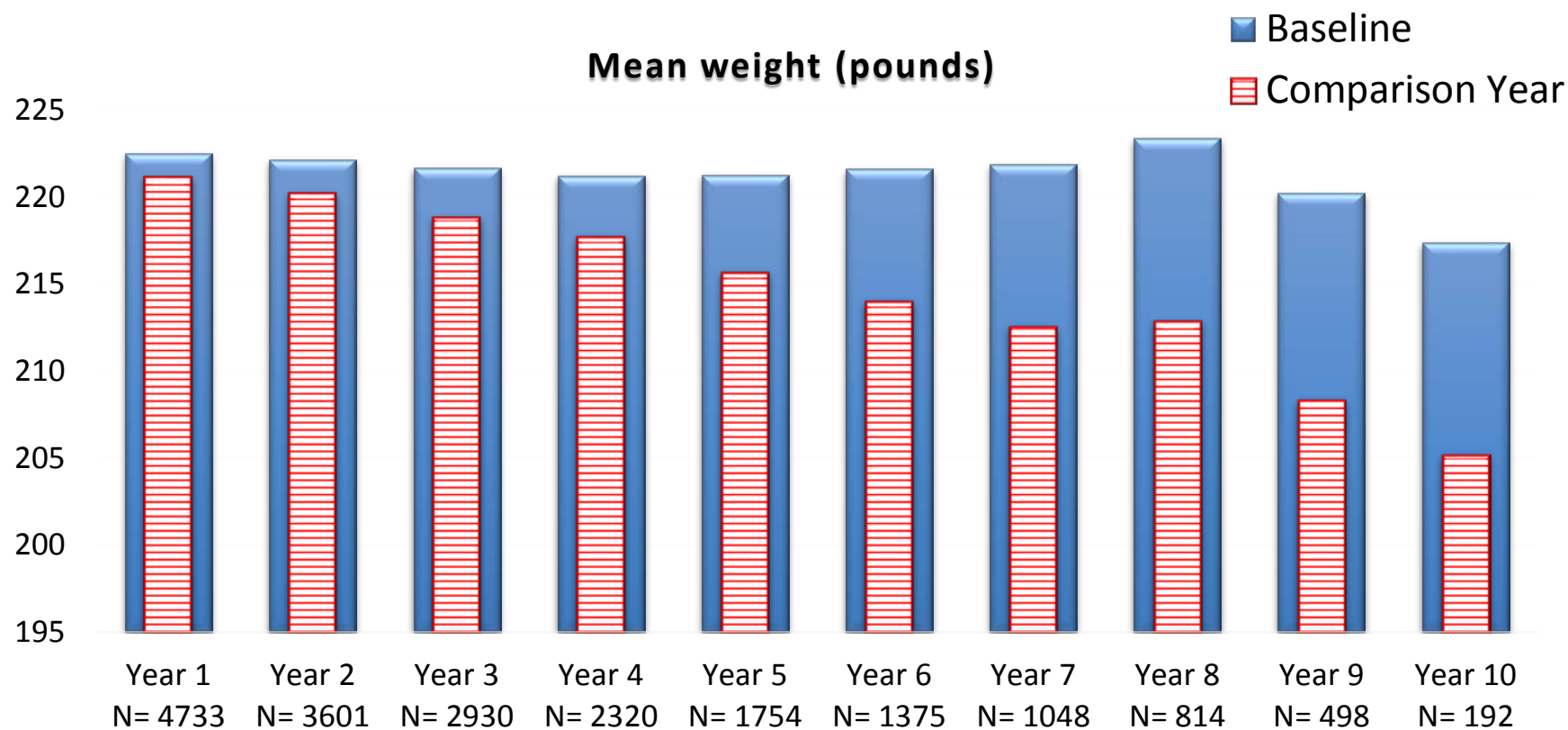
% of Participants Achieving Goal	Female																					
	Baseline		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
<b>Weight Loss (7%)</b>	4,864	n/a	3,054	10	2,332	16	1,888	19	1,512	22	1,156	29	909	35	706	39	531	40	336	47	133	47
<b>Waist (men &lt;=40", women &lt;=35")</b>	4,690	5	2,862	5	2,189	6	1,746	6	1,402	6	1,050	6	823	6	624	6	461	6	295	6	116	9
<b>Systolic BP (&lt; 130 mm Hg)</b>	4,863	57	3,052	61	2,335	61	1,891	58	1,512	60	1,156	58	909	56	707	58	531	54	340	49	135	53
<b>Diastolic BP (&lt; 80 mm Hg)</b>	4,863	62	3,052	67	2,335	69	1,891	70	1,512	71	1,156	70	909	72	707	72	531	70	340	73	135	73
<b>LDL (&lt; 100 mg/dl)</b>	4,733	55	2,924	63	2,243	65	1,826	68	1,456	68	1,111	68	880	70	685	71	508	74	327	76	121	79
<b>HDL (men &gt; 40 mg/dl, women &gt; 50 mg/dl)</b>	4,828	28	2,976	31	2,284	32	1,848	33	1,477	34	1,110	34	873	36	687	39	513	38	329	41	126	44
<b>Triglycerides (&lt; 150 mg/dl)</b>	4,830	46	2,973	49	2,282	49	1,839	49	1,474	52	1,104	50	871	53	686	52	508	54	324	50	124	53
<b>A1C (&lt; 7%)</b>	4,849	38	3,052	46	2,336	42	1,887	40	1,516	38	1,159	37	911	35	704	33	532	36	340	36	136	32
<b>Non-Smoker</b>	4,554	80	2,600	82	2,124	84	1,801	85	1,518	85	1,158	86	912	87	707	87	532	86	340	87	136	89
<b>Aspirin Use</b>	4,820	63	3,037	73	2,305	75	1,860	78	1,501	79	1,137	78	898	75	703	78	529	81	340	78	136	75

**Table 3B.06 HH Percentage of Participants Achieving Goals at Each Assessment by Gender (Unpaired Data) (Continued)**

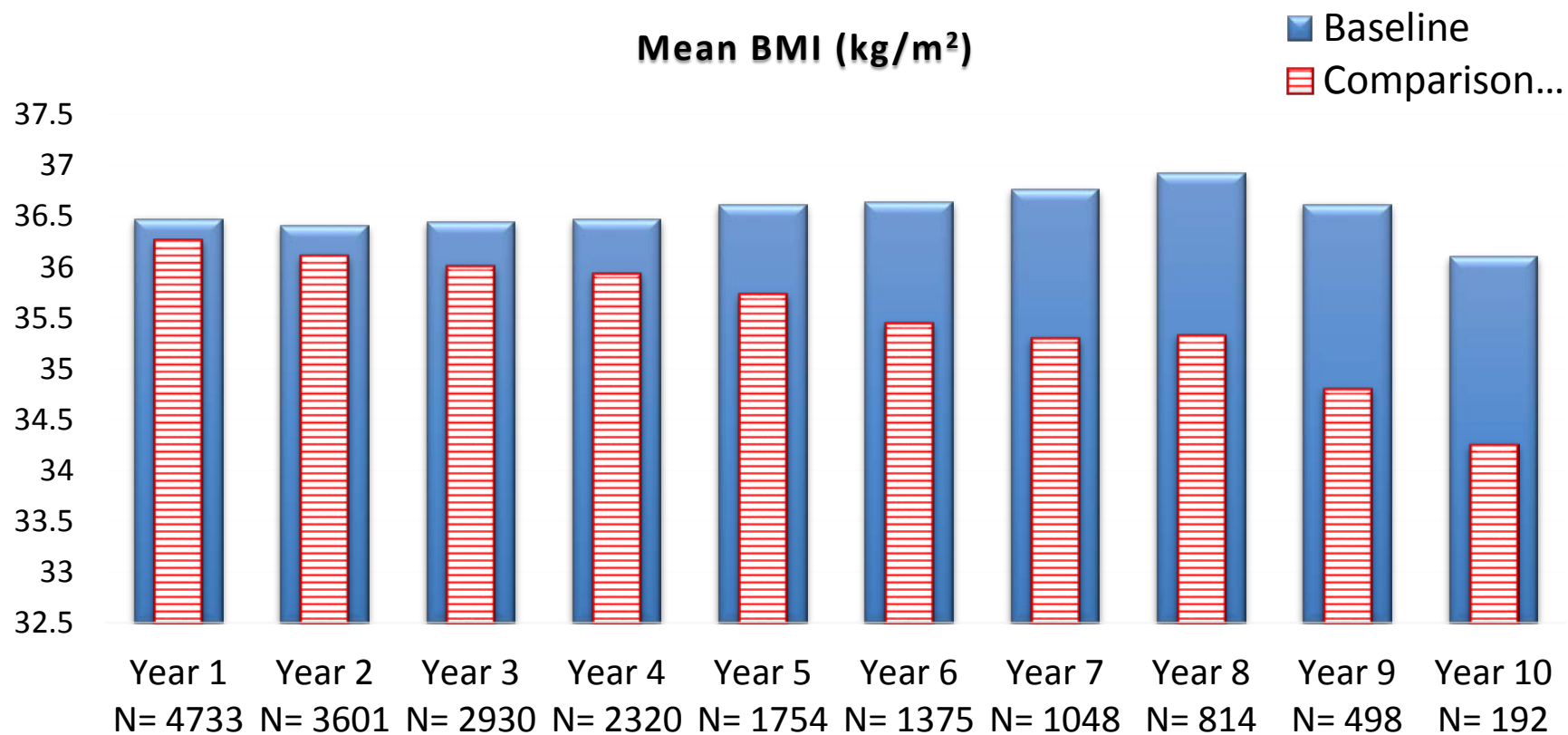
% of Participants Achieving Goal	Male																					
	Baseline		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Weight Loss (7%)	2,795	n/a	1,678	10	1,267	13	1,041	16	807	19	597	22	465	26	342	32	283	34	162	35	59	41
Waist (men <=40", women <=35")	2,671	22	1,549	21	1,172	21	943	21	742	21	511	20	402	20	296	18	242	17	136	19	45	22
Systolic BP (< 130 mm Hg)	2,794	49	1,678	54	1,269	52	1,044	54	810	54	599	51	467	51	344	51	283	49	163	48	59	59
Diastolic BP (< 80 mm Hg)	2,794	51	1,678	58	1,269	60	1,044	62	810	65	599	67	467	67	344	67	283	69	163	70	59	76
LDL (< 100 mg/dl)	2,660	59	1,601	68	1,215	69	988	73	769	74	567	73	441	81	321	81	265	80	151	86	56	79
HDL (men > 40 mg/dl, women > 50 mg/dl)	2,767	41	1,644	40	1,248	42	1,014	41	786	43	577	44	445	44	327	42	269	45	151	50	55	64
Triglycerides (< 150 mg/dl)	2,768	46	1,642	51	1,244	52	1,014	53	783	52	576	52	444	50	324	50	263	49	146	53	52	54
A1C (< 7%)	2,787	34	1,679	44	1,270	44	1,042	42	812	39	598	34	468	34	344	34	282	32	163	31	59	29
Non-Smoker	2,591	75	1,420	81	1,171	81	1,006	81	812	82	599	85	468	85	345	87	283	87	162	85	59	90
Aspirin Use	2,775	70	1,673	79	1,251	82	1,032	85	806	85	591	85	463	84	343	84	282	86	163	83	59	88



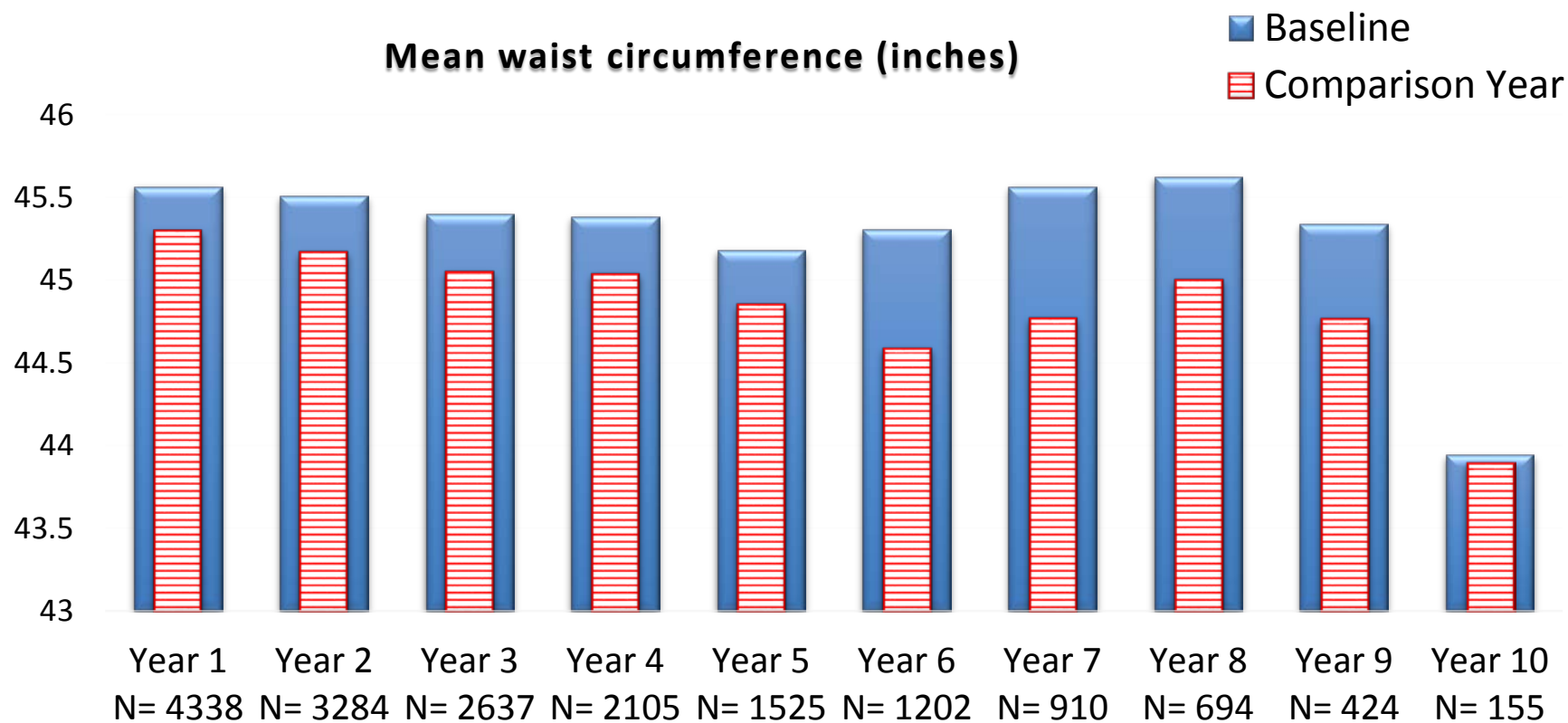
**Figure 3B.01 HH LDL Changes from Baseline to Year 1 (Paired Data, Illustration)**



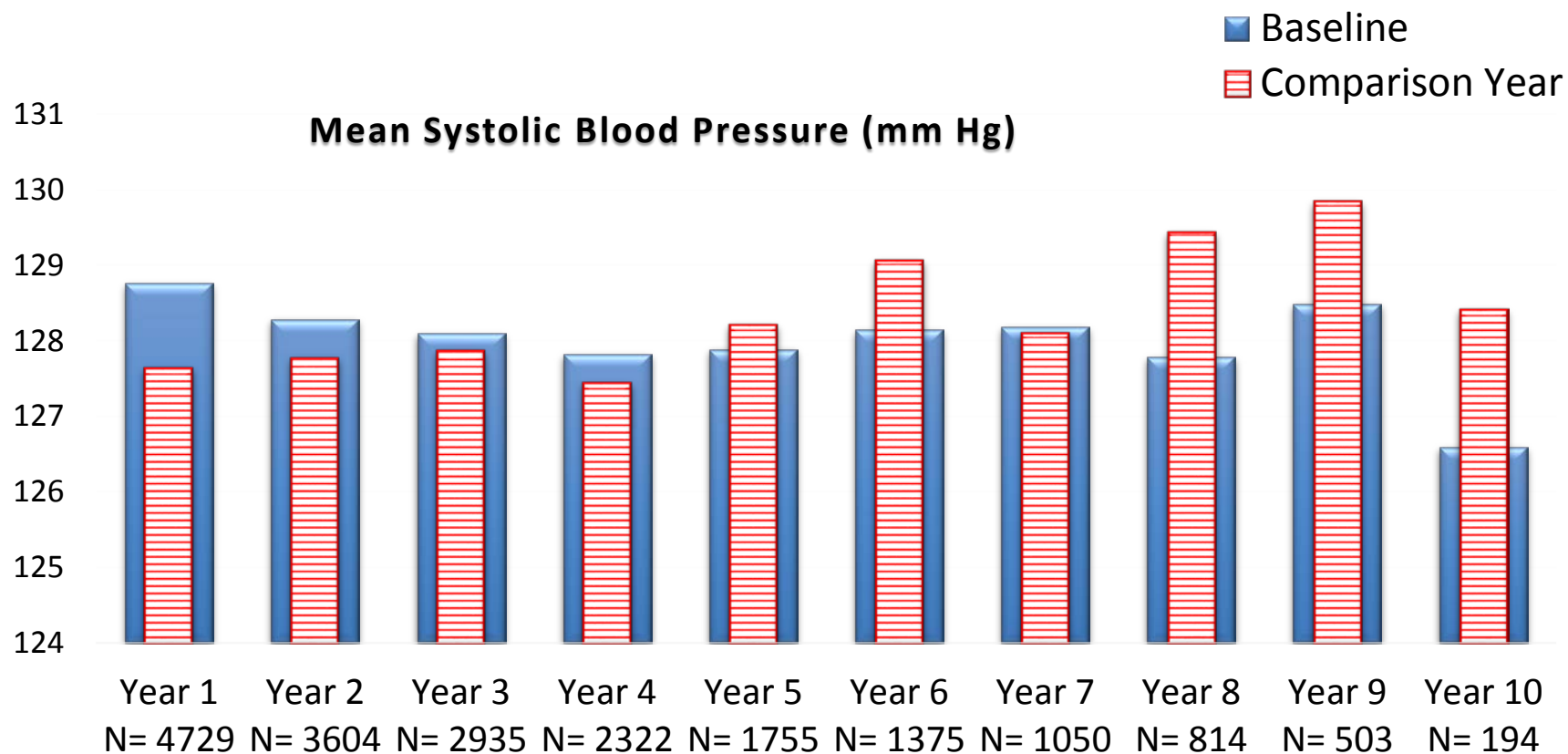
**Figure 3B.02 HH Weight Changes from Baseline (Paired Data)**



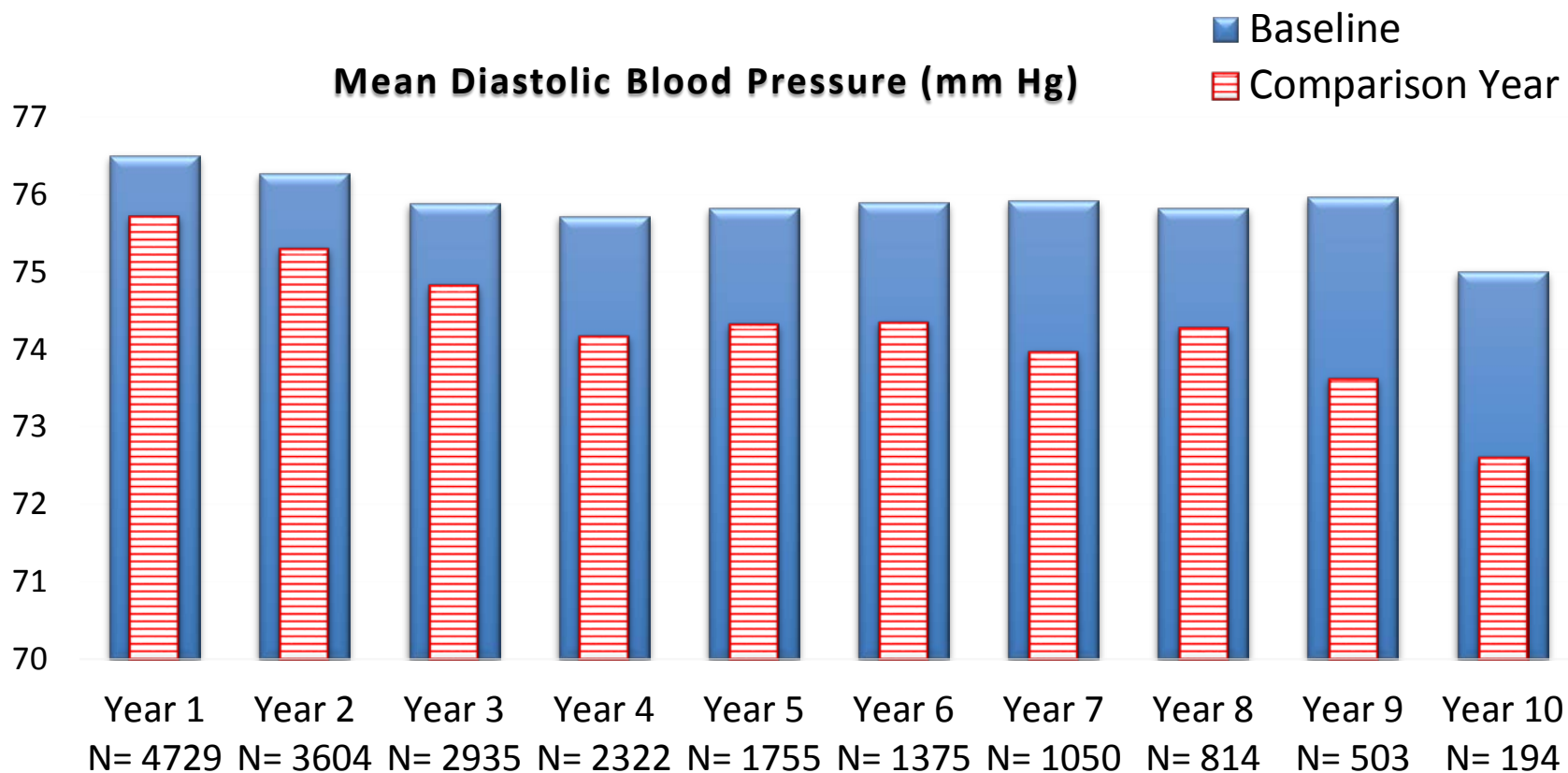
**Figure 3B.03 HH BMI Changes from Baseline (Paired Data)**



**Figure 3B.04 HH Waist Circumference Changes from Baseline (Paired Data)**

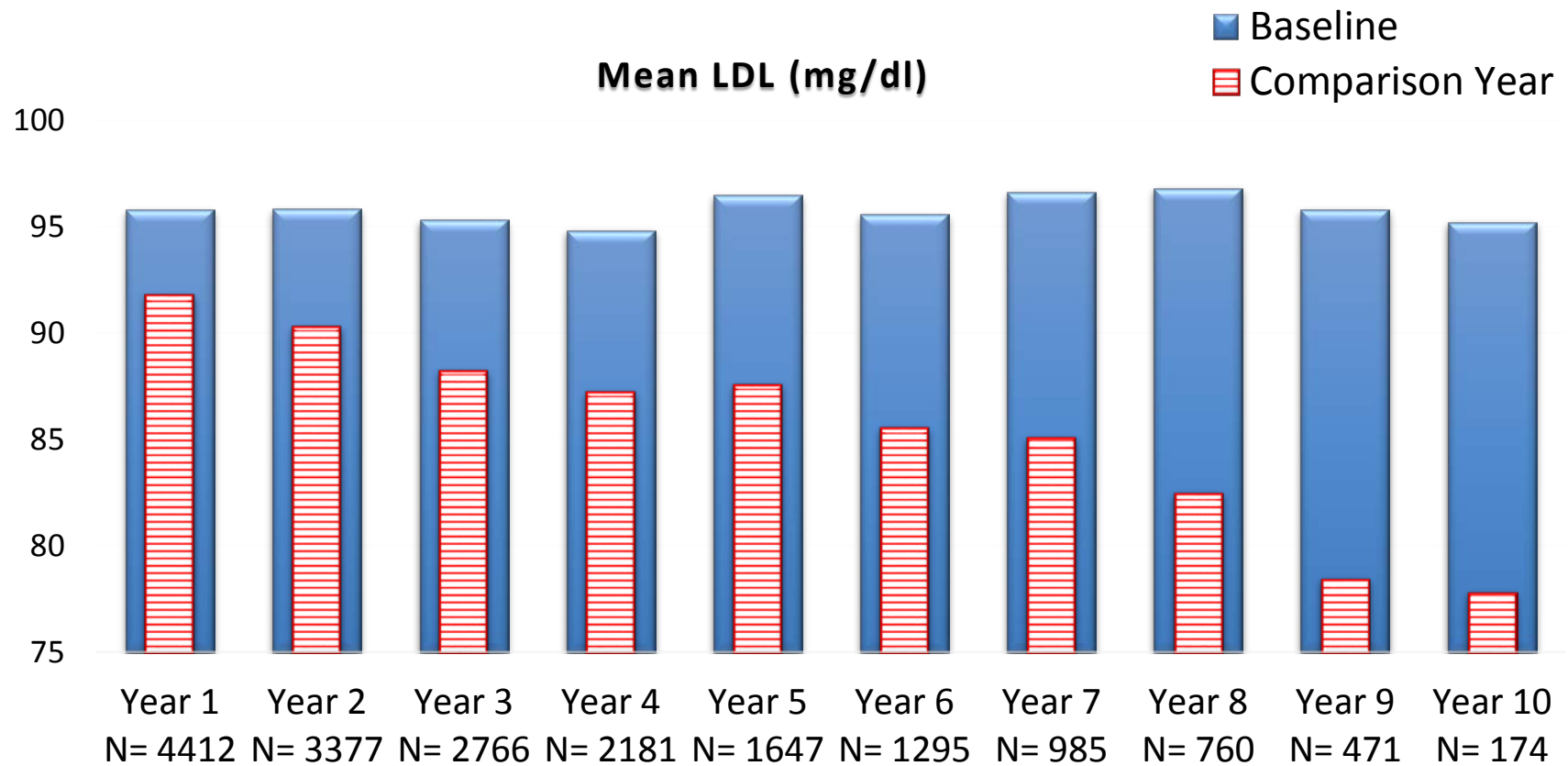


**Figure 3B.05 HH Systolic Blood Pressure Changes from Baseline (Paired Data)**

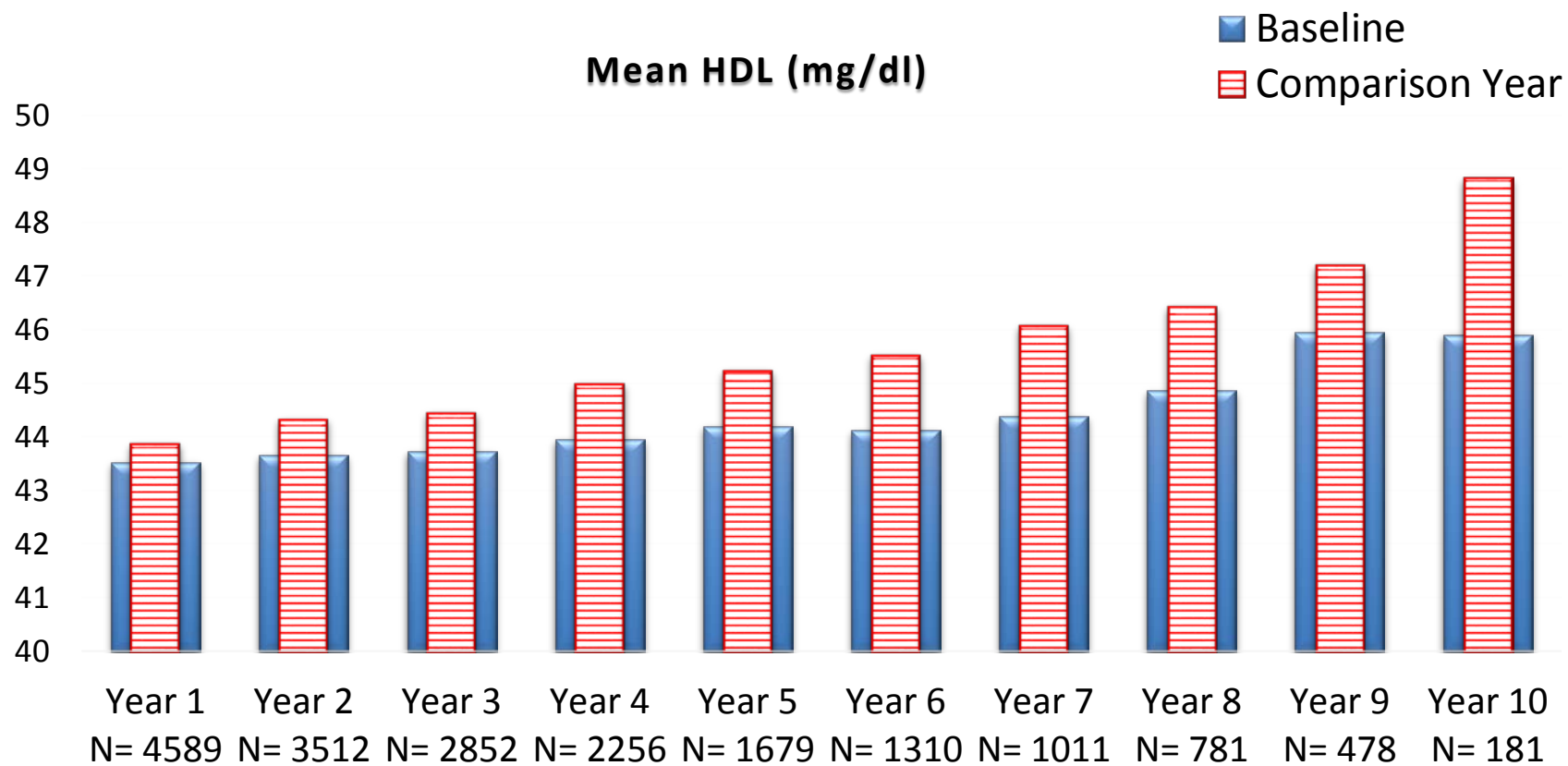


**Figure 3B.06 HH Diastolic Blood Pressure Changes from Baseline (Paired Data)**

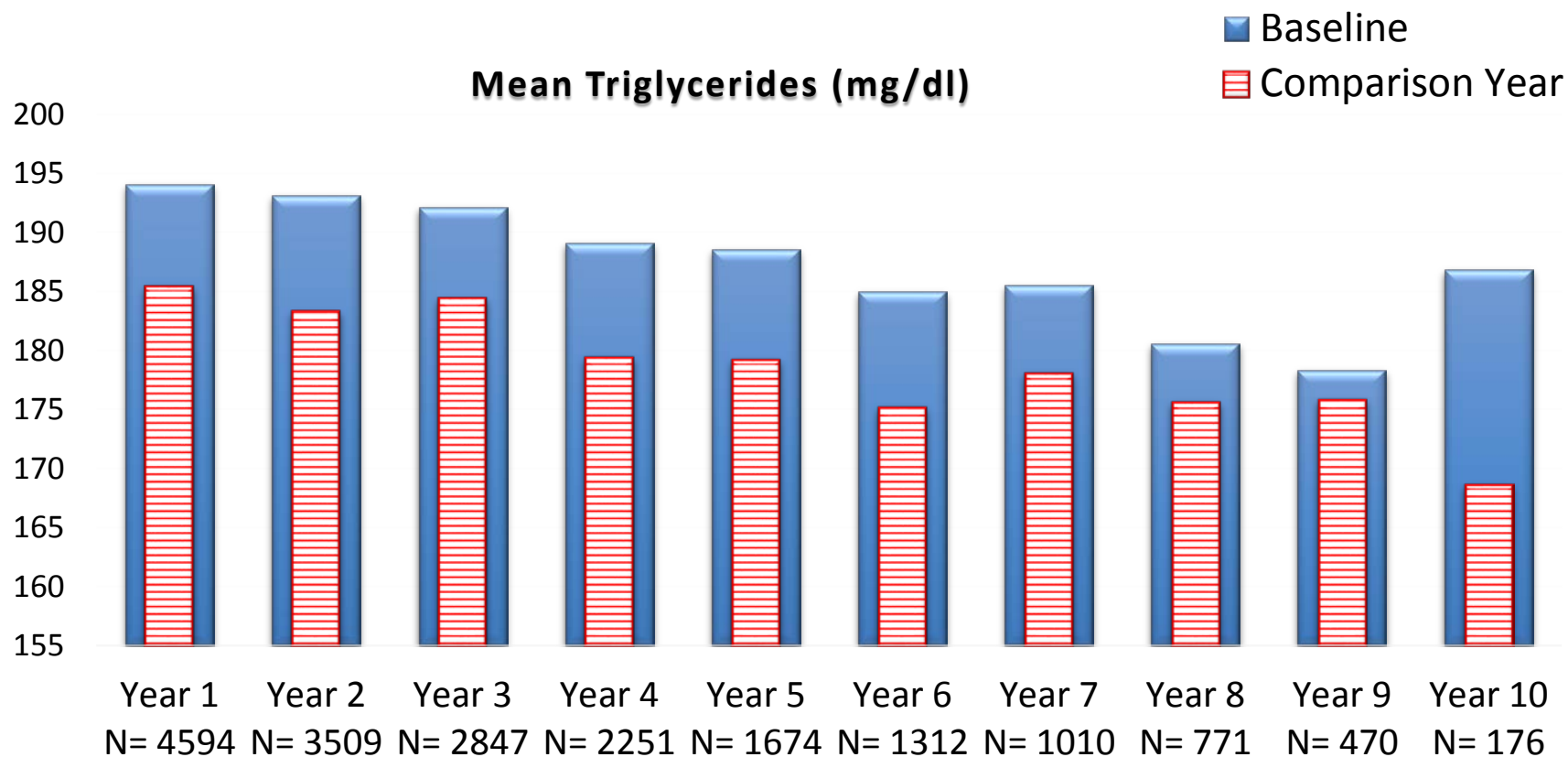




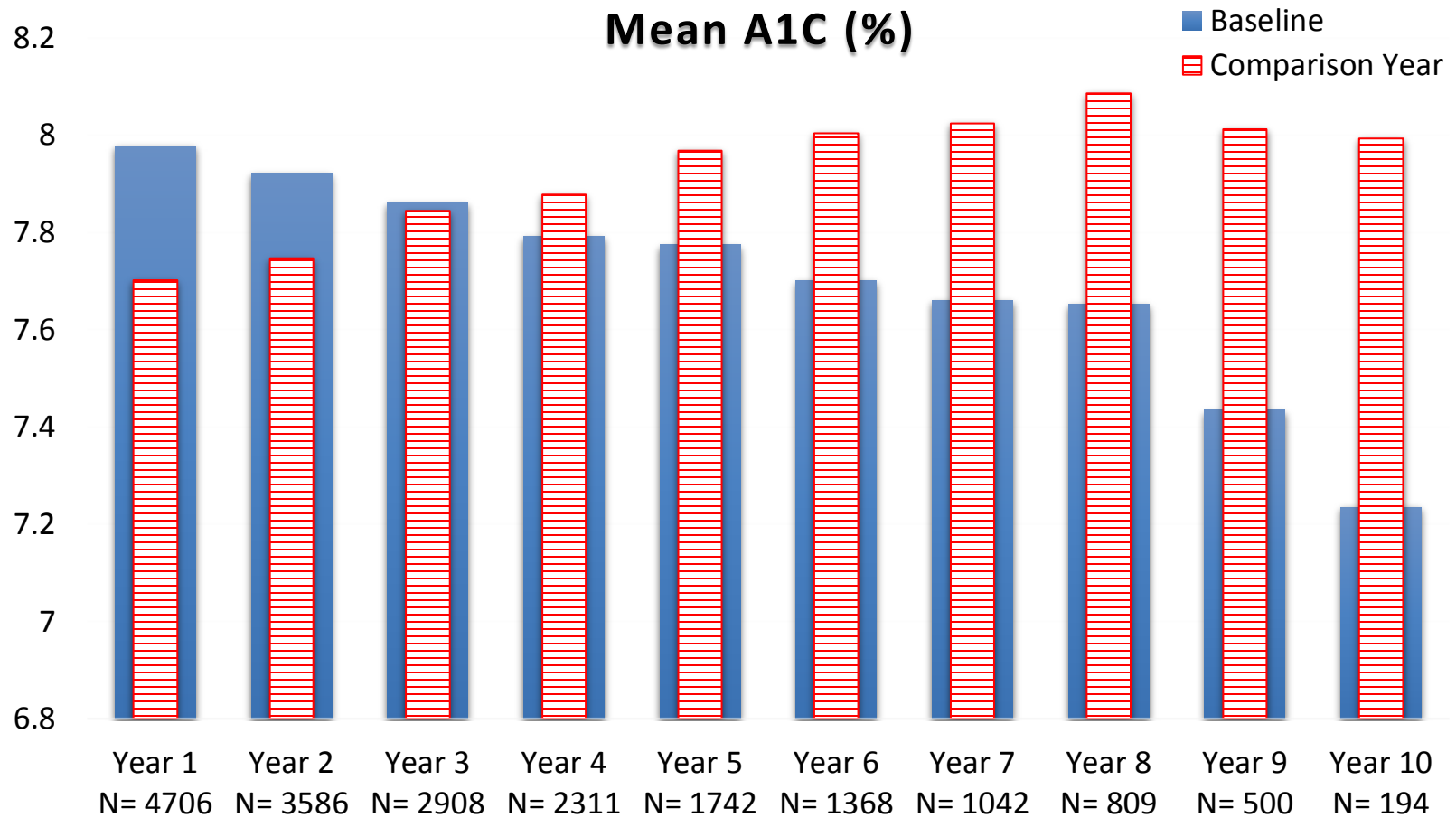
**Figure 3B.07 HH LDL Changes from Baseline (Paired Data)**



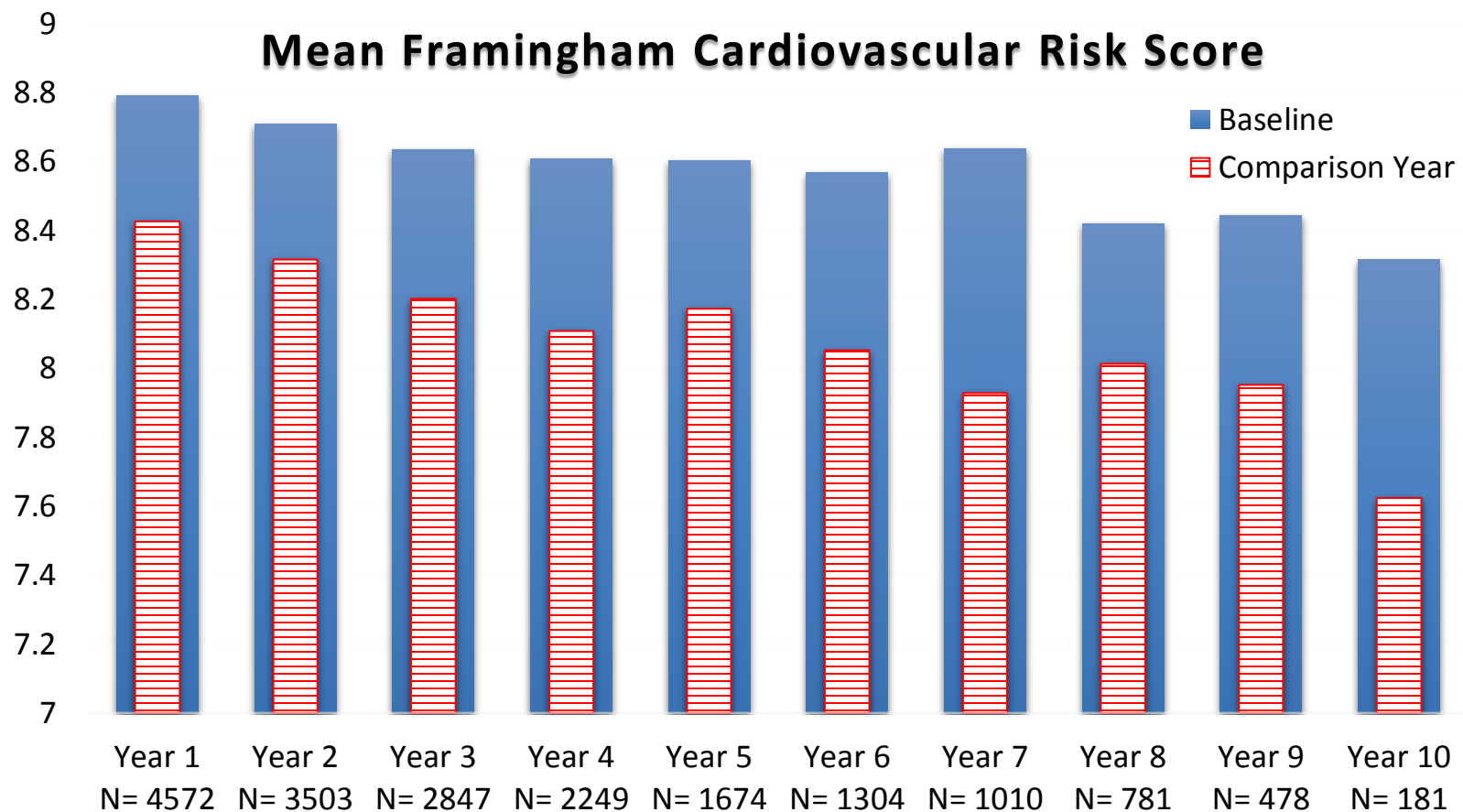
**Figure 3B.08 HH HDL Changes from Baseline (Paired Data)**



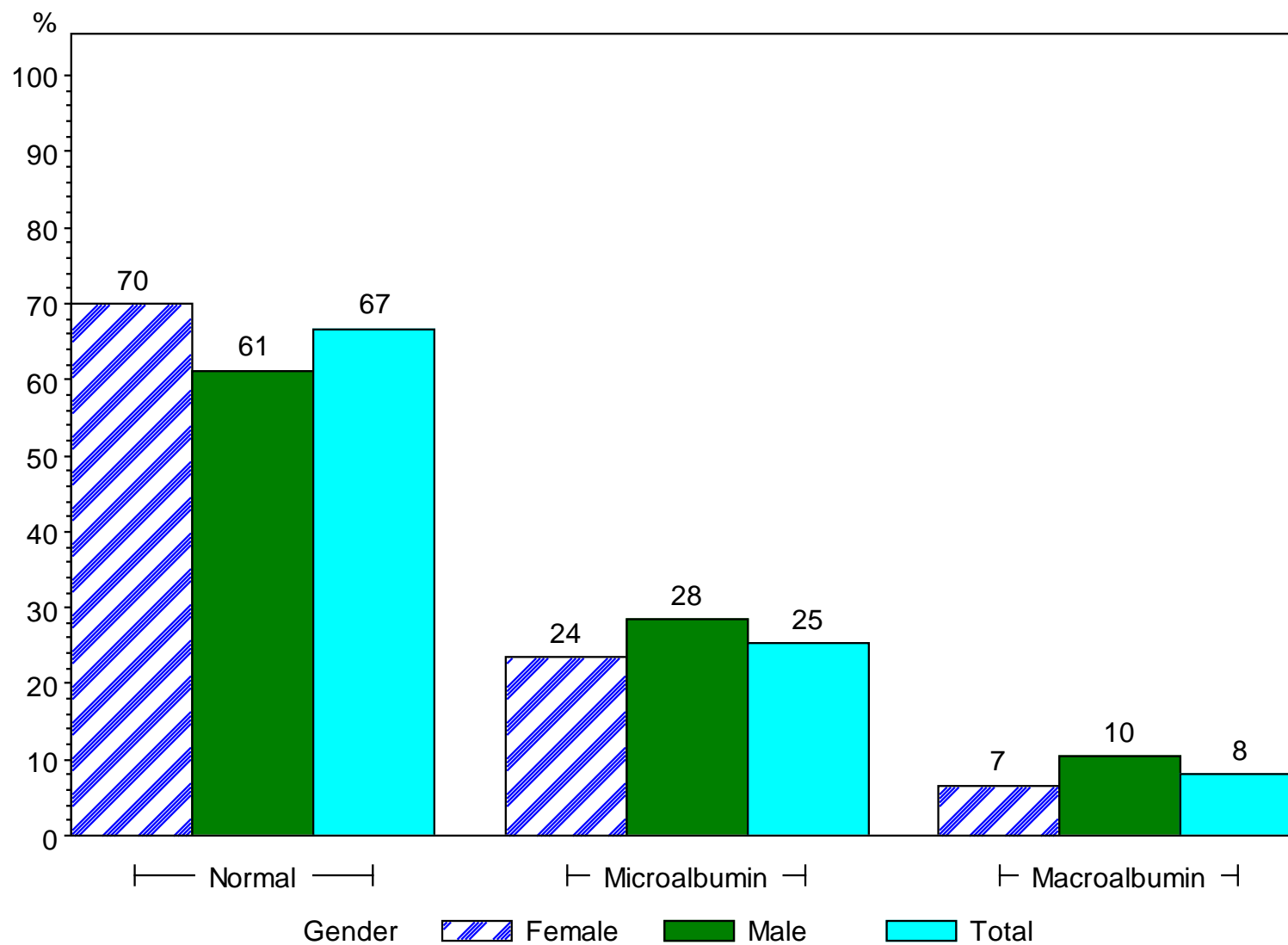
**Figure 3B.09 HH Triglycerides Changes from Baseline (Paired Data)**



**Figure 3B.10 HH A1c Changes from Baseline (Paired Data)**



**Figure 3B.11 HH Framingham Risk Score Changes from Baseline (Paired Data)**



**Figure 3B.12 HH Albumin to Creatinine Ratio at Most Recent Assessment**

### C. Lifestyle Measurements:

Lifestyle measurements are reported in Tables 3C.01 (unpaired data) and 3C.02 (unpaired data by gender).

- Physical Activity (Aerobic): 32% of the participants reported active engagement in aerobic physical activity at baseline, while 7% reported a sedentary lifestyle. The percentage of participants reporting active physical activity was higher than baseline in the first few years but later was less than baseline. The same trend held for paired data (Figure 3C.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 each annual assessment (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 3C.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 3C.03, paired data).

**Table 3C.01 HH Lifestyle Measurements at Each Assessment (Unpaired Data)**

		Baseline		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
Lifestyle Characteristic	Category	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 (%)	489	7.0	188	4.9	194	6.5	165	6.7	145	7.0	139	9.1	110	9.2	106	11.5	81	11.5	52	12.1	23	13.8
	Under-Active (%)	759	10.9	355	9.3	308	10.3	260	10.5	246	11.8	211	13.8	178	14.8	126	13.7	97	13.8	68	15.9	25	15.0
	Under-Active: Regular (%)	3464	49.6	1875	49.0	1389	46.5	1170	47.3	987	47.4	729	47.8	567	47.2	459	49.7	342	48.6	209	48.8	79	47.3
	Active (%)	2266	32.5	1406	36.8	1095	36.7	878	35.5	705	33.8	445	29.2	346	28.8	232	25.1	184	26.1	99	23.1	40	24.0
Rapid Assessment of Physical Activity: Strength and Flexibility	No Strength or Flexibility (%)	4016	59.5	1822	50.2	1411	49.5	1145	48.9	941	48.3	708	50.7	564	51.3	432	50.8	328	49.2	196	47.3	78	50.3
	Strength (%)	659	9.8	367	10.1	313	11.0	239	10.2	199	10.2	116	8.3	107	9.7	79	9.3	57	8.6	41	9.9	11	7.1
	Flexibility (%)	1047	15.5	684	18.8	534	18.7	460	19.6	367	18.8	266	19.1	197	17.9	174	20.5	136	20.4	88	21.3	29	18.7
	Both Strength & Flexibility (%)	1030	15.3	760	20.9	591	20.7	499	21.3	441	22.6	306	21.9	232	21.1	165	19.4	145	21.8	89	21.5	37	23.9
Food Consumption	Mean Healthy Diet Score	7106	3.6	3916	3.7	3056	3.7	2516	3.7	2104	3.7	1537	3.7	1218	3.7	938	3.7	710	3.6	436	3.6	169	3.7
	Mean Unhealthy Diet Score	7105	2.7	3925	2.6	3054	2.6	2525	2.5	2107	2.5	1540	2.5	1221	2.5	939	2.5	709	2.5	437	2.5	169	2.5



**Table 3C.02 HH Lifestyle Measurements at Each Assessment by Gender (Unpaired Data)**

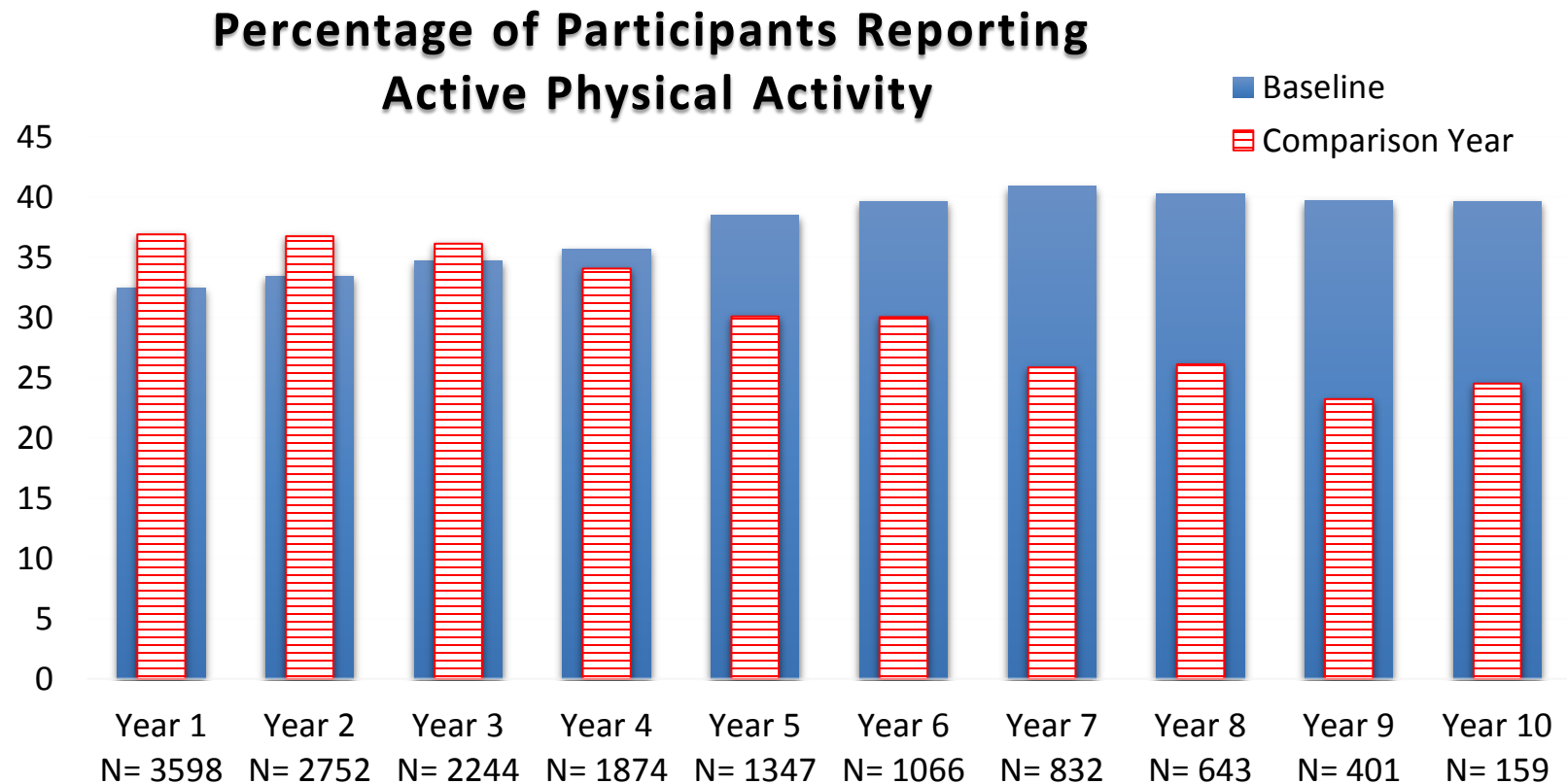
**Female**

		Baseline		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
Lifestyle Characteristic	Category	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 (%)	347	7.8	141	5.7	145	7.4	109	6.8	101	7.5	92	9.0	82	10.1	80	12.9	56	12.1	38	13.0	20	16.8
	Under-Active (%)	546	12.3	259	10.4	224	11.5	191	12.0	183	13.6	150	14.7	126	15.5	92	14.8	74	16.1	53	18.1	15	12.6
	Under-Active: Regular (%)	2332	52.5	1262	50.8	932	47.8	792	49.6	663	49.1	518	50.7	394	48.6	316	50.9	226	49.0	146	49.8	62	52.1
	Active (%)	1221	27.5	823	33.1	647	33.2	505	31.6	403	29.9	262	25.6	209	25.8	133	21.4	105	22.8	56	19.1	22	18.5
Rapid Assessment of Physical Activity: Strength and Flexibility	No Strength or Flexibility (%)	2712	63.0	1238	52.2	965	51.9	758	50.1	630	49.8	484	51.6	392	53.0	299	51.5	217	50.1	140	49.0	57	51.4
	Strength (%)	278	6.5	178	7.5	165	8.9	125	8.3	103	8.1	62	6.6	53	7.2	43	7.4	26	6.0	14	4.9	6	5.4
	Flexibility (%)	739	17.2	504	21.3	371	20.0	335	22.1	258	20.4	203	21.6	147	19.9	129	22.2	92	21.2	71	24.8	22	19.8
	Both Strength & Flexibility (%)	578	13.4	451	19.0	358	19.3	295	19.5	275	21.7	189	20.1	148	20.0	110	18.9	98	22.6	61	21.3	26	23.4
Food Consumption	Mean Healthy Diet Score	4527	3.6	2542	3.7	1994	3.7	1625	3.7	1369	3.7	1027	3.7	820	3.7	632	3.7	466	3.6	299	3.6	121	3.7
	Mean Unhealthy Diet Score	4525	2.7	2547	2.5	1992	2.5	1630	2.5	1372	2.5	1030	2.5	822	2.5	633	2.5	465	2.4	300	2.4	121	2.4

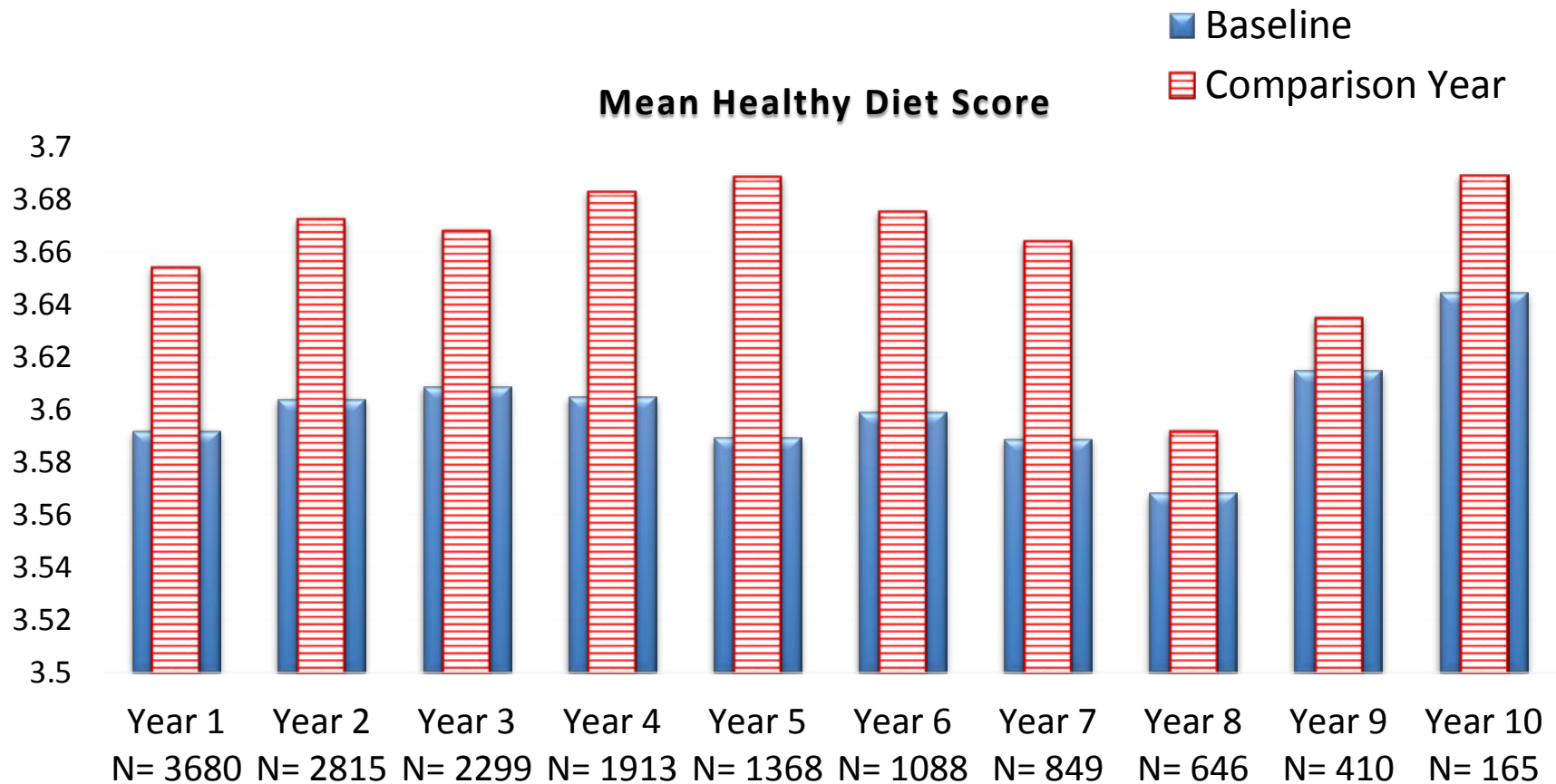
**Table 3C.02 HH Lifestyle Measurements at Each Assessment by Gender (Unpaired Data) (Continued)**

**Male**

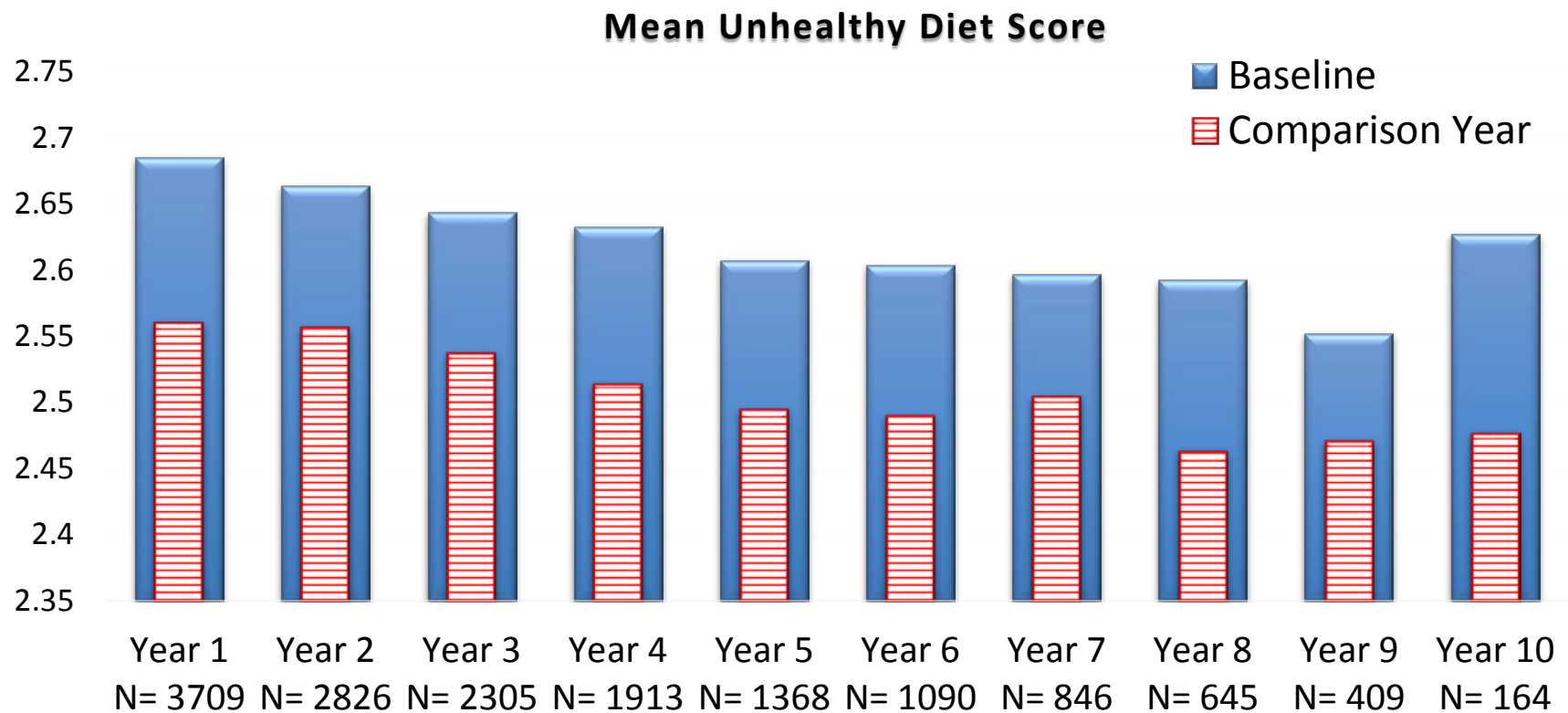
		Baseline		1st Annual		2nd Annual		3rd Annual		4th Annual		5th Annual		6th Annual		7th Annual		8th Annual		9th Annual		10th Annual	
Lifestyle Characteristic	Category	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean	N	% or mean
Rapid Assessment of Physical Activity: Aerobic	Sedentary (%)	142	5.6	47	3.5	49	4.7	56	6.4	44	6.0	47	9.4	28	7.2	26	8.6	25	10.3	14	10.4	3	6.3
	Under-Active (%)	213	8.4	96	7.2	84	8.1	69	7.9	63	8.6	61	12.2	52	13.3	34	11.3	23	9.5	15	11.1	10	20.8
	Under-Active: Regular (%)	1132	44.7	613	45.8	457	44.0	378	43.2	324	44.2	211	42.0	173	44.4	143	47.4	116	47.7	63	46.7	17	35.4
	Active (%)	1045	41.3	583	43.5	448	43.2	373	42.6	302	41.2	183	36.5	137	35.1	99	32.8	79	32.5	43	31.9	18	37.5
Rapid Assessment of Physical Activity: Strength and Flexibility	No Strength or Flexibility (%)	1304	53.3	584	46.3	446	45.1	387	46.6	311	45.6	224	48.9	172	47.8	133	49.4	111	47.6	56	43.8	21	47.7
	Strength (%)	381	15.6	189	15.0	148	14.9	114	13.7	96	14.1	54	11.8	54	15.0	36	13.4	31	13.3	27	21.1	5	11.4
	Flexibility (%)	308	12.6	180	14.3	163	16.5	125	15.1	109	16.0	63	13.8	50	13.9	45	16.7	44	18.9	17	13.3	7	15.9
	Both Strength & Flexibility (%)	452	18.5	309	24.5	233	23.5	204	24.6	166	24.3	117	25.5	84	23.3	55	20.4	47	20.2	28	21.9	11	25.0
Food Consumption	Mean Healthy Diet Score	2579	3.6	1374	3.6	1062	3.6	891	3.6	735	3.6	510	3.6	398	3.7	306	3.6	244	3.6	137	3.6	48	3.7
	Mean Unhealthy Diet Score	2580	2.8	1378	2.6	1062	2.7	895	2.6	735	2.6	510	2.6	399	2.6	306	2.6	244	2.6	137	2.6	48	2.6



**Figure 3C.01 HH Active Physical Activity (Paired Data)**



**Figure 3C.03 HH Healthy Diet Score Changes from Baseline (Paired Data)**



**Figure 3C.04 HH Unhealthy Diet Score Changes from Baseline (Paired Data)**

## **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<sup>th</sup> and the 75<sup>th</sup> 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  $\geq$  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  $\geq$  130 mm Hg or diastolic blood pressure  $\geq$  85 mm Hg
- FBG  $\geq$  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  $p^{\text{th}}$  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<sup>th</sup> 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 2<sup>nd</sup> 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 2<sup>nd</sup> annual assessment, or from the participants who have recently enrolled and are not yet due for the 2<sup>nd</sup> 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 project 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.

### **Timeline Compliance:**

The baseline timeline requirements mandate that the baseline data be collected within one month before each individual's first case management visit. This is necessary in order to ensure true baseline data. Many projects struggled to meet these timeline requirements. On average, 48% of the full evaluation baseline assessments and 30% of the minimum dataset baseline assessments did not meet all of the timeline requirements for the baseline assessment (Figure APP2.01).

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 case management visit. HH projects also had difficulty meeting the annual assessment timeline requirements. On average, 25% of both the full evaluation annual assessments and 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.

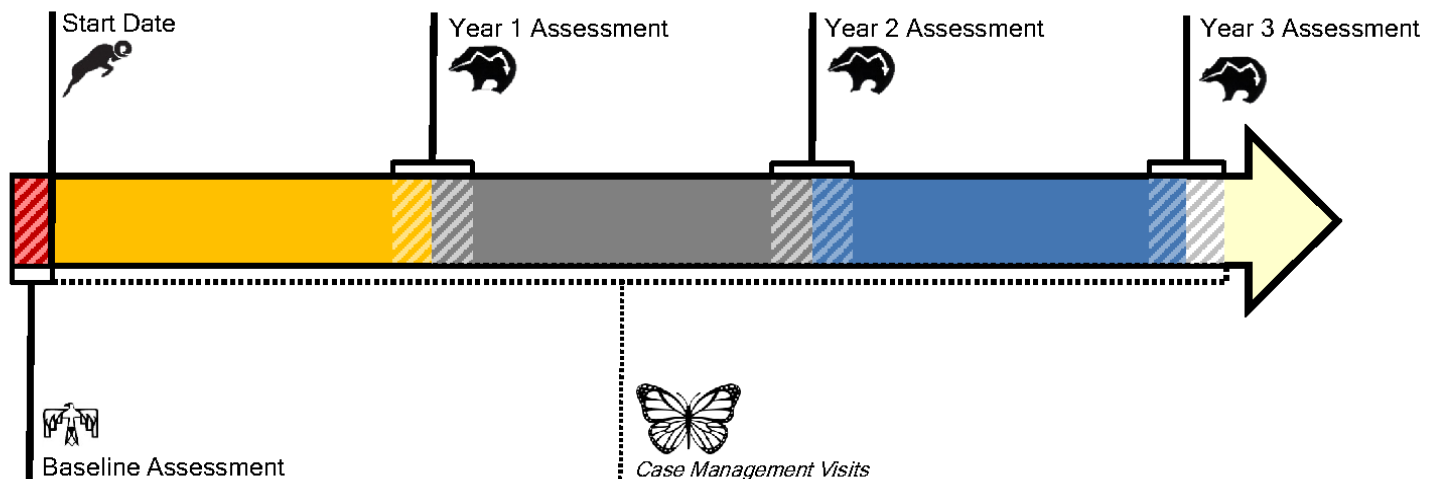


**Table APP2.01: HH Rates of Missing Data – Key Variables**

Variable (Range)	Baseline Assessment		Annual Assessment	
	Full Evaluation (N=3351)	Minimum Dataset (N=4312)	Full Evaluation (N=3636)	Minimum Dataset (N=15,688)
	Percentage of assessments missing variable			
Height (48-82 inches)	0	0	0	0
Weight (91-617 pounds)	< 0.1	< 0.1	0.1	0.4
Waist (24-79 inches)	1.5	5.8	3.6	10.1
SBP (72-223 mm Hg)	0.1	< 0.1	0.1	0.2
DBP (35-131 mm Hg)	0.1	< 0.1	0.1	0.2
HDL (5-146 mg/dl)	0.5	1.2	1.1	3.5
LDL* (2-284 mg/dl)	3.3	3.7	3.5	4.7
Triglycerides (22-15100 mg/dl)	0.4	1.2	1.0	3.9
Total Cholesterol (65-1200 mg/dl)	0.4	0.5	1.1	2.6
A1c (3.1% – 19.1%)	0.6	0.5	0.3	0.1
Smoking Status (Y/N)	0	0	0.1	< 0.1
Questionnaire? (Y/N)	9.9	3.3	25.8	10.8
Physical Activity – Aerobic (Scale 1-7)	13.5	5.4	29.7	12.4
Strength Activities (Y/N)	13.9	8.1	30.7	16.3
Flexibility Activities (Y/N)	13.9	8.6	3.5	16.3
Healthy Diet Score (Scale 1-6)	12.0	3.6	29.4	11.3
Unhealthy Diet Score (Scale 1-6)	12.2	3.5	28.4	11.2
Framingham Cardiovascular Risk Score	0.7	1.2	1.3	3.7

# SDPI Assessment Timeline

## Healthy Heart Program



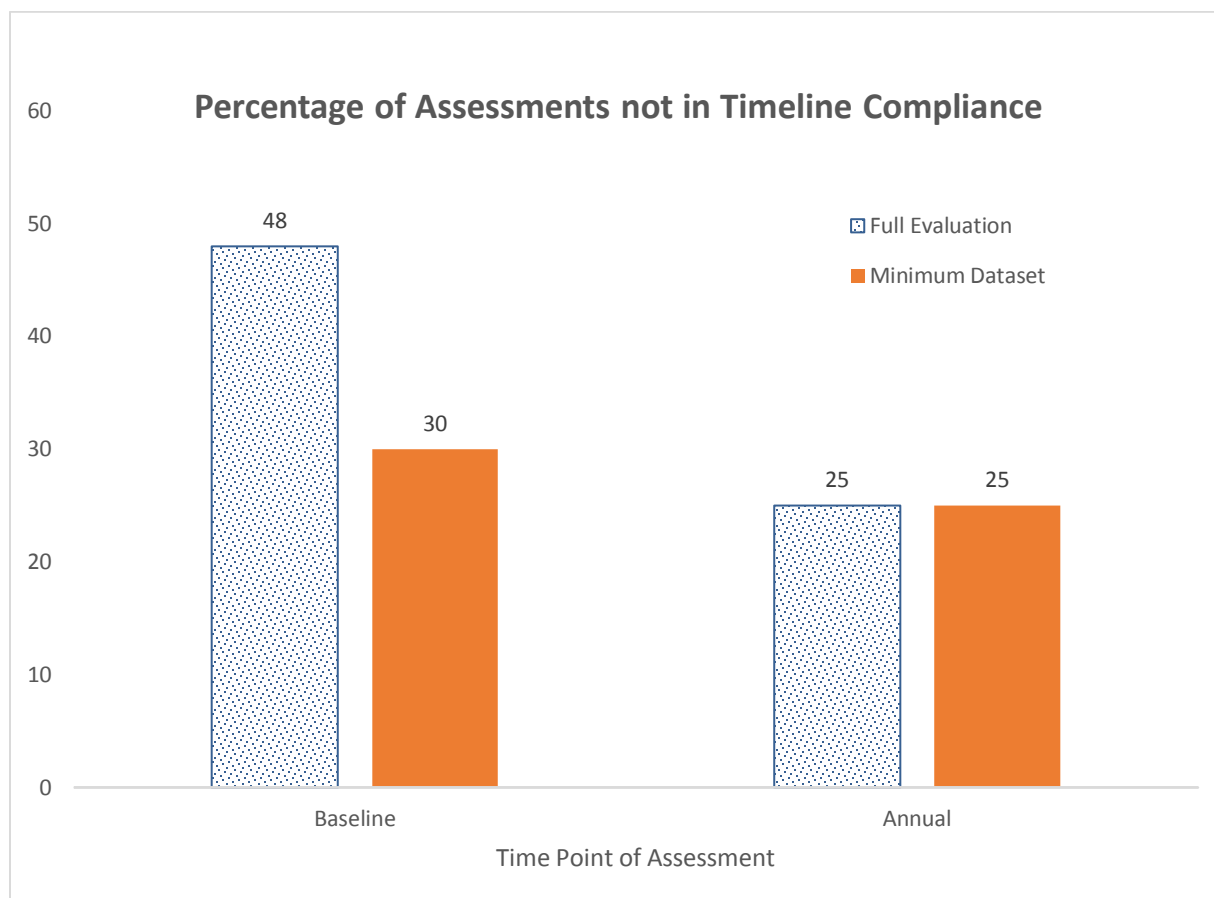
**Baseline Assessment**  
Complete 30 days  
before the Start Date

**Start Date**  
The first Case  
Management Visit

**Case Management Visits**  
Monthly or quarterly visits  
with a Case Manager,  
depending on status  
stabilization

**Annual Assessment**  
Complete yearly within  
30 days of the start  
date's anniversary

Figure APP2.01 HH Assessment Timeline Diagram



**Figure APP2.02 HH Rates of Timeline Non-Compliance**

### **APPENDIX 3. SDPI HH PROJECT ADDITIONAL DATA ITEMS**

The SDPI Healthy Heart Project 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 HH Projects. 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 variables designated as 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: HH Additional Data Items on Assessments**

<b>Variables obtained similarly on full evaluation and minimum dataset</b>		
<b>Variable</b>	<b>Range</b>	<b>Notes</b>
History of gestational diabetes?	Y/N	Women only
Delivered a baby > 9 pounds?	Y/N	Women only
History of cardiovascular disease?	Y/N	
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: HH 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	1947 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: Project 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	56 - 790 mg/dl	Optional
Albumin to creatinine ratio	0 – 13582 mg/g	
Date clinical history obtained	4/19/2006 – 8/3/2016	
Date of diagnosis of diabetes	1951 – 6/20/2016	Was obtained retrospectively for many full evaluation participants
History of proteinuria?	Y/N	
Date medication history obtained	4/19/2006 – 8/3/2016	

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

<b>Variables obtained on full evaluation only</b>		
<b>Variable</b>	<b>Range</b>	<b>Notes</b>
Hip circumference	25-85 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	0-3600 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 (general)	0-1	On questionnaire

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

<b>Variables obtained on full evaluation only</b>		
<b>Variable</b>	<b>Range</b>	<b>Notes</b>
Health literacy scale – print	1-5	On questionnaire
Health literacy scale – numeracy	0-1	On questionnaire
Perceived health competence scale	1-5	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	11.0 – 65.3	On questionnaire
Health-related quality of life (SF-12): Mental Component Summary	10.8 – 71.1	On questionnaire



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

<b>Form</b>	<b>Completed By</b>	<b>Frequency of Completion</b>	<b>Number Received</b>	<b>Notes</b>
<b>Family Baseline Questionnaire</b>	Support person (family member or friend of participant)	Once, at baseline	1800	Demographics, the family's participation in community-based activities, and how support person envisions the project working in their family and community
<b>Family Annual Questionnaire</b>	Support person (family member or friend of participant)	At each annual assessment (participant years 1, 2, 3)	1242	Similar to the family baseline questionnaire, plus questions about the family's experience in the HH Project
<b>Community Annual Questionnaire</b>	Community member, up to 10 per project	Once a year (December 2006, 2007, 2008)	724	Attitudes and perspectives about the HH Project
<b>Provider Annual Questionnaire</b>	Project staff members and care providers, up to 10 per project	Once a year (December 2006, 2007, 2008)	772	Demographics, plus questions about the how the HH Project is working in their setting
<b>Organization Annual Questionnaire</b>	Project staff members, up to 10 per project	Once a year (December 2006, 2007, 2008)	794	Questions concerning organizational culture, effectiveness, and whether these factors are associated with successful performance by grantee projects
<b>Recruitment Team Meetings Form</b>	Project staff	Ongoing but submitted once a year (December 2006, 2007, 2008)	108	Descriptions of 1232 recruitment team meetings attended by 589 project staff members
<b>Case Management Team Meetings Form</b>	Project staff	Ongoing but submitted once a year (December 2006, 2007, 2008)	114	Descriptions of 1211 case management team meetings attended by 540 project staff members

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

<b>Form</b>	<b>Completed By</b>	<b>Frequency of Completion</b>	<b>Number Received</b>	<b>Notes</b>
<b>Recruitment Activities Annual Report</b>	Project staff	Once a year (December 2006, 2007, 2008)	122	Descriptions of 1785 recruitment activities. Projects could also send brochures, flyers, etc.
<b>Retention Activities Annual Report</b>	Project staff	Once a year (December 2006, 2007, 2008)	111	Descriptions of 593 retention activities. Projects could also send brochures, flyers, etc.
<b>Participant Attendance Form</b>	Project staff	Ongoing but submitted once a year (December 2006, 2007, 2008)	3351	Full evaluation attendance information included case management date scheduled, whether attended, make-up date, whether trying for monthly or quarterly case management, etc., and did not information on HH group activities. The minimum dataset attendance data consisted only of actual dates attended for each type of activity (case management, HH group activity).
<b>Individual (Participant) Retention Form</b>	Project staff	Ongoing but submitted once a year (December 2006, 2007, 2008)	3351	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).
<b>Community Screening Worksheet</b>	Project staff	Optional	33	Screening worksheets for potential participants.
<b>Serious Adverse Event Form</b>	Project staff	As needed	356	During the full evaluation phase, projects 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 HH PROJECT PUBLICATIONS

**Special Diabetes Program for Indians: Retention in cardiovascular risk reduction** (Manson, Jiang, Zhang, et al.) *The Gerontologist*, 2011, 51:S21-S32.

- Baseline participant characteristics - higher age, BMI, and greater physical activity - were associated with better retention at Year 1.
- Having more staff who are highly educated and having more balanced proportions of female and male staff were also associated with better retention at Year 1.

**Special Diabetes Program for Indians: Reliability and validity of brief measures of print literacy and numeracy** (Brega, Jiang, Beals, et al.) *Ethnicity and Disease*, 2012, 22:207-214.

- Health-related numeracy – the ability to understand and use quantitative information – and print literacy were strong predictors of disease knowledge in AI/AN adults with diabetes.
- These results support the value of the brief tests of numeracy and print literacy in AI/ANs, and represent the first examination of the performance of health literacy measures in this population.

**Mechanisms underlying the relationship between health literacy and glycemic control in American Indians and Alaska Natives** (Brega, Ang, Vega, et al.) *Patient Education and Counseling*, 2012, 88:61-68.

- Diabetes-related knowledge was a key mediator of the relationship between health literacy and glycemic control.
- Educational interventions might enable individuals with limited health literacy to develop the knowledge needed to engage in self-management behavior.

**Case management to reduce cardiovascular disease risk in American Indians and Alaska Natives with diabetes: Results from the SDPI-HH Demonstration Project** (Moore, Jiang, Manson, et al.) *American Journal of Public Health*, 2014, 104:e158-64.

- HH Participants demonstrated improvements in multiple cardiovascular risk factors including A1c, blood pressure, and lipid control at Year 1.
- HH participants' average Framingham cardiovascular risk score declined significantly between baseline and Year 1.
- There were also improvements in smoking status, aspirin use, and prescribed medication use for cardiovascular risk factors between baseline and Year 1.
- After controlling for age, gender, and baseline cardiovascular risk factors, HH participants who had more case management visits also had significantly greater reductions in A1c and LDL cholesterol values at Year 1.

**Serious psychological distress and diabetes management among American Indians and Alaska Natives** (Huyser, Manson, Nelson, et al.) *Ethnicity and Disease*, 2015, 25:145-151.

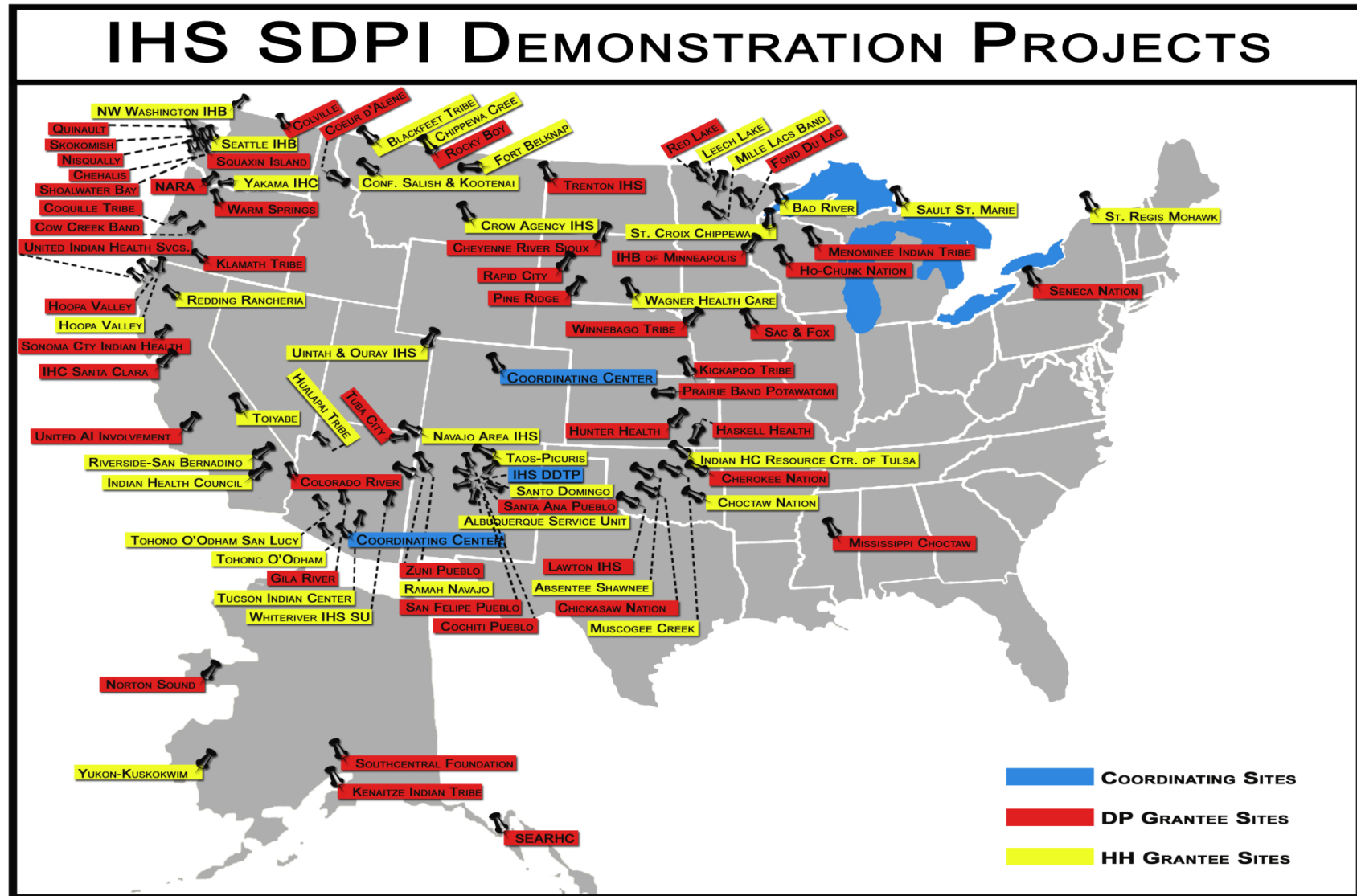
- Serious psychological distress was significantly associated with higher A1c levels at baseline, even after adjusting for demographic and health characteristics.
- Change in serious psychological distress did not predict A1c levels at Year 1.
- No associations between BMI and serious psychological distress were observed after adjustment for demographic and health characteristics.

**Assessing the Everyday Discrimination Scale among American Indians and Alaska Natives** (Gonzales, Noonan, Goins, et al.) *Psychological Assessment*, 2016, 28:51-58.

- Perceived discrimination is related to poorer health outcomes, but many measures of discrimination have not been tested in American Indian and Alaska Native populations.
- The Everyday Discrimination Scale had high reliability of scale score measures and reasonable convergent and divergent validity in HH participants and has promise for assessing perceived discrimination in American Indian and Alaska Native populations.

**[In Progress] Recruitment and effectiveness by cohort in a case management intervention among American Indians and Alaska Natives with diabetes** (Pratte, Jiang, Beals, et al.)

## APPENDIX 5. SDPI PROGRAM MAP – DEMONSTRATION PROJECTS



## APPENDIX 6. SDPI PROGRAM MAP – INITIATIVES

