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Impact of a Wellness Clinic Visit on Cardiovascular Risk Biomarkers in Employees of a VA Medical Center

By

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A thesis submitted in partial fulfillment of the requirements for the degree of
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Date of Approval:
November 1 2011

Keywords: lifestyle changes worksite health promotion cholesterol education lipid screening secondary prevention

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Dedication

This work is dedicated to my mother, Sandra Cohen, to my sister and brother Susan and David Asomaning, and to all my other family. Without your love, support and protection this goal would not have been achieved. I am grateful to Kristin Robie, M.D. for being a role model, and to my physician mentors in Public Health: Eve Hanna, Mel Bradley, and Joan Watkins. I also thank Hamisu Salihu and Alfred Mbah for their tireless teaching on research and statistics. Finally, I am deeply grateful to the Sunshine Education and Research Center (SERC) at the University of South Florida, a research branch of NIOSH, the National Institutes of Occupational Safety and Health. This community, through its financial support, accomplished faculty, and other educational resources, shows a commitment to students that is truly exemplary.

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ABSTRACT:

Background: Worksite screening programs are increasingly being provided by employers as a means to reduce cardiovascular risk in employees. A screening program that consists of fasting serum analysis of glucose plus a lipid panel is offered yearly to employees at the VA medical center in Tampa. A retrospective study was conducted to determine if a wellness clinic exposure resulted in significant changes in employees' markers of cardiovascular risk.

Methods: Computerized records were used to follow serial outcomes for glucose, triglycerides, HDL cholesterol, and LDL cholesterol in employees whose screening results showed abnormal levels of one or more of these markers. An intervention group with 66 subjects received a wellness clinic visit including a health risk assessment and education for lifestyle change, and a reference group with 109 subjects received only serum analysis. Outcomes at repeat screening were compared for the two groups.

Results: Both groups showed improvement in cardiovascular risk. In the intervention group there was significant intra-subject improvement from baseline for all markers except glucose. For triglycerides and LDL cholesterol there was a significantly greater proportion of subjects who improved in the intervention group. In addition, the improvement for triglycerides was significantly better in the intervention group.

Conclusions: This investigation confirms the value of a worksite wellness program in reducing cardiovascular risk in the population studied. A differential impact of age and gender was seen for glucose and triglycerides and indicates that such modifiers should be considered through covariate analysis in assessing wellness program effectiveness. Increasing levels of employee wellness participation to targets identified in this study and adding a health risk assessment for everyone screened will help to identify the specific benefits of the face to face wellness counseling intervention.

I. INTRODUCTION

Rationale, Scope, and Prevalence of Worksite Health Promotion

Worksites are an important setting for preventive health education because of the potential to reach a large audience, estimated at 130 million American workers. In addition to improving employee quality of life through interventions that help prevent illness, workplace health promotion can improve employee satisfaction due to the perceived investment by employers in workers' health, especially when programs emphasize stress reduction. Greater employee satisfaction can lead to improved morale, lower turnover, and improved productivity.

Workplace health promotion programs may take place at onsite employee health clinics, particularly when the worksite is a medical center. Many worksites**,** however**,** do not have onsite employee clinics. These organizations use methods such as mobile van units or clinics outside the corporate facilities to provide preventive medical services for their employees. Venues such as conference and dining areas provide additional space for large groups in both cases. For non-medical organizations**,** the screenings are usually conducted by outside medical personnel or trained in-house volunteers, while in medical centers, these services are performed by on-site medical staff.

Increasingly, preventive care programs given onsite at the workplace are known as worksite wellness programs. Use of the term ‘wellness’ in industrial and corporate settings arose during the 1970’s when a shift occurred in national health policy. This shift emphasized improving health and maintaining good health through lifestyle practices such as regular exercise, good nutrition, and smoking cessation, rather than a purely biomedical approach emphasizing the diagnosis and treatment of illness (Lovato, Green, & & Stainbrook, 1994) as cited in (Association for Worksite Health Promotion, 1994). The term ‘wellness’ provided an attractive label for advertising workplace preventive programs as it signified the opposite of ‘illness’.

The wellness concept also implied, from its inception, employer investment not only in physical health of workers but also in psychosocial health, which suggested the need to include diverse approaches to individual wellbeing. Worksite health promotion or wellness programs thus provide a broad range of interventions across work settings. In 1988, the most frequently cited health promotion activities in a survey of worksites were smoking control, health risk or health status assessment, back care, stress management, exercise and fitness, and off-the-job accident prevention (Christenson & Kiefhaber, 1988). Some less typical suggestions for programming include parenting tips and preventive dentistry (Partnership for Prevention, 2010). The US Department of Health and Human Services outlined 5 components of a comprehensive worksite health promotion program in *Healthy People 2010,* shown in Table 1 (Linnan et al., 2008).

Table 1**:** Components of a comprehensive worksite health promotion program

Component 1
Health Education: Establishes desired target levels in the following areas: *physical activity, nutrition with cholesterol education, weight management or counseling, smoking cessation classes or counseling, blood pressure classes or counseling, alcohol or drug abuse support, workplace injury prevention, workplace violence prevention, maternal or prenatal programs, HIV or AIDS education, cancer prevention.* Other areas in development are: *Diabetes prevention, recognition of early warning signs of acute MI, recognition of early warning signs of stroke.*
Component 2
Supportive social and physical environment: Addresses establishing workplace policies that promote health, such as: *formal tobacco policy that prohibits smoking or limits it to separately ventilated areas, nutrition or weight management classes, employer-sponsored physical activity such as walking trails or on-site fitness facilities, encouragement of health insurance acquisition.*
Component 3
Integration in organizational structure: Management or owner support of health promotion should exist, with health promotion as part of a strategic plan*, as evidenced by having staff, an office and a budget dedicated to such programs.*
Component 4
Linkage to other employee services: Refers to benefit from partnerships between worksite health promotion and other workplace programs. These include but are not limited to*: Employee Assistance Programs, Occupational Medicine programs for medical surveillance, Human Resources Programs for performance planning and development, and Disability Management Programs.*
Component 5
Screening programs: Establishes target numbers of adults screened for *high blood pressure and elevated cholesterol.*

The worksite health programs offered most frequently in a more recent national study of worksite health promotion were found to be employee assistance and

back injury prevention programs (Linnan et al., 2008). These interventions, along with blood pressure and blood cholesterol screening, were offered more frequently with increasing size of the workplace (measured by number of employees). Overall, the authors found that less than 10% of responding employers offered all 5 elements of a comprehensive worksite health promotion program, which sharply contrasts with the *Healthy People 2010* objective of 75% of worksites. The element most frequently incorporated was linkage to related programs. Worksite screening was the least frequently incorporated except in the largest size category of 750 employees or more. In this category a supportive social and physical environment was the component from Table 1 least often encountered.

Cardiovascular Disease Prevention in Workers

In regard to the link between employment and cardiovascular disease, Bosma, et al. showed a positive association between work stressors and elevated risk of cardiovascular disease (Bosma, Stansfeld, & Marmot, 1998). Calvert et al**.** compared occupation-specific rates of ischemic heart disease and found higher mortality from ischemic heart disease in certain categories of workers that included sheriffs, firefighters, and machine operators (Calvert, Merling, & Burnett, 1999). They suggested their results could be used as a starting point to target cardiovascular disease prevention programs to those occupations where such programs would be most beneficial.

Programs emphasizing cardiovascular disease prevention in the worksite setting have increased steadily. Several reasons explain this increasing emphasis on cardiovascular disease prevention in worksite health promotion. 1) Since the second half of the 1970's, prevention of cardiovascular disease through smoking cessation education and other lifestyle changes has been an important aspect of public health generally (Lovato et al., 1994) as cited in (Association for Worksite Health Promotion, 1994); 2) The influence of lifestyle on cardiovascular risk status means prevention is achievable through education; 3) Cardiovascular disease treatment is costly to insurers, and highly prevalent, thus prevention is of key importance to reduce employer insurance costs (Menzin, Wygant, Hauch, Jackel, & Friedman, 2008) and 4) As previously mentioned increasing numbers of working Americans provide worksite health educators with a potentially large audience, at any given session, toward whom to target health messages. This increases the efficiency of delivery of disease prevention education and thus enhances its potential to reduce risk and costs to insurers.

Numerous studies have evaluated the effects of specific worksite interventions on cardiovascular health risks. A selection of such studies is given in Table 2. Of note, MOVE! is a health promotion program for veterans. While veterans include retired persons and are therefore not a typical occupational group, the MOVE! program is nonetheless included in the present sample of studies because it has a high profile in the VA system**.** This could produce spill-over effects such that healthy behaviors would be expected in the VA employees who are the subject of the investigation detailed in this manuscript.

The studies reviewed in the table are primarily cardiovascular screening programs that were conducted for primary and secondary prevention at worksites across different industry types. They all used risk factor questionnaires and recorded metrics before and after health promotion interventions. Interventions included health education on multiple topics, blood pressure screening, healthy cafeteria food choices, weight loss, cholesterol reduction through diet and exercise counseling, and diabetes prevention. The programs' duration was from 5 months (for MOVE!) to 2 years. In addition to veterans, employees from industrial blue collar, technology sector, medical device manufacturing, and 'multiple employer' services were represented.

Outcome measures used in these studies included number of disability days per employee, weight, body mass index, blood pressure, smoking status, and blood levels of fasting blood glucose, triglycerides, high density lipoprotein (HDL) cholesterol and low density lipoprotein (LDL) cholesterol. Aerobic fitness, waist circumference, oral glucose tolerance testing, and fasting insulin were some infrequently used outcome measure

Table 2**:** Cardiovascular disease interventions in occupational health settings (plus veterans)

Reference & industry	***Intervention***	***Results***	***Control Group Y/N***	***Cost Impact***
(Bertera, 1990) *'blue-collar workers at an industrial company'*	*Health education: Pretest-posttest design, multi-faceted health promotion at 41 intervention/19 non intervention sites*	*Reduced disability days among blue collar employees; good return on investment (ROI)*	*Y*	*Y = $2 for each $1 invested, 200% yield*
(Karlehagen & Ohlson, 2003) *'technology based service enterprise '*	*Diet and exercise counseling to reduce cholesterol*	*5% reduction in total cholesterol vs. no change*	*Y*	*Not assessed*
(Aldana et al., 2006) *'medical device manufacturer'*	*Diabetes prevention (Diet ed, behavior change education in weekly sessions, onsite daily exercise classes, pedometer**)***	*Improvement in glucose tolerance testing and lipids after 6 months. 1/3 of subjects had normal glucose after 2 years.*	*N*	*Not assessed*
(Loeppke, Edington, & Beg, 2010) *multiple employer groups'*	*Customized personal prevention plan including one-on-one registered nurse coaching, 8 week nutrition action program and personal account on Prevention Plan website; progress score linked to rewards.*	*Aggregate health transitions: Increased percentage of the study group were in 'Low –Risk' category and decreased percentage in 'Moderate-' and 'High-Risk' categories after 1 year.*	*N*	*Not assessed*
(Bachman A.C., 2011) *MOVE 2009' data at Bay Pines and Fort Myers VA medical centers*	*Individualized treatment plan for weight control devised by Multi-disciplinary team including physician, nutritionist, physical therapist and psychologist; monthly monitoring and finite graduation date*	*5% - 10% weight loss within 3 months*	*N*	*Not assessed*

Although many individual programs report efficacy of interventions in improving employees' cardiovascular risk in the short term, it is not yet known how this translates into improved worker health in the long term.

Study on Employee Lipid Screening and Wellness at the James A. Haley VA Medical Center

Background: Employees at VA Medical Centers, because they are concerned with providing inpatient and outpatient medical care to veterans, are exposed to health awareness education as part of the treatments provided. This education includes the use of lifestyle measures such as good nutrition, exercise, weight control, and smoking cessation to prevent chronic disease. These employees constitute a large group of federal workers which has the potential to promote health education messages from within the workplace to their families and communities. Health promotion among employees of VA Medical Centers therefore presents a unique and rich opportunity to practice cardiovascular disease prevention.

Each year employees at the James A. Haley (JAHVA) Medical center are offered fasting blood glucose and lipid screening as part of the facility's wellness worksite health promotion program. Wellness clinic visits conducted at the Occupational Health Clinic (OHC) by residents in preventive medicine are offered to counsel employees whose screening results are abnormally elevated. These visits provide dietary and weight loss advice and counsel employees to incorporate therapeutic lifestyle changes that can prevent future illness and improve their quality of life.

Research question: This study looked at the results of blood glucose and lipid screening in employees at a VA medical center to assess whether a wellness clinic visit improved cardiovascular risk. All employees included in the study had abnormal glucose and lipid values at baseline; thus this was a secondary prevention intervention. The primary research question was: Does face-to-face education provided by a Preventive/Occupational Medicine resident at a scheduled wellness clinic visit improve serum cardiovascular risk biomarkers assessed on repeated screening at one year? The wellness clinic visit was an intervention to improve cholesterol through diet and exercise counseling conducted by a physician taking part in the preventive and occupational medicine residency training program. To our knowledge there are no other studies of a worksite health promotion intervention conducted by resident physicians or of secondary cardiovascular disease prevention in employees of a VA medical center.

Study protocol outline: A flow diagram of the study is provided in Figure 1. The study compared follow-up lab screening values between two groups – an exposed group consisting of those with abnormal screening values that received a wellness clinic visit, and an unexposed group consisting of those with abnormal screening values that declined a wellness clinic visit. Except for glucose, abnormal values were defined using the cut-off ranges used by the JAHVA lab. Although Figure 1 shows repeat lab values from the consecutive years 2009 to 2010, the study used all abnormal screening lab values obtained in 2007 to 2010 as a baseline if screening was repeated after at least 6 months.

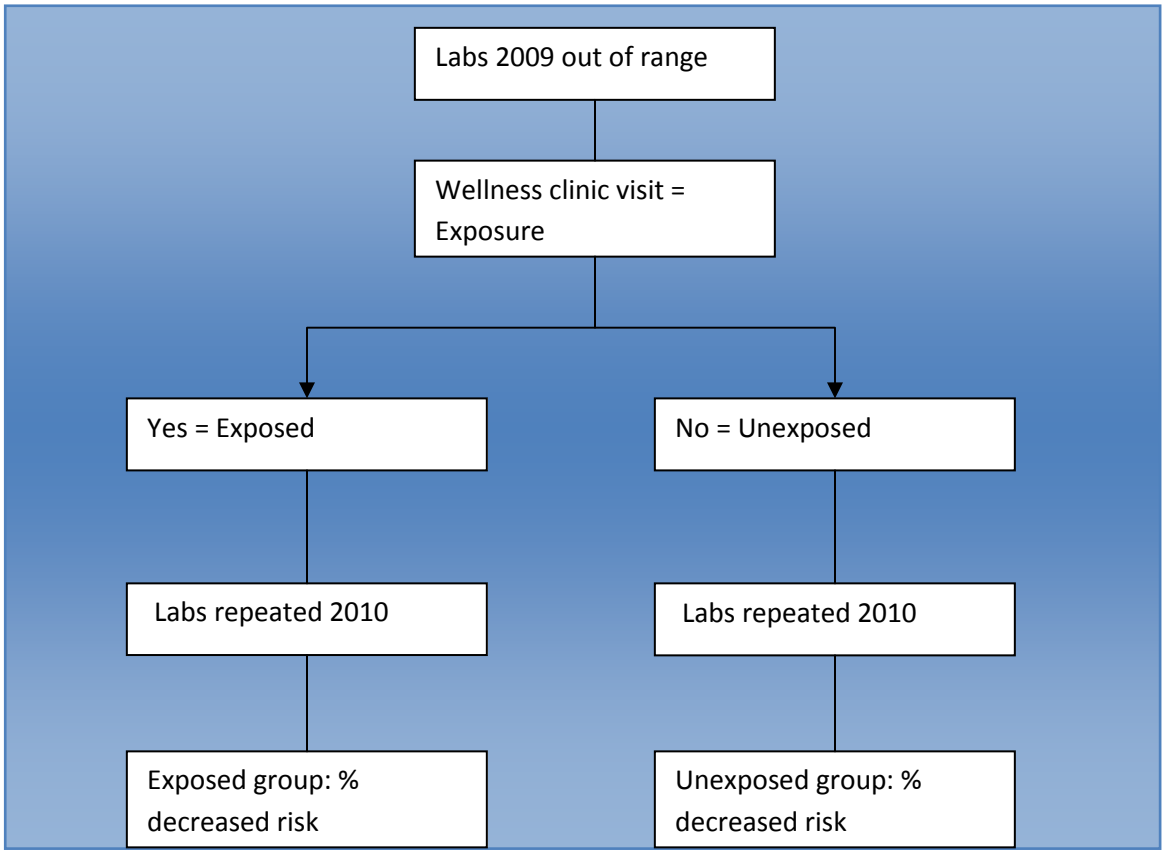

Figure 1. Protocol to compare follow-up biomarker values in 2 groups

II. METHODS

Health Promotion at the James A. Haley VAMC

Health promotion activities at the James A. Haley VA Medical Center include gym facilities for employees, employee MOVE! Program, smoking cessation classes, yoga classes, newsletter, communication bulletin board on wellness topics in the clinic waiting area, a website with calendar of wellness events such as yoga classes, and screening programs (blood pressure, blood glucose and lipids).

Annual employee blood glucose and lipid screening is scheduled over a period of several weeks, usually in February or March of each year. Blood is drawn between 7am – 9am on designated days by lab employees at the screening site**,** which is a conference room or dining room temporarily allocated for this purpose. Employees log on to the employee Wellness website to receive information including directions to the location, and are instructed to fast for 12 hours prior to testing. Employees wishing to participate print a consent form indicating willingness to be contacted to receive abnormal results. Alternatively employees may pick up a paper copy of the results themselves from the Occupational Health Clinic.

The wellness coordinator for the medical center oversees the wellness programs listed above. The residents in preventive and occupational medicine conduct the wellness clinic visits for employees with abnormal lipid screening results. These visits take place on-site at the medical center's occupational health clinic.

The Resident-conducted Wellness Clinic

The primary aim of the JAHVA wellness clinic is to improve employees' cardiovascular risk ratings by non-pharmacological means –such as using exercise to raise HDL cholesterol levels. This emphasis on enhancing cardiovascular health through lifestyle changes is seen as important due to its ability to lower costs, prolong life, and improve quality of life for employees (Association for Worksite Health Promotion, 1994; Carnethon et al., 2009). The program has the potential to make a significant impact due to the large and relatively stable workforce. Size is important because increased size of a workforce population exposed to health promotion not only creates a multiplier effect in the workplace but also increases the likelihood of spreading healthy lifestyle changes to the community. Workforce stability is important because it creates a long time horizon to establish and maintain preventive health habits. Such habits are particularly critical in a population that is aging and approaching retirement since this is the life stage when health costs are highest.

The first step during a typical wellness clinic visit is to obtain employees' answers to a health risk assessment tool in the form of a detailed questionnaire that

includes family history and smoking status. Health risk assessments are administered by worksite health promotion programs as an essential initial step in raising employee awareness and identifying individual employees' baseline risk factors. Sample health risk assessments for two wellness programs include the following 14 measures (Loeppke et al., 2010; VA Public Health Service, 2011):

1. Self-rating of health
2. Blood pressure by history or on-site measurement
3. Weight or Body Mass Index
4. Physical activity
5. Medical Illness history
6. Blood glucose by history or on-site measurement
7. Cholesterol and lipids by history or on-site measurement
8. Smoking status
9. Use of relaxation medication or sleep aids
10. Dietary habits such as fat consumption or lack of fiber
11. Alcohol use
12. Seat belt use
13. Stress/life satisfaction
14. Level of absenteeism

Programs vary as to the inclusion of the above health measures, or additional ones not present on this list such as miles travelled by automobile each year.

The wellness clinic visit at JAHVA conducted by residents includes the above 15 measures and also asks about family history of cardiac disease in order to obtain the necessary parameters for the National Cholesterol Education Program – Adult Treatment Panel III (NCEP – ATP III) algorithm to determine optimum LDL

level (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001).

Subsequently**,** blood pressure, BMI and abdominal circumference are measured and a focused cardiovascular physical exam is performed which includes searching for signs of atherosclerosis (e.g. carotid bruits and abdominal aneurysms). Screening lab values are reviewed and used along with other parameters to assess cardiovascular risk level. Three formal cardiovascular risk methods are used:

1. *The Framingham calculator* (National Cholesterol Education Program, 2011)
2. *The NCEP – ATP III algorithm for determining target LDL level* (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001)
3. *Assessment for the 5 metabolic syndrome indicators* (Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults, 2001)

These methods are shown in detail in the Appendix.

Finally, the residents counsel the employees on non-medical therapy, tailoring their advice to the individual based on the elements discussed above. The employee receives a written recommendation in the form of a Wellness 'prescription'. Recommendations include mutually agreed upon goals such as targets for exercise frequency, weight loss, or cholesterol level achievable

through diet. Suggestions are made for improving motivation for the behaviors necessary to achieve the goals, such as walking with a partner or using a pedometer to improve exercise motivation. An example of a Wellness Prescription is given in the Figure A4.

Data Overview

Study Parameters: Of the screening measures discussed above, those specific for increased risk of cardiovascular disease are obesity, defined as body mass index $\geq$ 30 (National Heart Lung and Blood Institute - NIH, 2011) smoking, high blood pressure, diabetes or elevated fasting serum glucose, elevated fasting serum triglycerides, elevated fasting serum LDL cholesterol, and low HDL cholesterol.

Risk ratings are performed as part of all wellness visits (as described above). The results of these ratings are included as a score in the electronic record documenting the clinic visit. These risk assessments require parameters besides serum markers such as height, weight, abdominal circumference, blood pressure, and family history that can only be obtained during a medical clinic visit. Therefore**,** these assessments are not performed on the employees who are screened for serum markers then subsequently decline a wellness clinic consultation.

The availability of serial serum biomarker screening data in computerized health records presented an opportunity to review data retrospectively and compare

follow-up results in patients who received individual counseling versus those who did not. For the purpose of having a control group of subjects for comparison, only serum markers could be used because, as afore-mentioned, clinical data is collected at the time of the wellness visit and could not, therefore, be available for those who declined a wellness clinic consultation. Consequently, this retrospective chart-based study used fasting levels of blood glucose and a fasting lipid panel as risk predictors of cardiovascular disease, and evaluated those with abnormalities in blood glucose, triglycerides, high-density lipoprotein (HDL) cholesterol and low-density lipoprotein (LDL) cholesterol. The abnormal values for the four parameters were glucose > 99mg/dL, triglycerides > 149 mg/dL, HDL cholesterol < 40 mg/dL, and LDL > 119 mg/dL. For the lipid panel, these values correspond to the cut-offs used by the JAHVA lab. For glucose, the lab cut-off is 110mg/dL for pre-diabetes. However**,** it was decided to use the lower cut-off value of 100mg/dL which is increasingly used internationally to define both pre-diabetes and the related metabolic syndrome, both of which are known risk factors for cardiovascular disease (American Diabetes Association, 2011; Meigs, Holman, Wolfsdorf, & Mulder, 2010).

Data abstraction: The data to be analyzed were selected by starting with results returned from the lab during the annual screening period in 2010. The year 2010 was the 'index' year reviewed as that coincided with the author's residency training rotations in the JAHVA occupational health clinic; this was the study site where paper copy lab results were available for review. If an abnormal result was returned, the subject was logged as a study subject. Further chart review in

the electronic records data base was performed to determine if previous labs were also abnormal, if repeat screening was done, and if a wellness clinic consultation had occurred. The inclusion criteria were thus: an initial abnormal lab value, a repeat sample obtained for the same individual more than 6 months after the initial sample, and, for inclusion in the exposed group, an intervening wellness clinic consultation that occurred in the time frame between the two screening results. Subjects were removed from the study log if data did not meet the criteria above. Not all subjects underwent screening in the consecutive years 2009-2010, however. In order to maximize the sample size it was therefore necessary to include data from other baseline years according to the inclusion criteria above, based on reviewing these years' data in the electronic records data-base. The final study sample consisted of 109 unexposed subjects and 66 that were exposed to a wellness clinic visit. The yearly breakdown of screening results is as shown in Table 3. As illustrated, the majority of repeat measurement pairs occurred in 2009-2010 followed by 2010-2011.

Table 3: Years in which screening measurements occurred

Screening years (baseline – repeat)	**2007-08**	**2008-09**	**2009-10**	**2010-11**
Number of subjects (Total n =175)	22	29	81	43

Data Analysis: Descriptive results are given 1) as distributions of biomarker value or proportional change frequencies and 2) as mean biomarker levels for baseline and repeat screening for the four biomarkers.

Bivariate data are of three types in this study: 1) the proportion of each group with improvement on repeat screening (shown graphically for the four markers using a side by side comparison of the two groups, 2) the intra-subject change from baseline measured at repeat screening, and 3) the difference in mean change (from baseline to repeat screening) between the unexposed and exposed groups.

P-values for proportional change differences between the groups were obtained using the formula for the binomial approximation to the normal distribution. P-values for intra-subject change were obtained using the paired samples t-test. For comparisons between groups the independent samples t-test was used. All tests of hypothesis for bivariate data were one-tailed (given that improvement was expected at the later screening in both groups) with a type I error rate fixed at 5%.

Bivariate comparisons could not compensate for differences between the unexposed and exposed groups while adjusting for baseline characteristics which potentially masked or increased an effect of the wellness clinic visit. These potential confounders included age, gender and the degree of risk as indicated by the level of initial biomarker abnormality. Multivariate testing using analysis of covariance (ANCOVA) was performed in order to correct for the differences in age and gender between the two groups. The General Linear Models procedure in SAS, Statistical Analysis Software (SAS Institute, 2008) was

used to conduct the analysis**.** Hypothesis testing for covariate analysis used the confidence intervals around adjusted means that were obtained from the models.

This study was approved by the Institutional Review Board at the University of South Florida.

III. RESULTS

For 2010, the core year analyzed, screening results were returned by the lab for a total of 355 subjects. Of these, 178 were considered abnormal by the criteria above, indicating cardiovascular risk, and 132 were normal. The remaining 45 were abnormal states without increased cardiovascular risk, such as HDL > 100mg/dL.

Descriptive Statistics for the Unexposed and Exposed Groups

Figures A5 – A8 in the Appendix give the distributions of the respective samples for age and gender. Table 4 shows the age and gender of the unexposed and exposed groups.

Table 4: Demographic data for unexposed and exposed groups

	Unexposed group N=109	Exposed group N=66	p-value
Male gender	61 (56 %)	52 (79%)	0.0038
Age N Mean (sd) Median Min-Max	 109 50.53 (8.89) 52 25-68	 66 48.36 (10.04) 49 24-68	0.1383

The lipid screening service was used by a predominance of individuals older than 45 in both groups, and a majority of the subjects in both groups were male. Age variability was higher for the exposed group than the unexposed group, which also had proportionally more males (79% compared with 56% for the unexposed group).

Proportion of exposed group with decreased, unchanged, or increased cardiovascular risk biomarker level, compared with unexposed group:

Figures 2 - 5 show the outcomes of repeated samples in each group for each of the four biomarkers: glucose, triglycerides, HDL cholesterol and LDL cholesterol. Comparing change by proportions across the two groups showed an improvement in cardiovascular risk indicators both with and without exposure to a wellness clinic visit.

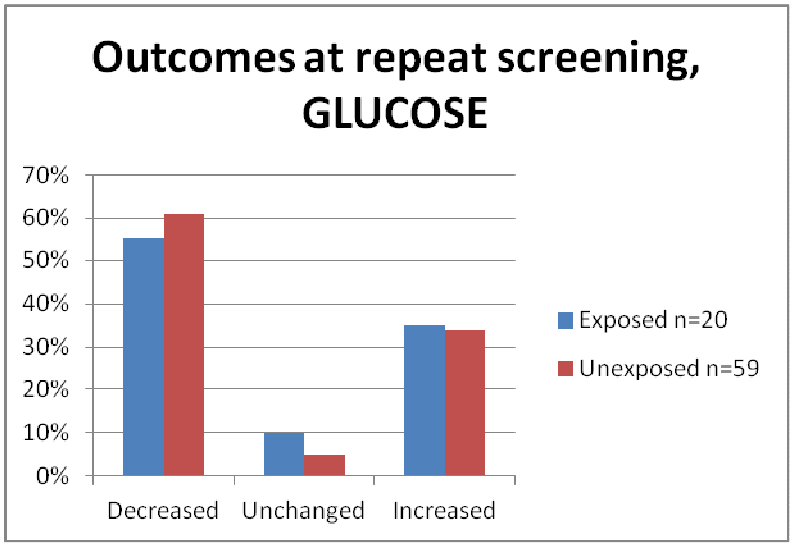

Figure 2 Comparison of repeat results for glucose in exposed and unexposed group, **p =0.8629**

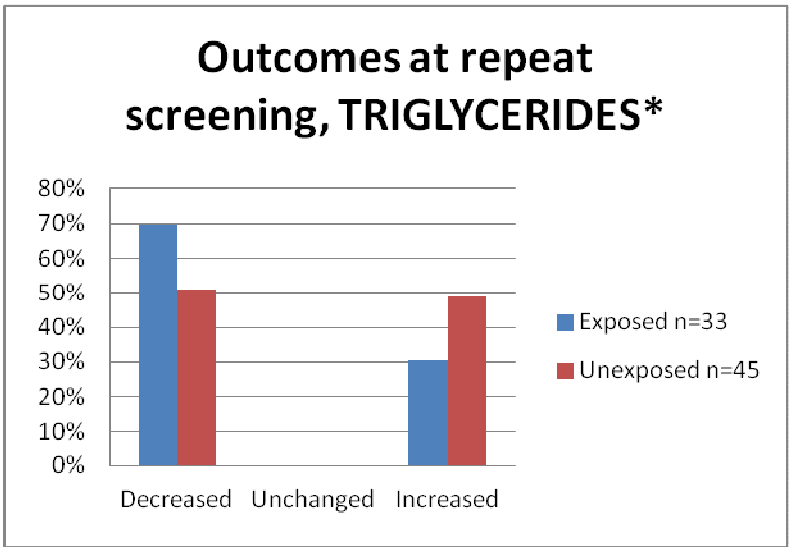

Figure 3 Comparison of repeat results for triglycerides in exposed and unexposed group, **p = 0.0004**

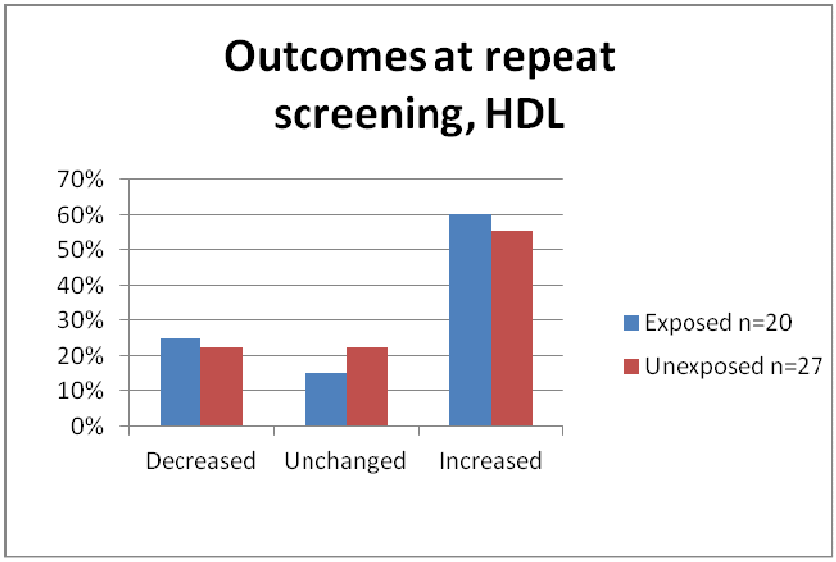

Figure 4 Comparison of repeat results for HDL cholesterol in exposed and unexposed group, **p=0.2903**

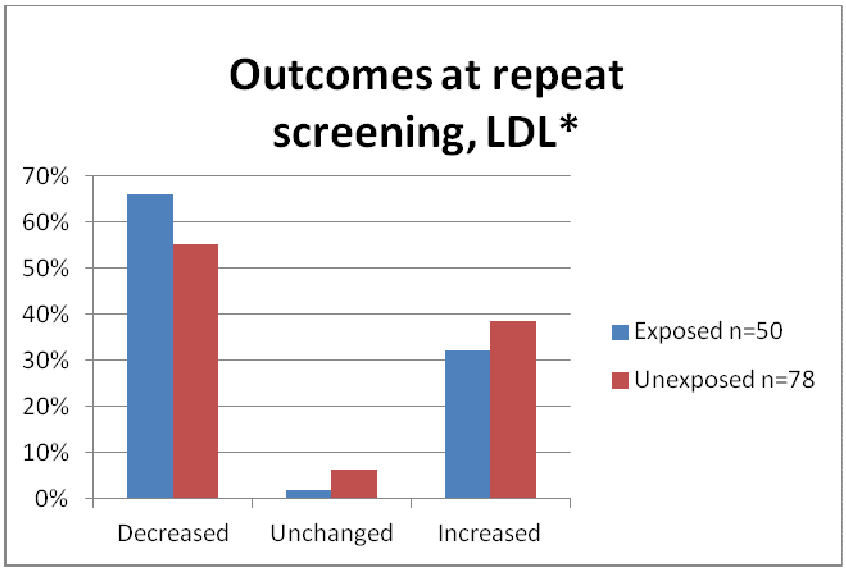

Figure 5 Comparison of repeat results for LDL cholesterol in exposed and unexposed group, **p=0.0062**

For 3 out of the 4 biomarkers analyzed: triglycerides, HDL and LDL cholesterol, a greater proportion of the exposed population than the unexposed population improved on repeat sampling. With regard to glucose, a greater proportion of the group that received a wellness clinic visit had glucose values that increased - indicating higher risk - on repeat sampling.

Direction of change in the exposed and unexposed groups: Serum biomarker levels were improved on repeat screening for both groups. That is, both exposed and unexposed groups showed a mean decrease in serum levels for glucose, triglycerides and LDL cholesterol, and a mean increase for HDL cholesterol. (Table 5).

Hypothesis Testing Results

For the proportional change outcomes illustrated above, the result was significant for two biomarkers, triglycerides and LDL cholesterol (Figures 2-5). The intra-subject change, i.e. the difference between baseline values and values on repeat measurements, was significant for triglycerides, HDL cholesterol, and LDL cholesterol and was non-significant for glucose (Table A1, in Appendix).

Table 5 provides significance levels for comparisons between the groups. The difference in the observed improvement between the intervention and reference groups was significant only for triglycerides.

Table 5: Mean difference between the unexposed and exposed groups

		Unexposed Group	Exposed Group	p-value
Glucose				
	N	59	20	0.0661
	Mean (sd)	-1.63(23.942)	-19.75 (49.917)	
	Median	-4	-5.5	
	Min, Max	-81,113	-168,13.0	
Triglycerides*				
	N	45	33	0.0359
	Mean (sd)	-5.04 (91.497)	-44.45 (97.785)	
	Median	-2	-40	
	Min, Max	-238,267	-287,198	
HDL Cholesterol				
	N	27	20	0.4085
	Mean (sd)	3.11 (5.508)	2.75 (4.898)	
	Median	3	1.5	
	Min, Max	-9,14.0	-7,11.0	
LDL Cholesterol				
	N	78	50	0.0595
	Mean (sd)	-9.4 (22.258)	-17.6 (32.272)	
	Median	-3.5	-8.5	
	Min, Max	-73,39.0	-115,58.0	

Analysis of covariance was done to adjust the two groups for comparison given their differences in gender and age (Table 6).

Table 6: Adjusted means after analysis of covariance

Adjusted means after analysis of covariance by gender			*Unadjusted Mean Differences*	
	Unexposed Mean (95% CI)	Exposed Mean (95% CI)	*Unexposed Mean*	*Exposed Mean*
Glucose	-1.29 (-10.02 to 7.45)	-19.16 (-34.17 to -4.15)	*-1.63*	*-19.75*
Triglycerides	-0.53 (-29.27 to 28.22)	-33.56 (-70.30 to 3.18)	*-5.04*	*-44.45*
HDL cholesterol	4.82 (1.90 to 7.75)	4.73 (1.34 to 8.12)	*3.11*	*2.75*
LDL cholesterol	-9.57 (-15.58 to -3.56)	-18.30 (-26.13 to -10.47)	*-9.4*	*-17.6*
Adjusted means after analysis of covariance by age				
	Unexposed Mean (95% CI)	Exposed Mean (95% CI)	*Unexposed Mean*	*Exposed Mean*
Glucose	-1.62 (-9.96 to 6.72)	-19.77(-34.10 to -5.45)	*-1.63*	*-19.75*
Triglycerides	-5.14 (-33.40 to 23.13)	-44.33 (-77.38 to -11.28)	*-5.04*	*-44.45*
HDL cholesterol	3.08 (1.11 to 5.05)	2.79 (0.50 to 5.08)	*3.11*	*2.75*
LDL cholesterol	-9.39 (-15.37 to -3.40)	-17.60 (-25.07 to -10.12)	*-9.4*	*-17.6*
Adjusted means after analysis of covariance by age and gender				
	Unexposed Mean (95% CI)	Exposed Mean (95% CI)	*Unexposed Mean*	*Exposed Mean*
Glucose	-1.05 (-9.73 to 7.63)	-18.78(-33.70 to -3.86)	*-1.63*	*-19.75*
Triglycerides	0.12 (-29.17 to 29.41)	-33.36 (-70.36 to 3.64)	*-5.04*	*-44.45*
HDL cholesterol	4.60 (1.75 to 7.45)	4.55 (1.25 to 7.84)	*3.11*	*2.75*
LDL cholesterol	-9.58 (-15.62 to -3.54)	-18.35 (-26.26 to -10.44)	*-9.4*	*-17.6*

Adjustment with analysis of covariance for gender produced significant mean differences between the groups for glucose. Adjusting for age showed significant inter-group differences for both glucose and triglycerides. Significance here is defined as a confidence interval not containing zero in the exposed group while the confidence interval contains zero in the unexposed. Analysis of covariance for age and gender combined showed a significant difference between the groups for glucose only. These findings and their implications are discussed in the next section.

IV. DISCUSSION

Significance of Findings

This study included only wellness program participants whose screening results were abnormal and who sought effects of lifestyle changes in improving these parameters. Interestingly, more than half (or 178 of 355) of subjects screened in 2010 had abnormally elevated serum biomarkers for cardiovascular disease. This implies that half or more of those seeking screening have an actual need for secondary prevention, as opposed to being the 'worried well' (Lynch, Gilfillan, Jennett, & McGloin, 1993). Although these annual data were not obtained for other years, it would be useful to do so in similar studies undertaken in the future in order to determine the trends in prevalence of abnormal screening parameters in this worksite population.

The study result showing improvement in both groups has several possible explanations. The improvement in the controls as well as intervention groups could have been due to a beneficial effect of screening at baseline. This explanation, a type of screening bias, has been suggested for similar results observed in other cardiovascular disease prevention studies such as the Multiple Risk Factor Intervention Trial also known as MR FIT and a more recent worksite health promotion study by Racette et al (Kjelsberg, Cutler, & Dolecek, 1997; Racette et al., 2009). This constitutes volunteer bias. The fact that both

intervention and control groups of the study underwent blood glucose and lipid screening indicates that both were likely motivated to pursue good health, with or without a wellness clinic visit.

Other factors than lifestyle changes in addition to the screening bias mentioned could have caused the observed improvement. One example is that employees could have incorporated prescriptions from their private physicians as a way to lower their glucose or lipid levels. Other possible explanations include differences in risk status at the outset between the two groups and insufficient sample size to provide valid results

Initial differences between groups: The significant result observed for triglycerides could have been due to initial mean biomarker differences between the exposed and unexposed groups. Table A1 shows the mean baseline values in the exposed and unexposed groups for the four biomarkers. For triglycerides data there was a large initial abnormality in the exposed versus the unexposed group (257 mg/dL vs. 217 mg/dL). The mean difference in this value between exposed and unexposed groups was 26% of the normal cut-off value used of 149, compared with 15% for the larger mean initial abnormal value in the exposed versus the unexposed group for glucose (129 mg/dL vs. 114 mg/dL). For HDL and LDL the initial abnormal value difference between groups was only between 2% and 3% of the cutoff (Table A1). This difference between exposed and unexposed groups in initial biomarker elevation above normal is also illustrated in Figures A9 – A12 in the Appendix.

Sample sizes: The observed significant result only for triglycerides could have been due to sample size differences along with the initial value differences, for the four biomarkers studied. Because this was a retrospective study using data that were already gathered and from a voluntary participant pool, sample sizes obtained for analysis for the four biomarkers in the two groups were not flexible.

The sample size necessary to show particular effect sizes in changes of the four biomarkers at a study power of 80% was estimated. These estimates are given in Table 7. The table also shows effect sizes used in other published studies (cited by first author's name), as well as the present study's sample sizes. Estimated sample sizes in the table were calculated using the online sample size calculator from Open Epi (Dean, Sullivan, & Soe, 2011). Estimates were calculated for two effect sizes, for trial purposes. The effect sizes were arrived at by using either:

1. 0.4 of the standard deviation, using the larger standard deviation of the exposed and unexposed groups, or
2. 10% of the lowest abnormal, which was, for glucose 100mg/dL, for triglycerides 150mg/dL, for HDL 40 mg/dL and for LDL 120 mg/dL

The calculation in both cases relates the chosen effect size to the variability, or standard deviation of the obtained measures. To avoid the need for large sample sizes from using unbalanced groups in the calculation, the equation for equal group sizes was used. By convention, power = .80 and alpha two-tailed of .05 were used.

Table 7**:** Sample size calculation examples

Sample sizes from selected studies	**Biomarker screened**	**Effect Size mg/dL**	**Std Dev Exp/Unexp**	**Estimated Sample Size from Open Epi**
Karlehagen 2003 Exposed = 95 Unexposed = 74	Total Cholesterol	10	25	99 per group
Racette 2009	Glucose	4	Not reported	N/A
Exposed = 68 Unexposed =55	Triglycerides	5	Not reported	N/A
	HDL Chol	1	Not reported	N/A
	LDL Chol	3	Not reported	N/A
This study Exposed/Unexposed		1. Estimate: 0.4 X SD or 2. Estimate: 10% of lowest abnormal (3. Actual, i.e. observed mean difference between exposed and unexposed)		
20/59	Glucose	20 v 10 (18)	50/24	61 v 242 each
33/45	Triglycerides	39 v 15 (39)	98/91	93 v 624 each
20/27	HDL	4 v 2 (0.36)	5/6	30 v 120 each
50/78	LDL	13 v 12 (8.2)	32/22	71 v 83 each

As the table shows, the samples obtained in the present study were smaller than what would be required, based on the estimates, to obtain sufficient power for statistically significant results. Despite this, it is not surprising that triglycerides showed a significant improvement whereas glucose and HDL did not, given that the sample sizes were lower, less than 30 for the exposed, for these two biomarkers. LDL had the largest sample size and a significant intra-subject change (Table 4), so the improvement observed in the exposed group could have been expected to be significant. However for LDL the mean initial abnormal

value was only slightly larger for the exposed group than the unexposed and the difference between the two groups was just 3% of normal (Table A1).

A larger effect size was observed for triglycerides than for LDL in this study (Table 7). This large effect size was maintained even after adjusting for the high variability of triglycerides with a standard deviation of 98 in the exposed group, and reflects the greater abnormality at baseline in the exposed group for triglycerides previously discussed (Figure A6). Thus the combination of sufficient sample size and larger demonstrable effect size for this biomarker, could account for the significance of the improvement observed for triglycerides but not for LDL or the other biomarkers.

Table 7 also shows that future studies using a similar method will require relatively modest increases in sample sizes to compensate for the effect size differences. For example, for LDL cholesterol, given the standard deviation of 32 for the exposed sample in this study, the exposed group would have to be increased from 50 to 71 to show a significant benefit of the wellness clinic. Increasing the sample sizes in future assessments will likely also decrease the variability in biomarker levels that was seen in the present study which would have an added effect toward enhancing the validity of findings in this population.

Effect of covariates: Results for adjustments (Table 6), showed both age and gender have an impact on outcomes. These data indicate gender has a greater masking effect on glucose improvement, and age is more likely to affect

triglycerides, also as a confounder. However, significance for these results is weak. The trends require confirmation with studies that have larger sample sizes for greater study power.

Benefits and limitations of the study

This is the first study that looks at an intervention conducted by resident physicians entirely within a VA medical center. It is also the first study in this setting that looks at four different specific biomarkers for cardiovascular disease employing a control group and adjusting by covariate analysis for age and gender. The positive results from this study come at a time when preventive health care is increasingly urgent. Clinics such as the JAHVA employee wellness program provide training to residents in preventive medicine. Such training will become indispensable in today's health care arena, and as it does the resident clinic described in this study has potential to serve as a model intervention.

The medical centers of the VA already contribute greatly to training residents in diverse medical disciplines. The VA is important in continually improving medical training through innovative practices. Two examples are MOVE!, a program addressing the specific occupational cohort of former service personnel, and the VA's system-wide diffusion of electronic medical records as the way forward for patient data management. The VA's electronic records system allows for seamless access to a wide variety of records in a way that greatly facilitates individual care as well as population studies. Thus the improvement obtained through the VA's dedication to innovation is evident.

In the present study an electronic records based system is used to evaluate a worksite health promotion program and to recommend improvements in its design. Such use of electronic records systems is another model practice for residents in preventive medicine. As mentioned the VA provides leadership in this and other areas of medical education, and partnerships between the VA and university training centers are likely to continue to grow.. Benefits to residents and VA employees have been described, both from the performance of this study and its results. This study thus provides input to help shape the increasing role of VA medical centers in medical education.

This investigation employed a retrospective study design to evaluate a health promotion program. The evaluation method has several strengths and limitations. Strengths of this study method are high replicability due to the standard nature of parameters established by a large volume of pre-existing research. Another strength is the use of password-protected electronic records. These are more detailed, more easily handled, and more private than paper records and thus greatly facilitate data collection. Improved uptake of wellness education is likely to occur in the future as worksites constantly seek to enhance public image and competitiveness. Outcomes data from wellness programs is therefore likely to grow significantly in the future along with a need for methods such as this one to assess wellness programs. The use of computerized records should facilitate continual improvements in these evaluation methods. The use of a control group to provide a rigorous comparison method was another strength of this study.

Weaknesses of this method include the use of a convenience sample, which resulted in sample sizes too small to achieve statistical significance for some of the biomarkers. As mentioned, this limitation is likely to improve in future replications of this study due to the likelihood of increased numbers of workers seeking wellness counseling. Another limitation is that occupational category was not included in the demographic descriptors. This was due to confidentiality considerations, to prevent identifiable information that could conflict with employees' rights to participate anonymously in the lipid screening program. Finally, in this study initial health indicators were limited to age, gender, and baseline biomarker values while outcomes were limited to repeated biomarker levels. Other indicators of initial risk such as body mass index (BMI), high blood pressure, or smoking status were thereby excluded, as were outcomes indicative of reduced risk through lifestyle change such as lowering BMI, lowering blood pressure without medications and quitting smoking. Program changes are suggested to address this limitation when using this method in future evaluations.

V. CONCLUSIONS AND FUTURE DIRECTIONS

The findings of improved biomarker levels and attendant cardiovascular risk in employees who participate in wellness clinic compared with controls are encouraging. They provide impetus for continued tracking of results for both participants in wellness clinic and non-participants. Such tracking can be accomplished more easily in future years given the templates for data collection and the flow process for analysis established for this study, although modifications will be necessary for future data. There is a need for increased sample sizes to further clarify results from this study. Concomitantly, there is capacity to increase participation levels in the JAHVA lipid screening program from the current levels of less than 10% of the estimated 5000 employees at the medical center. (353/5000 = 7%).

This study showed improvement in serum biomarkers for cardiovascular risk in an intervention group compared with control subjects. Improvement could have been due to other factors than lifestyle changes. For example, employees could have incorporated prescriptions from their private physicians as a way to lower their cholesterol. This possibility was not controlled for, a limitation due to the study's exclusive reliance on retrospective analysis of records from participants who voluntarily presented for screening. Employees' opting out of repeat annual screening and follow-up wellness visits limits program evaluators' ability to

survey the employees' behavior over time to find out how they implemented lifestyle changes and which ones were successful. This limitation can be addressed in future studies by wellness program measures to sustain the participants' repeated involvement over time and by including regular health risk assessments as part of the yearly lipid screening.

In conclusion, this study suggests the following 5 potential refinements to the JAHVA employee wellness lipid screening program

1. Target employee participation increases to levels that are either suggested by sample size calculations above, or that are in alignment with other VA regional and national programs
2. Increase employee participation in annual lipid screening by
    a. Increasing employee awareness of the lipid screening and wellness clinic benefits as central to their optimal use of health promotion activities and resources generally available at the JAHVA facility, and
    b. Providing rewards for participating such as lunch bags, pedometers, gym bags and discounts for gym clothes
3. Require baseline health risk assessments prior to lipid screening (so as to amplify data available for evaluation of health promotion at JAHVA) and,
4. Continuously analyze incoming data retrospectively for program evaluation purposes.

Requiring a preliminary health risk assessment or HRA for all who elect to undergo glucose and lipid screening may deter some from participating. There will be extra time required to complete the HRA which is a change from current practices. Resistance to this change may exist for various reasons such as employee unwillingness to schedule time to complete the HRA.
Making the HRA a requirement will likely also increase costs to the health promotion program for implementing and managing the collection of additional data. It may then also be necessary to pass on this extra cost to participants in contrast to the current program charge, a nominal $3 fee.

Changing the current practice to one of mandating an HRA may thus seem counterproductive. However, rationing a product can enhance its desirability and thereby increase demand for it. In this case the rationing mechanisms of time and price costs are actually investments intended to improve program quality. Such a change will therefore not necessarily cause decreased participation but could, on the contrary, enhance employee participation by raising the profile of the lipid screening program, and by highlighting a convenient, accessible resource that employees may increasingly consider to be a worthwhile investment.

Age and gender are both elements of cardiovascular risk, with risk being lower for younger age and female gender (seen in Figures A1-A3). Covariate analysis of our data showed an impact from age and gender indicating that difficulty in improving triglyceride levels may be related to age, and difficulty in improving

glucose levels may be related to age and gender. However, other confounders were present in this study and could also have affected outcomes. Age and gender were the only health risk parameters available for both exposed and unexposed groups due to the lack of a health risk assessment in subjects who underwent only screening. With the recommendation to obtain a health risk assessment, additional covariates will be available, such as body mass index (BMI), family history, and smoking status. Analyzing these will better characterize the specific population at this worksite and enhance knowledge of the specific contribution of above-named health indicators in future assessments of wellness program outcomes.

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APPENDIX: ADDITIONAL FIGURES & TABLE

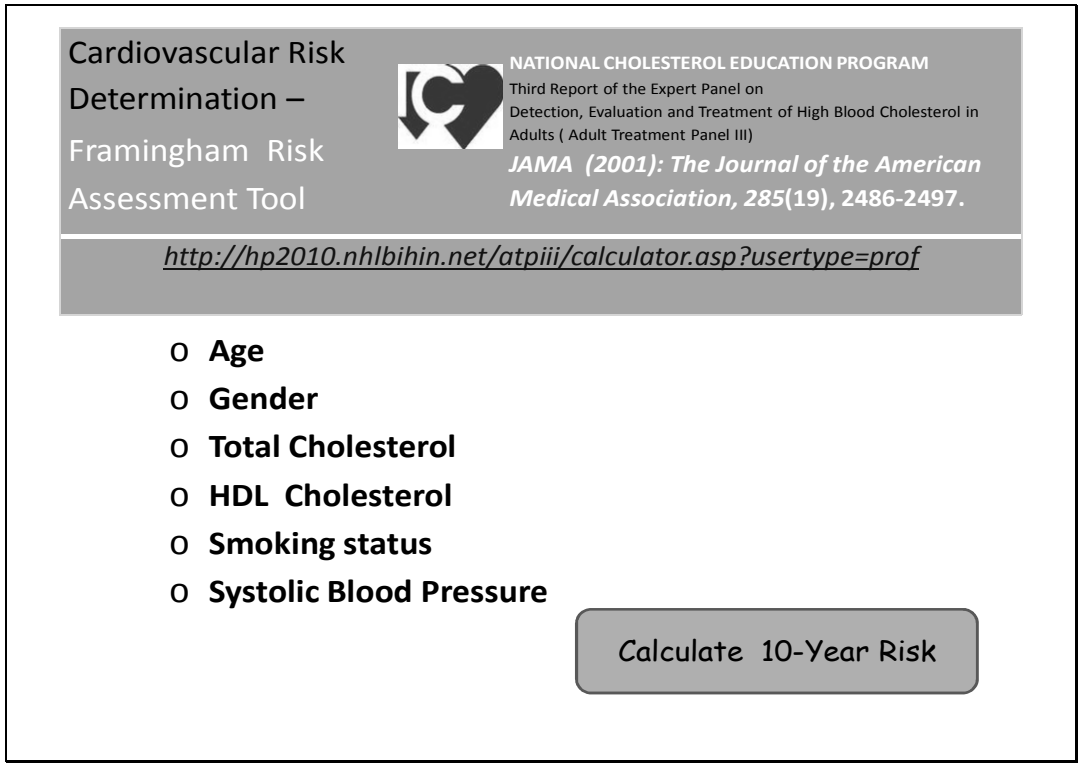

Figure A1. Framingham Risk Calculator

APPENDIX (Continued)

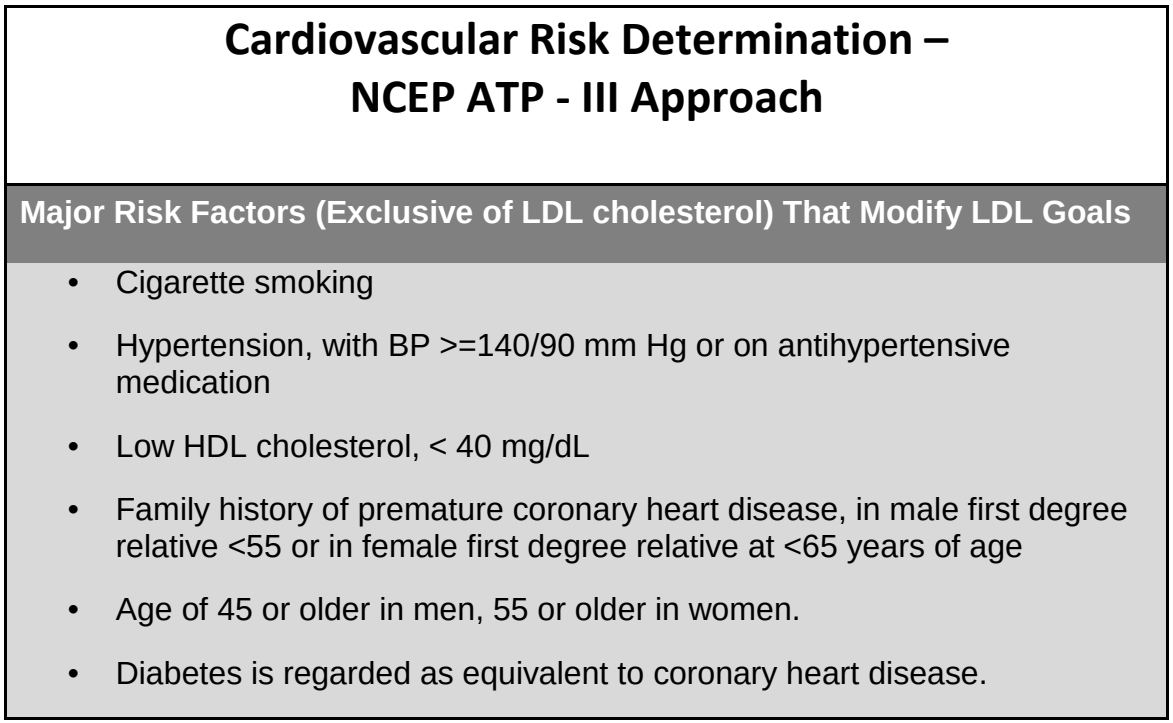

Figure A2. NCEP ATP – III algorithm for determining target LDL level

APPENDIX (Continued)

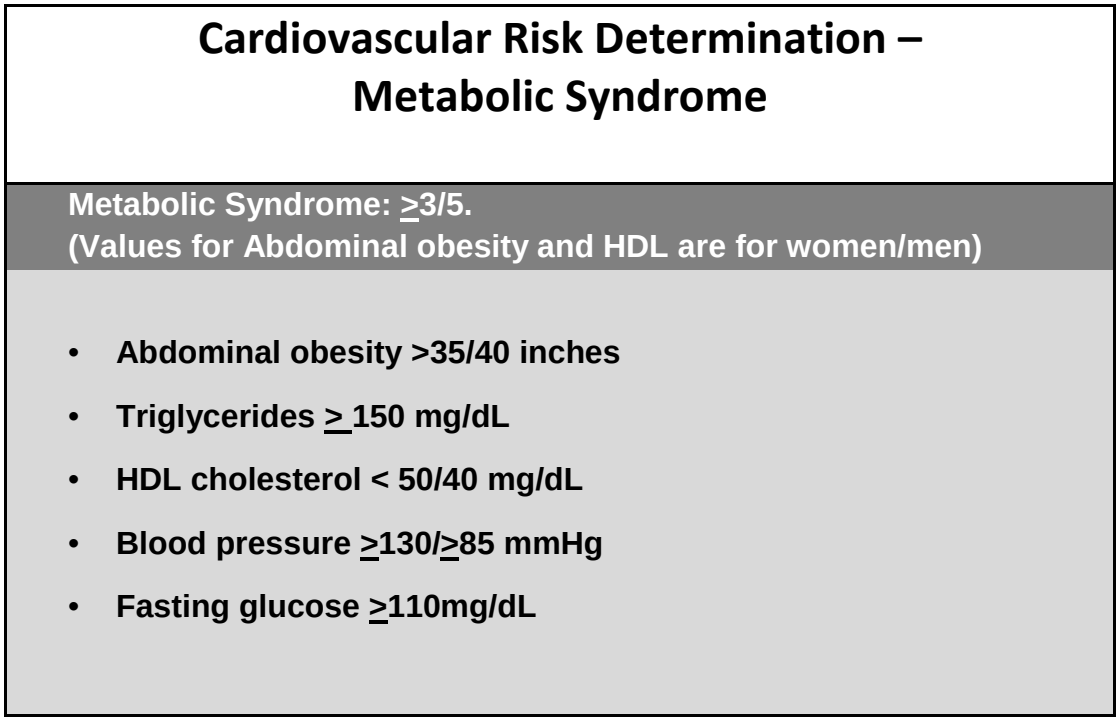

Figure A3. NCEP ATP – III criteria for diagnosing metabolic syndrome

APPENDIX (Continued)

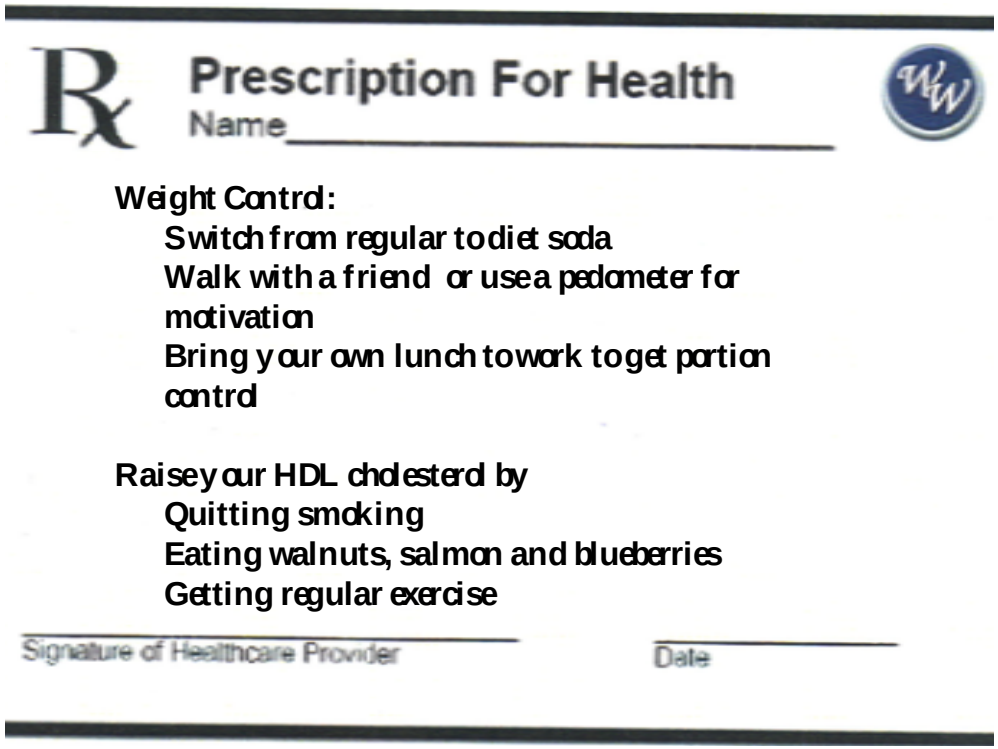

Figure A4. Example of Wellness 'prescription'

APPENDIX (Continued)

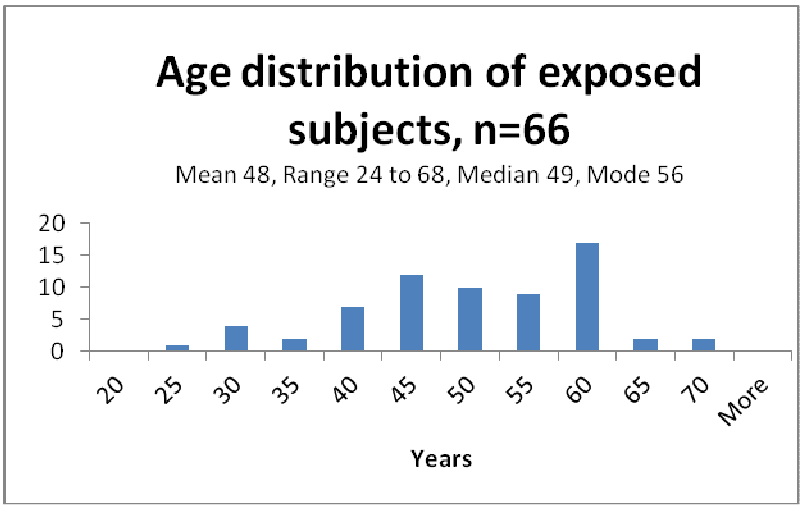

Figure A5. Age distribution of exposed group

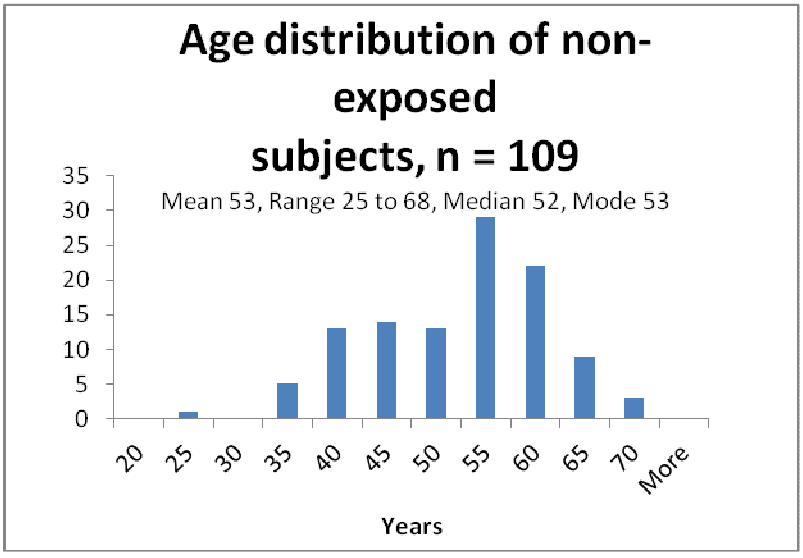

Figure A6. Age distribution of non-exposed group

APPENDIX (Continued)

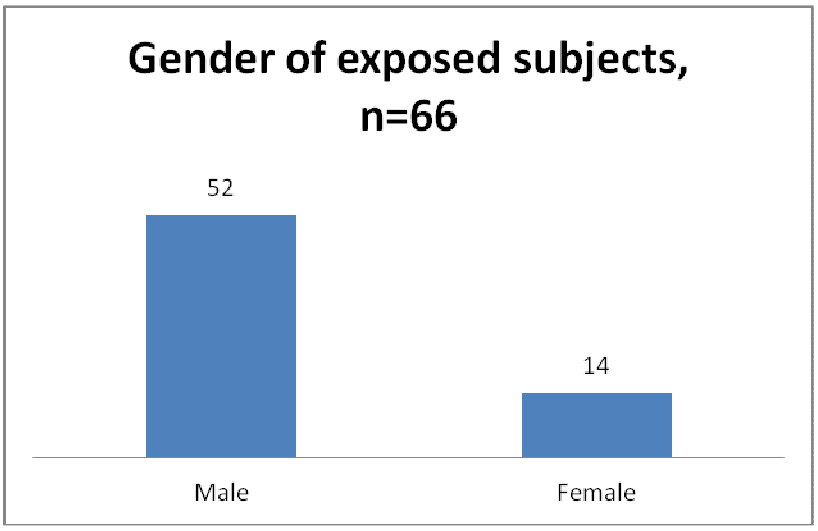

Figure A7. Gender of exposed group

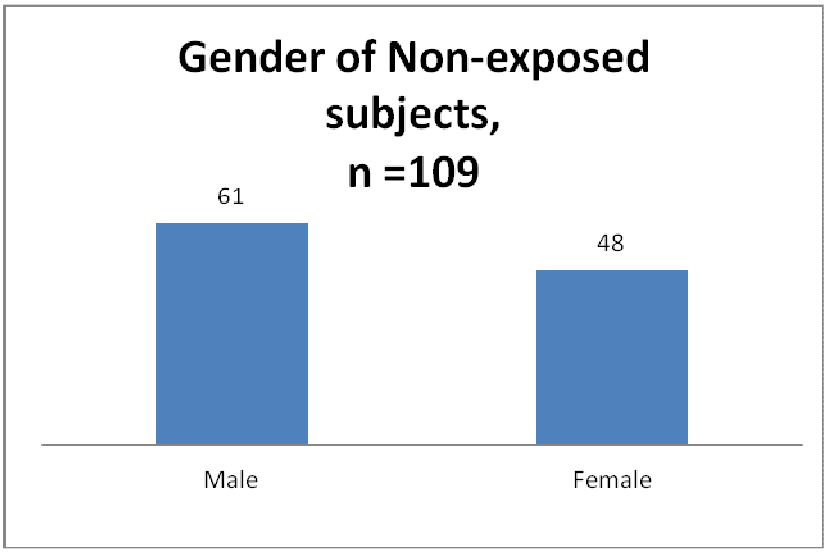

Figure A8 Gender of non-exposed group

APPENDIX (Continued)

Table A1: Mean difference for paired measurements

	N	Mean baseline value (mg/dL)	Mg/dL decrease (or increase)	% Decrease (or increase)	P-value for paired measurements
Glucose					
Exposed	20	129.3	19.7	15.2	.092868
Unexposed	59	114.4	1.7	1.4	.603641
Triglycerides					
Exposed	33	256.6	44.5	17.3 *	.013607
Unexposed	45	217.7	5.1	2.3	.713276
HDL cholesterol					
Exposed	20	34.5	(2.8)	(8.1) *	.010619
Unexposed	27	35.7	(3.1)	(8.7) *	.006884
LDL cholesterol					
Exposed	50	146.7	17.6	12.0 *	.000336
Unexposed	78	143.6	9.4	6.5 *	.000371

APPENDIX (Continued)

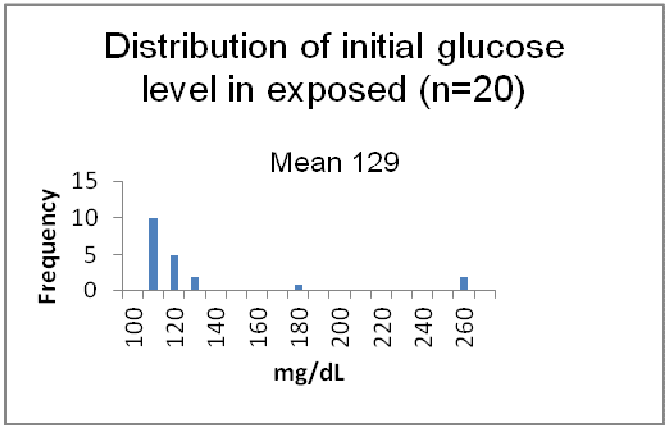

Figure A9-1. Initial glucose level in exposed

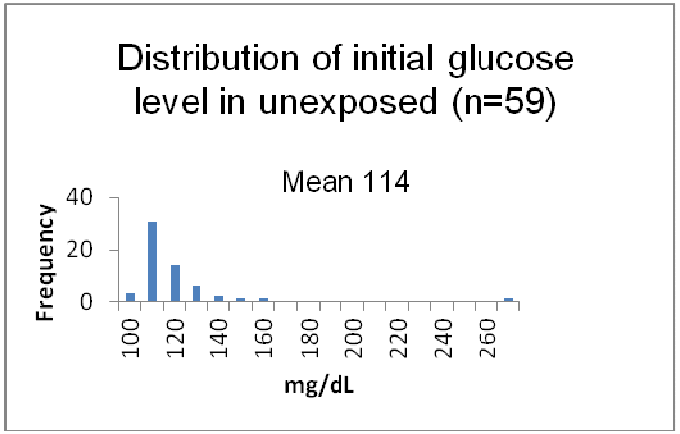

Figure A9-2. Initial glucose level in unexposed

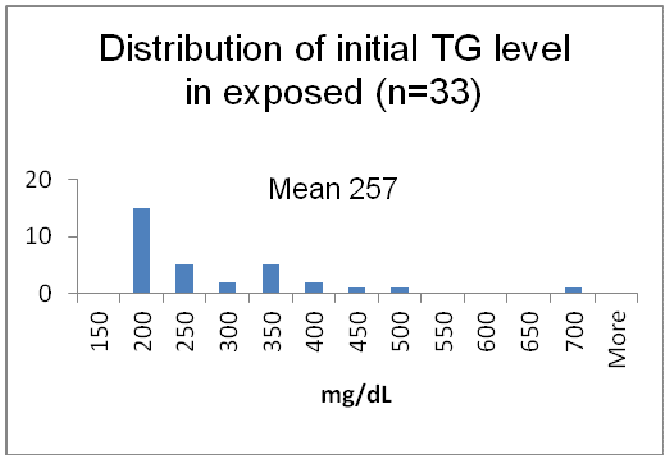

Figure A10-1. Initial triglyceride level in exposed

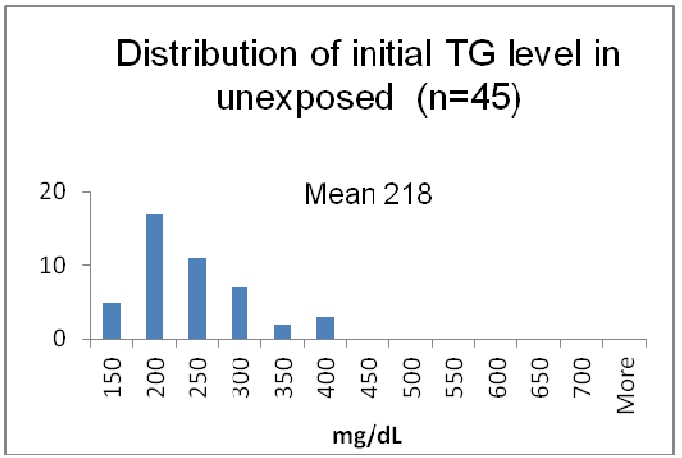

Figure A10-2. Initial triglyceride level in unexposed

APPENDIX (Continued)

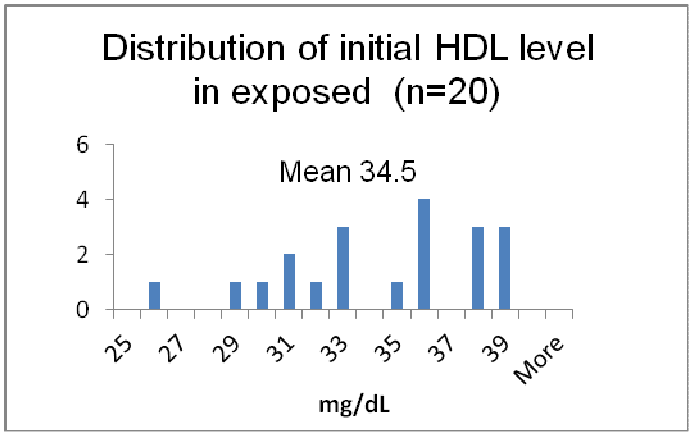

Figure A11-1. Initial HDL level in exposed

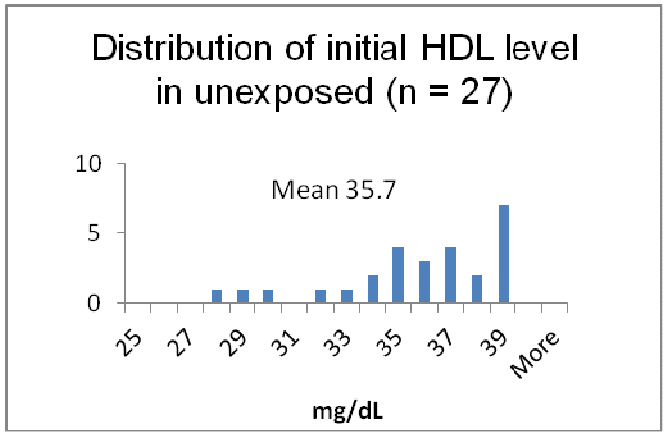

Figure A11-2. Initial HDL level in unexposed

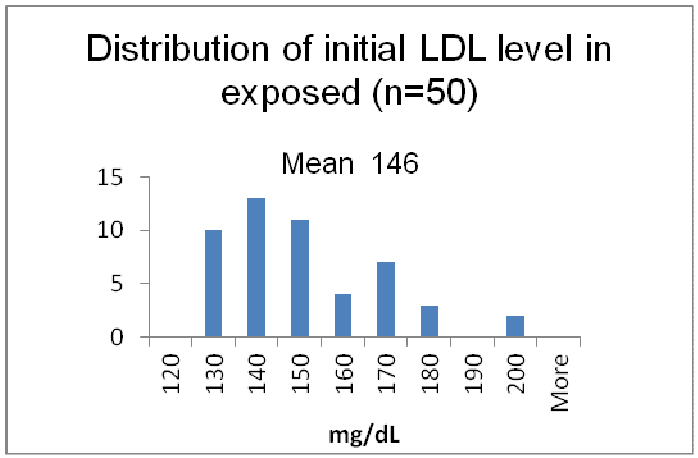

Figure A12-1. Initial LDL level in exposed

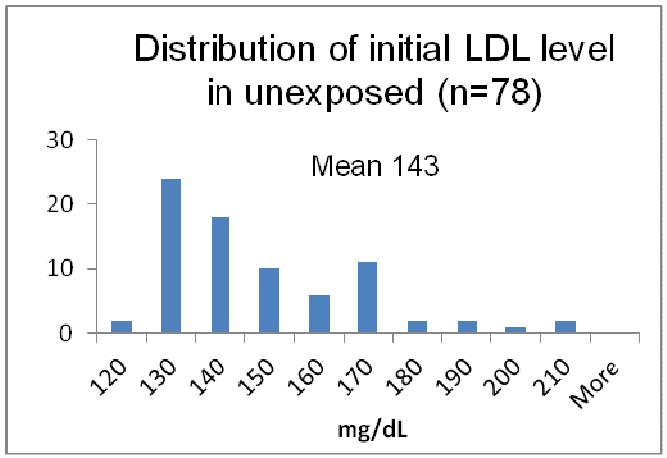

Figure A12-2. Initial LDL level in unexposed