Women's Health Initiative
Clinical Trial and Observational Study

Semi-Annual Progress Report
March 1, 2002 to August 31, 2002

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WHI Semi-Annual Progress Report

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Executive Summary

This report, summarizing data accumulated through August 31, 2002, presents the current status of the three clinical trial components and the Observational Study (OS) of the Women's Health Initiative (WHI). The primary areas for this report are adherence to the interventions, completeness of follow-up, safety and outcome rates for these study components.

The Hormone Replacement Therapy (HRT) component randomized 27,347 women into two trials, one of unopposed estrogen (ERT) for the 10,739 women who previously had a hysterectomy and a parallel one 16,608 of estrogen plus progestin (PERT) in women with a uterus. The PERT trial was stopped early, in July of this year, at the recommendation of the DSMB. Because of this change, the current report provides adherence data only for the ERT trial. The average follow-up is now approximately 5.5 years. Drop-out rates have been generally stable but somewhat higher than design assumptions. "Drop-in" rates are also larger than projected. Analyses of intermediate effects, including blood biomarker analyses, bone density and blood pressure are provided. Vital status is known within the last 18 months for all but 3.8% of women. 3.2% of HRT participants are deceased. The current event rates for CHD, breast cancer, colorectal cancer, and hip fractures are approximately 70%, 85%, 75%, and 35%, respectively, of projected rates. Event rates by age, race/ethnicity and hysterectomy status are provided for all monitored outcomes.

The Dietary Modification (DM) component randomized 48,836 women. Intervention adherence is monitored by the difference between the Intervention and Control arms in Food Frequency Questionnaire (FFQ) percent energy from fat (C-I). Studywide, the FFQ mean difference between Intervention and Control women is 10.9% energy from fat at AV-1 decreasing to 7.7% at AV-7. The corresponding design assumptions for the C-I comparisons were 13% at year 1, diminishing to 0.25% per year though adequate power can be maintained as long as this difference remains at or above 10%. For fruit and vegetable intake, the mean difference between the arms of the trial remains consistently in excess of 1 more serving per day. Compared to Control women, Intervention women consumed almost 1 more serving per day of grains at AV-1, decreasing to one-half serving from AV-4 – AV-7. Currently 3.7% of the DM participants are lost-to-follow-up or have stopped follow-up, and 2.6% of participants are deceased. The average follow-up time for DM women is approximately 5.6 years. The current incidence rates of breast cancer, colorectal cancer, and CHD are approximately 115%, 75%, and 60%, respectively, of what was assumed in the study design. Event rate comparisons by age and race/ethnicity are presented for all monitored outcomes.

The Calcium and Vitamin D (CaD) component randomized 36,282 women previously recruited to the trial. Adherence to CaD supplements, defined as those women known to be consuming 80% or more of the prescribed dose, has remained steady since the last report and is now 56%-65%, though still lower than desirable. Follow-up rates for CaD participants are better than for the other CT components in part because of the delayed randomization into this trial component; as only 1.9% of participants are lost to follow-up or have stopped follow-up, and 2.2% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. With just over 4.5 years of average follow-up, the current rates of hip fractures, invasive breast cancer, and colorectal cancer are approximately 40%, 110%, and 80%, respectively, of what was assumed in the study design. Event rates by age and race/ethnicity are shown for all monitored outcomes.

Observational Study recruitment ended with 93,676 women enrolled. Follow-up rates suggest strong retention overall as only 3.7% are considered lost to follow-up or have stopped follow-up, and <1% have not provided recent outcomes data. Responses to mailings are generally high (≥93%). Approximately 84% of the 3-year clinic visits due have been conducted, as judged by task completeness. Event rates by age, race/ethnicity and follow-up time (pre- vs. post-year 3 visit) are presented for all adjudicated outcomes.

Additional information on the timeliness and quality of outcomes ascertainment is provided. Clinical center performance monitoring is summarized and a tabulation of ancillary studies and clinical center participation in these studies is also provided.

1. Preliminary Remarks

This report documents study activities of the Women's Health Initiative (WHI) Clinical Trial (CT) and Observational Study (OS) through August 31, 2002. Topics include intervention adherence, follow-up, safety, outcomes and specialized scientific efforts. Updates are provided for each study component separately with a separate section on outcomes devoted to data quality, processing and timeliness issues.

During the past 6 months, the major WHI activities have been those surrounding the historic events of the early stopping and publication of results of the randomized trial of combined estrogen plus progestin (PERT)[1]. This was an intensive effort for all of WHI. The report was published on the world-wide-web on July 9, 2002, just five and a half weeks after the DSMB recommendation to stop the trial. By that time, all 27,000 women in the hormone program had been mailed a letter from Dr. Lenfant, Director, NHLBI, describing this decision with informational materials presenting primary study results in lay terms. The remaining 130,000 WHI participants were provided similar materials within a few weeks thereafter. Clinical centers then made personal contacts with all PERT trial participants. Final outcomes data were collected, and the participants were unblinded and provided an opportunity to discuss study findings.

The participant response to this has been overwhelmingly positive. WHI participants have expressed their pride in being a part of this history-making event and of helping answer these questions. They were very appreciative of being informed of the results by WHI before hearing it through other sources. The value of their participation, not only in the PERT trial but in other study components, has been reinforced through the media coverage. There have been anecdotal reports of a few women in the estrogen alone trial (ERT) expressing anxiety in continuing with the intervention but overall, the early stopping of PERT has been a retention boost to the entire study.

WHI Investigators have been active in presenting these results to various communities and also in developing additional reports. There are 10 priority papers under development devoted to coronary heart disease, stroke, venous thromboembolism, breast cancer, gynecologic cancers, colorectal and other cancers, fractures, quality of life/cognition, diabetes, and gynecologic symptoms. These reports will present the more detailed analyses of the completed trial database (data and health events through July 7, 2002), using centrally adjudicated outcomes. The work of the HRT-CVD biomarkers study is progressing. The writing committees for the corresponding committees will use the data from the PERT trial in their developing manuscripts.

Routine activities of the other trials have proceeded in parallel. Major efforts involved included:

- Implementation of the Personalized Evaluation of Fat Intake (PEFI) in the summer of 2002.

[1] Writing Group for the Women's Health Initiative Investigators. Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women: Principal Results of the Women's Health Initiative Randomized Controlled Trial. JAMA 2002; 283:321-333.

- Planning for a clinical center nutritionist workshop in December 2002 to discuss adherence issues

- Further development of close-out planning, including special emphasis on possible early close-out of other trial components.

All reports summarize clinical center (CC) data provided to the CCC by August 31, 2002. All data presented are derived from WHILMA, the study database. Data managed in WHILMA are those defined by standardized data collection procedures and instruments (see *WHI Manuals, Vol. 2 - Procedures* and *Vol. 3 - Forms*).

Clinical center locations and Principal Investigators are listed in *Table 1.1*.

Table 1.1
WHI Clinical Centers and Principal Investigators

Institution	Principal Investigator	Location
Albert Einstein College of Medicine	Sylvia Wassertheil-Smoller, PhD	Bronx, NY
Baylor College of Medicine	Jennifer Hays, PhD	Houston, TX
Brigham and Women's Hospital	Joann Manson, MD DrPH	Boston, MA
Emory University	Larry Phillips, MD	Atlanta, GA
Fred Hutchinson Cancer Research Center	Shirley Beresford, PhD	Seattle, WA
George Washington University	Judith Hsia, MD	Washington, DC
Kaiser Foundation Research Institute	Bette Caan, PhD	Oakland, CA
Kaiser Foundation Research Institute	Cheryl Ritenbaugh, PhD	Portland, OR
Medical College of Wisconsin	Jane Morley Kotchen, MD MPH	Milwaukee, WI
MedStar Research Institute	Barbara Howard, PhD	Washington, D.C.
Memorial Hospital of Rhode Island	Annlouise Assaf, PhD	Pawtucket, RI
Northwestern University	Linda Van Horn, PhD RD	Chicago/Evanston, IL
Ohio State University	Rebecca Jackson, MD	Columbus, OH
Research Foundation of SUNY, Stony Brook	Dorothy Lane, MD MPH	Stony Brook, NY
Rush Presbyterian- St. Luke's Medical Center	Henry Black, MD	Chicago, IL
Stanford University	Marcia Stefanick, PhD	San Jose, CA
State University of New York, Buffalo	Maurizio Trevisan, MD MS	Buffalo, NY
University of Alabama at Birmingham	Cora Lewis, MD MSPH	Birmingham, AL
University of Arizona	Tamsen Bassford, MD	Tucson/Phoenix, AZ
University of California, Davis	John Robbins, MD	Sacramento, CA
University of California, Irvine	Allan Hubbell, MD	Irvine, CA
University of California, Los Angeles	Howard Judd, MD	Los Angeles, CA

Table 1.1 (continued)
WHI Clinical Centers and Principal Investigators

Institution	Principal Investigator	Location
University of California, Los Angeles	Rowan Chlebowski, MD PhD	Torrance, CA
University of California, San Diego	Robert Langer, MD MPH	La Jolla/Chula Vista, CA
University of Cincinnati	Margery Gass, MD	Cincinnati, OH
University of Florida	Marian Limacher, MD	Gainesville/Jacksonville, FL
University of Hawaii	David Curb, MD	Honolulu, HI
University of Iowa	Robert Wallace, MD	Iowa City/Bettendorf, IA
University of Massachusetts	Judith Ockene, PhD	Worcester, MA
University of Medicine and Dentistry	Norman Lasser, MD PhD	Newark/New Brunswick, NJ
University of Miami	Mary-Jo O'Sullivan, MD	Miami, FL
University of Minnesota	Karen Margolis, MD	Minneapolis, MN
University of Nevada	Robert Brunner, PhD	Reno, NV
University of North Carolina at Chapel Hill	Gerardo Heiss, MD MPH	Chapel Hill, NC
University of Pittsburgh	Lewis Kuller, MD DrPH	Pittsburgh, PA
University of Tennessee	Karen Johnson, MD	Memphis, TN
University of Texas	Robert Schenken, MD	San Antonio, TX
University of Wisconsin	Catherine Allen, PhD	Madison, WI
Wake Forest University	Gregory Burke, MD MS	Winston-Salem/ Greensboro, NC
Wayne State University	Susan Hendrix, DO	Detroit, MI

2. HRT Component

The intervention activities of the estrogen plus progestin trial (PERT) were stopped in July 2002, following the recommendation of the DSMB. PERT trial participants were informed with a centralized mailing beginning July 8, with personal contacts by clinic staff over the next few weeks. A procedure was put in place to collect final outcomes for the intervention period, to unblind the women, explain the study results, and provide information on the transition to a follow-up phase without intervention. These participants are no longer being dispensed study medications but the remaining elements of the WHI protocol are continuing. At the same time, participants in the estrogen only arm (ERT) were informed of the PERT study findings and the continuing need for their participation was reinforced.

A few changes to this report have been implemented, reflecting the change in the PERT trial status. For this report we have omitted the reports of adherence to PERT study medicine, and endometrial aspiration results since there are few additional data from the last report. Additional changes will be incorporated as post-intervention data accumulate.

2.1 Recruitment

27,347 women were randomized into the HRT component (99.4% of goal). Of these, 10,739 women had a prior hysterectomy (39%) and were randomized to ERT or placebo in equal proportions. The remaining 16,608 women with an intact uterus were randomized to PERT or its placebo, again in equal proportions for most of the recruitment period. *Table 2.1* documents the age and racial/ethnic distribution for each trial.

2.2 Adherence

Adherence to study medications is determined at clinic visits by weighing returned bottles, if available, or by self-report in the small proportion of women with missed pill collection. *Table 2.2 – HRT Adherence Summary* gives descriptive data on all women who are considered due for each contact for participants with hysterectomy (ERT vs. placebo) trial. At this point, essentially all participants (99.7%) were randomized more than four years ago, 8,243 (77%) more than five years, 4,516 (42%) more than six and only 1,965 women (18%) have been in the study more than seven years. Experience in the eighth year is too sparse yet to be reliable. The current estimates of rates of stopping pills in follow-up years five through seven are between 4% and 6% per year. The adherence summaries for AV-4 through AV-7 are 58%, 55%, 52%, and 48%. *Figure 2.1* presents the secular trends in adherence rates for each visit type for the entire ERT trial cohort. A change in the methodology for calculating adherence (described previously) has not been applied retrospectively to the results prior to the February 2002 report. The increase between the previous two cycles is likely to be an artifact of this change.

Drop-out and drop-in rates are presented in *Table 2.3* along with associated design assumptions for combined stopping pills and death or loss to follow-up. Results for each interval as well as the overall cumulative loss to intervention are provided. In AV-4 through AV-8 the difference between the observed and projected cumulative stopping intervention rates appear to be somewhat divergent. At AV-6, where the estimates should be stable, 41.3% had dropped out, as compared to a projected 32.7%. The cumulative rate at AV-7, though less reliable, is 45.5%, as compared to the design projection of 36.7%. Overall, approximately 48% of the ERT trial cohort has stopped their study

pills at some point but 56% were active at their last contact.

A small proportion (1.5% per year) of the HRT participants were expected to stop study hormone pills and begin taking hormones outside of the trial. Among hysterectomized women the observed (design) cumulative rates are 2.9% (1.5%) at AV-1, 7.0% (4.4%) at AV-3, and 9.8% (8.7%) at AV-6, notably larger than expected. Reported reasons for stopping pills are listed in *Table 2.4*. Tabulations of these reasons by age and race/ethnicity are presented in *Table 2.5*.

2.3 Symptoms

Women may report symptoms potentially related to HRT at routine follow-up contacts or through non-routine contacts with the CC. The primary symptoms being monitored are bleeding and breast changes. Reports of bleeding and breast changes by contact type and hysterectomy strata are shown in *Tables 2.6* and *2.7*, respectively. Reports of bleeding in women on PERT reached a high of nearly 50% at 6 months (SAV-1), declining to approximately 7% after AV-5. Reports of breast changes peaked at 6 weeks after randomization and have declined to less than 2% in both strata.

2.4 Laboratory Studies

Tables 2.8 and *2.9* present the results of blood specimen analyses from a small (8.6%) cohort of HRT women selected randomly at baseline for these prospective analyses. These results are essentially the same as our last report and are shown here only for completeness. The subsample analyzed incorporated over-sampling of minorities. The results in *Table 2.8* are weighted to reflect the overall WHI-CT distribution of race/ethnicity. In *Table 2.9*, similar results are provided for each racial/ethnic group, though some groups have rather small sample sizes.

2.5 Intermediate Outcomes

Bone mineral density (BMD) measures are collected in three clinical centers (Pittsburgh, Birmingham, and Tucson) at baseline and at follow-up years 1, 3, 6, and 9. These data, shown in *Table 2.10* suggest small but significant increases in BMD between baseline and AV-1, with larger differences observed over greater follow-up time (AV-3 and AV-6) for whole body and spine. For hip, the largest increase occurs at AV-3. The pattern of treatment effects is similar in both hysterectomy strata. *Table 2.11* presents BMD data for Black/African American, Hispanic/Latino, and White women participating in the HRT component at these three centers.

2.6 Vital Status

Table 2.12 presents data on the vital status and the participation status of participants in the HRT trial. A detailed description of CCC and clinic activities to actively locate participants who do not complete their periodic visits is given in *Section 6 – Outcomes Processing*. For operational purposes, we define CT participants to have an "unknown" participation status if there is no outcomes information from the participant for 18 months and no other contacts for 6 months. There is a substantial difference in the rate of lost to follow up participants between the women without a uterus (2.0%) and the women with a uterus (1.1%). The difference was much smaller 6 months ago. Presumably this is the result of the recent closure of the intervention of the E+P component. Currently, 3.8% of the HRT participants are lost-to-follow-up or have stopped follow-up, and 3.2% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. The design assumed that 3% per year would be lost-to-follow-up or dead. Currently, the average follow-up for HRT participants

is about 5.5 years, suggesting that approximately 15.4% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions. Follow-up in women with a uterus is slightly better than in women who have had a hysterectomy.

2.7 Outcomes

Table 2.13 contains counts of the number of locally verified, major WHI outcomes for HRT participants by age and race/ethnicity. The estimates of annualized incidence rates for many event types in several racial/ethnic subgroups should be viewed with caution as the small number of events observed to-date results in unstable estimates. Approximately 4% of the self-reported outcomes have not yet been verified, so the numbers in this table can be seen as a lower bound of the actual number of outcomes that have occurred.

Compared to the design assumptions, we have observed about 70% of the expected number of CHD events, 85% of the expected number of breast cancers, 75% of the expected number of colorectal cancers, and about 35% of the expected number of hip fractures.

We have classified the strokes among HRT participants in one of six classes of the Glasgow scale, based on the condition of the participant at discharge:

1. Good recovery – participant can lead a full and independent life with or without minimal neurological deficit.

2. Moderately disabled – participant has neurological or intellectual impairment but is independent.

3. Severely disabled – participant conscious but totally dependent on others to get through daily activities.

4. Vegetative survival – participant has no obvious cortical functioning.

5. Dead. (All participants who died within one month of their stroke were classified in this category, irrespective of their actual cause of death.)

6. Unable to categorize based on available documentation.

The subclass *Non-disabling stroke* contains strokes with Glasgow scale class 1 and 2; *Fatal/ disabling stroke* contains strokes with Glasgow scale class 3 through 5; *Unknown status from stroke* contains strokes with Glasgow scale 6 and strokes for which the Glasgow classification was not yet complete.

Table 2.14 compares the rates of the same locally verified outcomes according to baseline hysterectomy strata. For most cardiovascular outcomes the event rates are slightly larger for the women without a uterus, while for most cancers the rates are slightly larger for women with a uterus. The differences in cardiovascular disease rates are consistent with the risk profile differences we have previously observed.

Table 2.15 presents the distribution of stroke diagnostic categories for HRT participants by hysterectomy status. The distribution of the subtype of stroke appears to be similar for the women

with and without a uterus.

Table 2.16 compares the Glasgow scale for strokes between hysterectomy strata. From this table it appears that the largest number of strokes fall in Glasgow classes 1 and 2, the less disabling strokes, but a substantial number of participants die within one month of a stroke.

Table 2.17 contains counts of the number of self-reports by age and race/ethnicity for some outcomes that are not locally verified in WHI. As most of the self-reported outcomes are somewhat over-reported (see *Section 6.3 – Outcomes Data Quality*), the numbers in this table should be taken as an upper bound on the number of events that have occurred in HRT participants.

2.8 WHI Memory Study (WHIMS)

The WHI Memory Study is an ancillary study in the HRT component, funded by Wyeth Ayerst through a grant to Dr. Sally Shumaker, Wake Forest University. The aim of this study is to determine whether hormone replacement therapy reduces the incidence of dementia in women over 65 years of age. 7,526 women were enrolled in the 39 participating centers, representing approximately 61% of the age-eligible cohort and 28% of the entire HRT study. Baseline characteristics of WHIMS participants are shown in *Table 2.18* hysterectomy status.

2.9 Issues

The closing of the PERT trial has been the focus of study activities over the past 6 months. In addition to informing all HRT participants and transitioning the PERT participants to a follow-up only phase, investigators and staff have been working diligently to communicate the results underlying the early stopping recommendation to the medical community and general population, including a publication and many opportunities to present these results in public forums. This publication has generated considerable interest and questions regarding the design of the trial (choice of agents, dosing, study population), size and statistical significance of the effects, and rationale for early stopping. The investigators are working to respond to these issues in multiple forums, including providing JAMA with a response to letters to the editor and providing both the FDA and Wyeth with a dataset from the JAMA publication.

Operationally, considerable effort is being devoted to completing the trial database and developing a full set of trial results. The complete database will include all events occurring through July 7, 2002, since participant were informed of study results and began to be unblinded on July 8. The reports of these events was approximately 70% complete as of August 31. The effort to adjudicate these events, both locally and centrally, is a current study-wide priority. Another data source under development is the HRT-CVD biomarker study, an effort initiated previously but now of greater interest and urgency.

There was considerable concern that ERT trial participants would drop out of the study after learning of the PERT trial results. Currently we have no evidence of any change in the rate of drop-outs over time. Many anecdotes regarding PERT trial participants have been relayed to the CCC indicating how well received this information was in general, particularly because participants were given information before it was made public. There have been fewer reports from ERT trial participants but it is assumed that the release of these results have given much needed visibility to the program and reinforced the importance of these studies to all WHI participants.

Looking forward, the investigators have planned 10 priority papers geared toward looking at the effects of PERT on CHD, stroke, venous thromboemolism, breast cancer, gynecologic cancers, colorectal and other cancers, fractures, quality of life and cognitive function, gynecologic symptoms, and diabetes using the final trial database. A final summary paper examining overall risks and benefits in the complete dataset is also anticipated. The plan is to complete these manuscripts over the next nine to twelve months.

Table 2.1
Hormone Replacement Therapy Component Age – and Race/Ethnicity – Specific Recruitment

Data as of: August 31, 2002

HRT Participants	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age				
Overall	**27,347**			
50-54	3425	125%	13%	10
55-59	5408	99%	20%	20
60-69	12364	100%	45%	45
70-79	6150	90%	22%	25
Without Uterus	**10,739**			
50-54	1396	113%	13%	10
55-59	1916	78%	18%	20
60-69	4852	88%	45%	45
70-79	2575	84%	24%	25
With Uterus	**16,608**			
50-54	2029	135%	12%	10
55-59	3492	116%	21%	20
60-69	7512	111%	45%	45
70-79	3575	95%	22%	25
Race/Ethnicity				
Overall	**27,347**			
American Indian	130		<1%	
Asian	527		2%	
Black	2738		10%	
Hispanic	1537		6%	
White	22030		81%	
Unknown	385		1%	
Without Uterus	**10,739**			
American Indian	75		1%	
Asian	164		2%	
Black	1616		15%	
Hispanic	651		6%	
White	8084		75%	
Unknown	149		1%	
With Uterus	**16,608**			
American Indian	55		<1%	
Asian	363		2%	
Black	1122		7%	
Hispanic	886		5%	
White	13946		84%	
Unknown	236		1%	

Table 2.2
HRT Adherence Summary for Participants Without a Uterus

Data as of: August 31, 2002

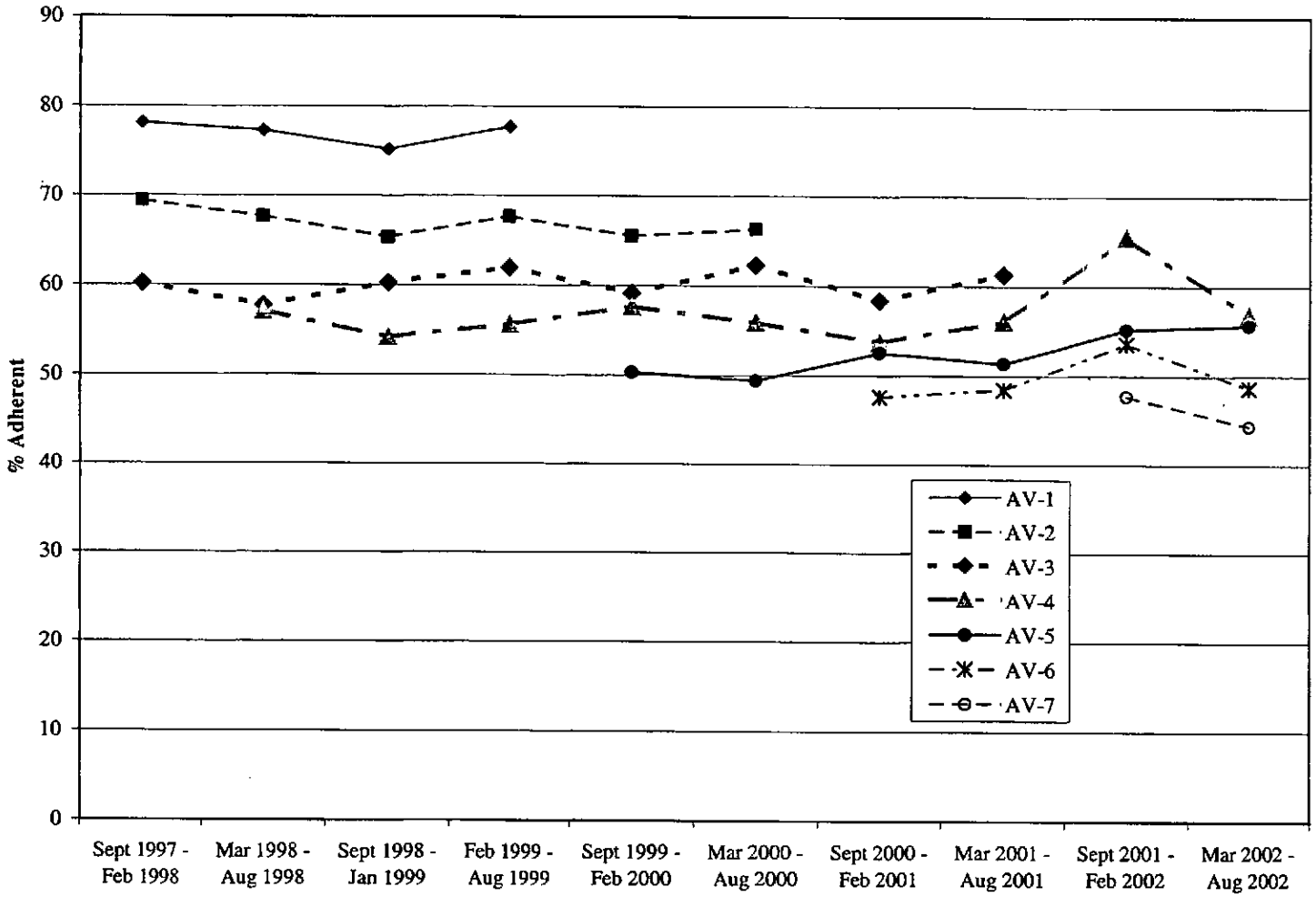
Contact	Due N	Conducted N	%	Conducted in Window N	%	Stopped HRT during interval N	%	Missed Pill Collection N	%	Total with Collections N	%	Medication Rate[1] <50% N	%	Medication Rate[1] 50%-80% N	%	Medication Rate[1] 80% + N	%	Adherence Summary[2] %
Semi-Annual Visit - 1	10739	10448	97	8785	82	381	4	96	1	10627	99	741	7	957	9	8929	84	83
Annual Visit - 1	10739	10349	96	8536	79	476	4	133	1	10190	99	916	9	1108	11	8166	80	76
Annual Visit - 2	10739	10063	94	7944	74	1005	9	211	2	9594	98	966	10	1190	12	7438	78	70
Annual Visit - 3	10739	10043	94	7445	69	809	8	225	3	8525	97	842	10	1046	12	6637	78	63
Annual Visit - 4	10705	9787	91	6758	63	661	6	204	3	7671	97	617	8	939	12	6115	80	58
Annual Visit - 5	8243	7418	90	5022	61	448	6	146	3	5444	97	418	8	647	12	4379	80	55
Annual Visit - 6	4516	4051	90	2583	57	221	5	85	3	2769	97	194	7	319	12	2256	81	52
Annual Visit - 7	1965	1713	87	1054	54	69	4	27	2	1116	98	83	7	121	11	912	82	48
Annual Visit - 8	545	456	84	285	52	28	5	15	5	297	95	19	6	38	13	240	81	47

[1] Medication rate calculated as number of pills taken divided by number of days since bottle(s) were dispensed.
[2] Adherence summary calculated as number of women consuming ≥ 80% of pills / # due for visit.
Note: Deceased women are excluded from all medication adherence calculations, but are included in the number "Due."

Figure 2.1
HRT Adherence Summary
% Participants Due for a Visit Who Took at Least 80% of Study Pills[1]

Data as of August 31, 2002

Participants Without Uterus



[1] Adherence calculations changed as of the September 2001 – February 2002 interval.

Table 2.3
HRT Drop-Out and Drop-In Rates (%) by Follow-Up Time

Data as of: August 31, 2002

	Design		Without Uterus			
	Int	Cum	Stopped[1]	Dead/ Lost[2]	Int[3]	Cum[4]
Drop-Outs[5]						
AV-1	8.8	8.8	7.8	0.4	8.3	8.3
AV-2	5.9	14.2	9.4	0.9	10.3	17.7
AV-3	5.9	19.2	7.7	1.3	9.0	25.2
AV-4	5.9	24.0	6.3	1.7	8.0	31.2
AV-5	5.9	28.5	5.6	1.9	7.5	36.3
AV-6	5.9	32.7	5.0	2.8	7.8	41.3
AV-7	5.9	36.7	3.7	3.6	7.3	45.5
AV-8	5.9	40.4	5.4	5.5	10.9	51.5
Drop-Ins[6]						
AV-1	1.5	1.5			2.9	2.9
AV-3	2.9	4.4			4.2	7.0
AV-6	4.4	8.7			3.0	9.8

[1] Estimated rate of stopping hormones in the interval.
[2] Death or lost to follow-up rate in the interval.
[3] Combined rate of stopping and death or lost to follow-up in the interval.
[4] Estimated cumulative rate of stopping and death or lost to follow-up.
[5] Drop-out rates derived from Form 7 by date. Cumulative rates calculated as life-table estimates.
[6] Cumulative Drop-in rates derived from medication inventory collected at AV-1, AV-3, AV-6, AV-9. Interval estimates back-calculated from cumulative rates.

Table 2.4
Reasons for Stopping HRT[1]: HRT Participants Without Uterus

Data as of August 31, 2002

Reasons[2]	(N = 4684)	
Personal/family		
Demands of work	82	1.8%
Family illness, emergency or other family demands[3]	199	4.2%
Financial problems	9	0.2%
Lack of cooperation/support from family/friends[4]	47	1.0%
Living in nursing home	9	0.2%
Issues of interest in study[5]	107	2.3%
Travel		
Too far to CC	166	3.5%
Moved out of area or refuses to be followed to another CC	34	0.7%
Other travel issues[6]	97	2.1%
Visits & Procedures		
Doesn't like visits, calls	58	1.2%
Mammogram Issues[7]	27	0.6%
Doesn't like gynecologic procedures	13	0.3%
Doesn't like required forms or safety procedures[8]	81	1.7%
Problems with other procedures[9]	11	0.2%
Worried about health effects of medical tests/procedures	18	0.4%
Wants test results[10]	1	<0.1%
Problems with CC[11]	31	0.7%

(continues)

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Family illness, emergency or other family demands", "Death in the family or of a close friend", and "Caregiver responsibilities demanding time, effort, lifestyle changes".
[4] Combines "Lack of cooperation/support from family and/or friends" and "Family/friends request that she withdraw".
[5] Combines "Conflicting priorities other than work or family", "Feels discouraged regarding participation overall", "Loss of interest, boredom", "Feels it is not an important study", and "In another study in conflict with WHI intervention".
[6] Combines "Transportation problems (other than distance)", "Traffic", "Parking at CC", and "CC neighborhood/safety".
[7] Combines "Doesn't like mammograms (DM, HRT)" and "Cost of mammograms (DM, HRT)".
[8] Combines "Doesn't like filling out forms (other than those required for safety)", and "Doesn't like required safety forms and/or procedures (HRT, CaD)".
[9] Combines "Doesn't like having blood drawn", "Doesn't like ECG (DM, HRT)", and "Doesn't like other procedures (other than those required for safety)".
[10] Combines "Wants results of blood analyses", and "Wants results of bone mineral density measurement (BD sites only)".
[11] Combines "Problem with the CC", "Problem with CC staff person (other than DM Group Nutritionist)", and "Staff change/turnover".

Table 2.4 (continued)
Reasons for Stopping HRT[1]: HRT Participants Without Uterus

Data as of August 31, 2002

Reasons[2]	(N = 4684)	
Symptoms		
Vaginal Bleeding	6	0.1%
Breast Symptoms[3]	183	3.9%
Vaginal Changes	14	0.3%
Hot flashes/night sweats	33	0.7%
Other[4]	1042	22.2%
Health Conditions		
Breast Cancer	85	1.8%
Complex or atypical hyperplasia	0	0.0%
Endometrial cancer	2	<0.1%
Venous thromboembolism[5]	52	1.1%
High triglycerides (> 1000 mg/dL)	2	<0.1%
Malignant melanoma	11	0.2%
Gallbladder disease	7	0.1%
Heart Attack	59	1.3%
Stroke	89	1.9%
Meningioma	4	0.1%
Depression	11	0.2%
Cholesterol (high or concern about levels)	9	0.2%
Osteoporosis	37	0.8%
Cognitive/memory changes	22	0.5%
Other[6]	475	10.1%

(continues)

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Breast tenderness (HRT)" and "Other breast changes (HRT)".
[4] Combines "Experiencing health problems or symptoms not due to intervention", "Reports other health problems or symptoms from the WHI intervention", "Reports health problems or symptoms from the WHI intervention", "Hair/skin changes", "Bloating/Gas", "Constipation", "Other gastrointestinal problems", "Headaches", "Weight loss/gain", "Low energy/too tired", "Possible allergic reaction", and "Other symptoms not listed above".
[5] Combines "Deep vein thrombosis", and "Pulmonary embolism".
[6] Combines "Removed from intervention due to WHI symptom management", "Removed from intervention due to adverse health event", "Communication problem", "Hypercalcemia", "Kidney failure/dialysis", "Renal calculi", "Arthritis", "Diabetes", "Loss of vision and/or hearing", and "Other health conditions not listed above".

Table 2.4 (continued)
Reasons for Stopping HRT[1]: HRT Participants Without Uterus

Data as of August 31, 2002

Reasons[2]	(N = 4684)	
Intervention		
Doesn't like randomized nature of intervention	87	1.9%
Expected some benefit from intervention	40	0.9%
Feels guilty, unhappy, or like a failure for not meeting study goals of intervention	3	0.1%
Takes too many pills	35	0.7%
Other pill issues[3]	134	2.9%
CaD Issues[4]	28	0.6%
DM Issues[5]	5	0.1%
Taking active HRT[6]	196	4.2%
Will not be on any HRT[7]	373	8.0%
Taking SERMs or other hormone medications[8]	44	0.9%
Other Health Issues		
Worried about cost if adverse effects occur	11	0.2%
Expected more health care	12	0.3%
Advised not to participate by health care provider[9]	626	13.4%
Study conflicts with other health issues[10]	588	12.6%
Other		
Other reasons not listed above	991	21.2%
Refuses to give a reason	74	1.6%

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Multiple reasons may be reported for a woman
[3] Combines "Doesn't like taking pills (HRT, CaD)", "Doesn't like taste of pills (HRT, CaD)", and "Unable to swallow pills (HRT, CaD)".
[4] Combines "Wants to take her own calcium (CaD)", "Feels diet is already sufficient in calcium/Vitamin D (CaD)", "Taking more than the maximum allowable IU of Vit D (CaD)", and "Taking Calcitriol (CaD)".
[5] Combines "Doesn't like DM requirements", "Problem with DM Group Nutritionist or group members (DM)", "Doesn't like DM eating pattern", "Doesn't like attending DM intervention classes (DM)", "Doesn't like self-monitoring (DM)", "Doesn't like budgeting fat grams (DM)", "Has concerns regarding long-term risks/benefits of low fat diet (DM)", "Unhappy that not losing weight (DM)", "Not in control of meal preparation (DM)", "Too difficult to meet or maintain dietary goals (DM)", "Doesn't like eating low fat diet (DM)", "Doesn't like eating 5 vegetables/fruits per day (DM)", "Doesn't like eating 6 grains per day (DM)", "Feels fat gram goal is unrealistic (DM)", and "Eating pattern conflicts with personal health beliefs (DM)".
[6] Combines "Has made a personal decision to go on active HRT (HRT)" and "Advised to go on active HRT by health care provider (HRT)".
[7] Combines "Has made a personal decision that she does not want to be on HRT (HRT)" and "Advised to not be on active HRT by health care provider (HRT)".
[8] Combines "Has made a personal decision to go on SERM (e.g., Evista/raloxifene, tamoxifen) (HRT)", "Advised to go on SERM (e.g., Evista/raloxifene, tamoxifen) by health care provider (HRT)", and "Taking testosterone medications (HRT)".
[9] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason".
[10] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues".

Table 2.5
Reasons for Stopping HRT[1] by Age at Screening and Race/Ethnicity: HRT Participants Without Uterus

Data as of August 31, 2002

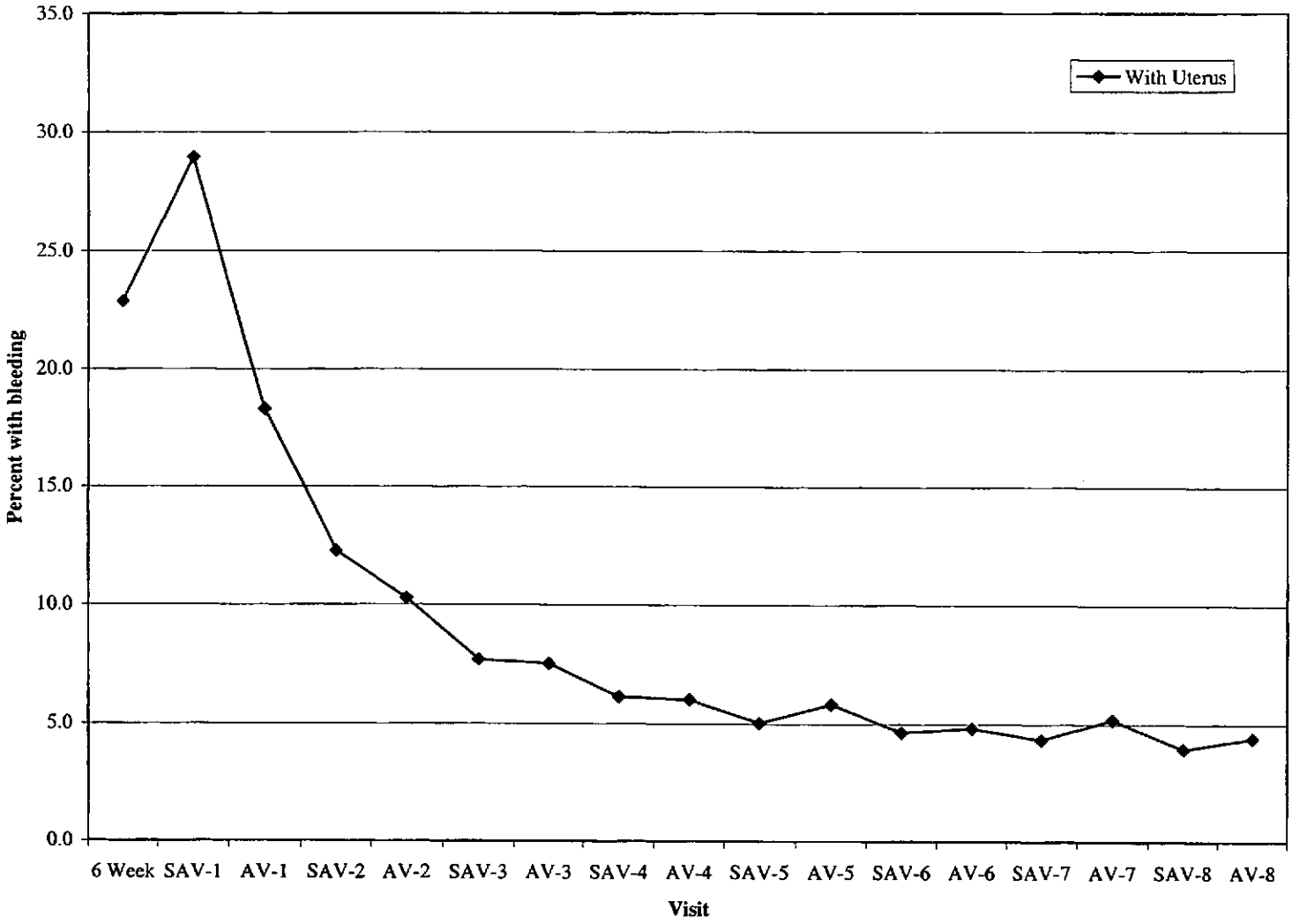
			Age at Screening							
	All (N = 10,739)		50 – 54 (N = 1,396)		55 – 59 (N = 1,916)		60 – 69 (N = 4,852)		70 –79 (N = 2,575)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping HRT	4684	43.6%	611	43.8%	800	41.8%	2058	42.4%	1215	47.2%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	199	4.2%	24	3.9%	41	5.1%	93	4.5%	41	3.4%
Vaginal bleeding	6	0.1%	2	0.3%	2	0.3%	1	<0.1%	1	0.1%
Breast symptoms[6]	183	3.9%	13	2.1%	23	2.9%	74	3.6%	73	6.0%
Taking active HRT[7]	196	4.2%	29	4.7%	45	5.6%	81	3.9%	41	3.4%
Will not be on any HRT[8]	373	8.0%	29	4.7%	47	5.9%	187	9.1%	110	9.1%
Advised not to participate by health care provider[9]	626	13.4%	86	14.1%	101	12.6%	266	12.9%	173	14.2%
Study conflicts with other health issues[10]	588	12.6%	83	13.6%	96	12.0%	262	12.7%	147	12.1%

	Race/Ethnicity											
	American Indian/ Alaskan Native (N = 75)		Asian/Pacific Islander (N = 164)		Black/African American (N = 1,616)		Hispanic/Latino (N = 651)		White (N = 8,084)		Unknown (N = 149)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping HRT	32	42.7%	60	36.6%	737	45.6%	333	51.2%	3460	42.8%	62	41.6%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	1	3.1%	2	3.3%	44	6.0%	25	7.5%	124	3.6%	3	4.8%
Vaginal bleeding	0	0.0%	0	0.0%	2	0.3%	1	0.3%	3	0.1%	0	0.0%
Breast symptoms[6]	1	3.1%	2	3.3%	26	3.5%	15	4.5%	137	4.0%	2	3.2%
Taking active HRT[7]	1	3.1%	0	0.0%	22	3.0%	11	3.3%	159	4.6%	3	4.8%
Will not be on any HRT[8]	1	3.1%	5	8.3%	56	7.6%	19	5.7%	286	8.3%	6	9.7%
Advised not to participate by health care provider[9]	5	15.6%	10	16.7%	68	9.2%	36	10.8%	498	14.4%	9	14.5%
Study conflicts with other health issues[10]	5	15.6%	11	18.3%	68	9.2%	29	8.7%	467	13.5%	8	12.9%

[1] Does not include reasons reported by women who stopped and later restarted HRT.
[2] Percentages are of HRT participants without uterus in the same age or race/ethnicity category.
[3] Multiple reasons may be reported for a woman.
[4] Percentages are of HRT participants without uterus in the same age or race/ethnicity category who stopped HRT.
[5] Combines "Family illness, emergency or other family demands", "Death in the family or of a close friend", and "Caregiver responsibilities demanding time, effort, lifestyle changes".
[6] Combines "Breast tenderness (HRT)" and "Other breast changes (HRT)".
[7] Combines "Has made a personal decision to go on active HRT (HRT)" and "Advised to go on active HRT by health care provider (HRT)".
[8] Combines "Has made a personal decision that she does not want to be on HRT (HRT)" and "Advised to not be on active HRT by health care provider (HRT)".
[9] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason".
[10] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues".

Table 2.6
Reports of Bleeding

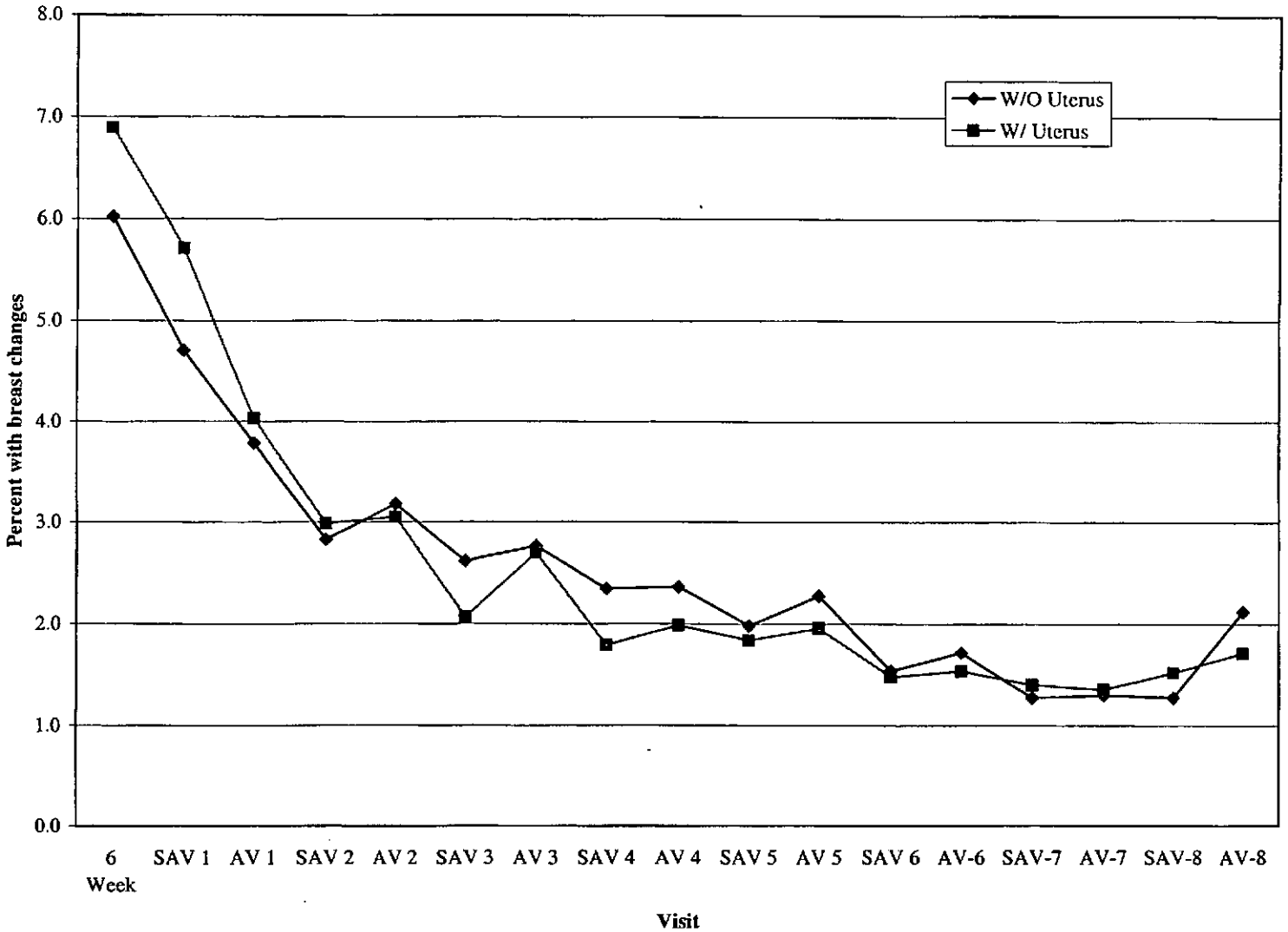
Data as of: August 31, 2002



Contact	With Uterus	
Semi-Annual Visit 3 – Number with Bleeding	1195	(7.7%)
Annual Visit 3 – Number with Bleeding	1186	(7.5%)
Semi-Annual Visit 4 – Number with Bleeding	951	(6.1%)
Annual Visit 4 – Number with Bleeding	934	(6.0%)
Semi-Annual Visit 5 – Number with Bleeding	699	(5.0%)
Annual Visit 5 – Number with Bleeding	679	(5.8%)
Semi-Annual Visit 6 – Number with Bleeding	406	(4.6%)
Annual Visit 6 – Number with Bleeding	299	(4.8%)
Semi-Annual Visit 7 – Number with Bleeding	181	(4.3%)
Annual Visit 7 – Number with Bleeding	133	(5.2%)
Semi-Annual Visit 8 – Number with Bleeding	59	(3.9%)
Annual Visit 8 – Number with Bleeding	30	(4.4%)

Table 2.7
Reports of Breast Changes

Data as of: August 31, 2002



Contact	Without Uterus		With Uterus	
Semi-Annual Visit 3 – Number with Breast Changes	220	(2.6%)	275	(2.1%)
Annual Visit 3 – Number with Breast Changes	229	(2.8%)	355	(2.7%)
Semi-Annual Visit 4 – Number with Breast Changes	182	(2.3%)	223	(1.8%)
Annual Visit 4 – Number with Breast Changes	177	(2.4%)	243	(2.0%)
Semi-Annual Visit 5 – Number with Breast Changes	131	(2.0%)	197	(1.8%)
Annual Visit 5 – Number with Breast Changes	125	(2.3%)	173	(2.0%)
Semi-Annual Visit 6 – Number with Breast Changes	62	(1.5%)	97	(1.5%)
Annual Visit 6 – Number with Breast Changes	49	(1.7%)	70	(1.5%)
Semi-Annual Visit 7 – Number with Breast Changes	24	(1.3%)	42	(1.4%)
Annual Visit 7 – Number with Breast Changes	15	(1.3%)	25	(1.4%)
Semi-Annual Visit 8 – Number with Breast Changes	9	(1.3%)	16	(1.5%)
Annual Visit 8 – Number with Breast Changes	7	(2.1%)	8	(1.7%)

Table 2.8
Blood Specimen Analysis: HRT Participants

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Micronutrients						
Alpha-Carotene (μg/ml)						
Baseline	1163	0.07	0.07	1468	0.09	0.08
AV-1	1022	0.07	0.06	1365	0.08	0.08
AV3	838	0.06	0.06	1151	0.07	0.08
AV-1 – Baseline	1000	-0.01	0.06	1332	-0.01	0.06
AV-3 – Baseline	822	-0.01	0.06	1123	-0.01	0.07
Beta-Carotene (μg/ml)						
Baseline	1162	0.29	0.27	1468	0.34	0.33
AV-1	1021	0.26	0.25	1366	0.31	0.30
AV3	838	0.25	0.25	1151	0.32	0.38
AV-1 – Baseline	999	-0.03	0.22	1333	-0.04	0.21
AV-3 – Baseline	821	-0.04	0.24	1123	-0.03	0.32
Alpha-tocopherol (μg/ml)						
Baseline	1163	16.09	7.04	1468	16.31	7.70
AV-1	1022	17.70	8.91	1366	16.81	7.42
AV3	838	17.84	8.33	1151	18.26	8.25
AV-1 – Baseline	1000	1.63	6.25	1333	0.51	5.73
AV-3 – Baseline	822	1.85	6.81	1123	2.02	7.33
Gamma-tocopherol (μg/ml)						
Baseline	1163	2.48	1.65	1468	2.24	1.40
AV-1	1022	2.22	1.84	1366	1.84	1.24
AV3	838	1.99	1.49	1151	1.67	1.25
AV-1 – Baseline	1000	-0.30	1.13	1333	-0.37	0.93
AV-3 – Baseline	822	-0.55	1.19	1123	-0.58	1.17
Beta-Cryptoxanthine (μg/ml)						
Baseline	1163	0.08	0.08	1468	0.09	0.10
AV-1	1022	0.08	0.07	1365	0.09	0.09
AV3	838	0.08	0.07	1151	0.10	0.09
AV-1 – Baseline	1000	0.00	0.06	1332	-0.01	0.07
AV-3 – Baseline	822	0.00	0.07	1123	0.00	0.09
Lycopene (μg/ml)						
Baseline	1163	0.40	0.20	1468	0.41	0.20
AV-1	1022	0.39	0.19	1366	0.40	0.19
AV3	838	0.35	0.18	1151	0.38	0.21
AV-1 – Baseline	1000	-0.01	0.17	1333	-0.01	0.17
AV-3 – Baseline	822	-0.05	0.20	1123	-0.03	0.21
Lutein and Zeaxanthin (μg/ml)						
Baseline	1163	0.20	0.10	1468	0.21	0.09
AV-1	1022	0.20	0.10	1366	0.21	0.10
AV3	838	0.19	0.10	1151	0.20	0.09
AV-1 – Baseline	1000	0.00	0.07	1333	0.00	0.06
AV-3 – Baseline	822	-0.01	0.07	1123	-0.01	0.08
Retinol (μg/ml)						
Baseline	1163	0.60	0.15	1468	0.60	0.15
AV-1	1022	0.63	0.16	1366	0.61	0.15
AV3	838	0.62	0.15	1151	0.60	0.16
AV-1 – Baseline	1000	0.03	0.11	1333	0.01	0.10
AV-3 – Baseline	822	0.02	0.13	1123	0.01	0.13

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 2.8 (continued)
Blood Specimen Analysis: HRT Participants

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	1121	128.49	28.82	1415	123.49	28.32
AV-1	973	139.42	35.19	1319	129.64	31.02
AV-3	805	136.01	33.79	1095	128.62	31.65
AV-1 – Baseline	927	10.40	25.42	1248	5.94	22.53
AV-3 – Baseline	766	8.32	30.71	1036	5.43	27.63
Factor VII C (%)[2]						
Baseline	1101	129.99	28.24	1396	125.15	27.13
AV-1	961	136.32	31.68	1308	124.89	27.96
AV-3	803	135.45	34.47	1090	127.55	32.20
AV-1 – Baseline	899	6.23	23.93	1220	-0.58	21.84
AV-3 – Baseline	748	7.39	29.00	1016	2.50	27.33
Fibrinogen (mg/dl)						
Baseline	1118	312.18	63.50	1413	306.41	59.37
AV-1	971	301.34	61.46	1316	299.11	59.45
AV-3	805	294.65	59.69	1095	290.34	57.50
AV-1 – Baseline	923	-11.50	52.68	1243	-7.95	53.17
AV-3 – Baseline	763	-17.85	61.89	1034	-15.77	56.80
Hormones / Other						
Glucose (mg/dl)						
Baseline	1160	105.16	35.35	1466	100.47	26.73
AV-1	1020	102.91	31.69	1362	98.72	24.59
AV-3	857	102.16	31.94	1167	98.77	26.67
AV-1 – Baseline	995	-2.76	21.30	1326	-1.94	17.24
AV-3 – Baseline	840	-3.49	26.17	1138	-2.39	20.73
Insulin (μIU/ml)						
Baseline	1139	12.88	10.62	1421	11.42	6.86
AV-1	1004	12.16	8.14	1317	11.37	7.18
AV-3	813	13.67	11.48	1107	12.49	7.32
AV-1 – Baseline	964	-0.74	5.98	1264	-0.09	5.56
AV-3 – Baseline	784	0.62	9.09	1046	1.18	6.64

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.
[2] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.8 (continued)
Blood Specimen Analysis: HRT Participants

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	1163	162.97	99.73	1469	146.01	74.89
AV-1	1020	176.31	132.80	1365	149.20	74.99
AV-3	856	170.16	82.87	1165	152.48	82.27
AV-1 – Baseline	997	13.67	73.57	1332	3.01	55.53
AV-3 – Baseline	838	6.88	81.77	1137	6.62	65.69
Total Cholesterol (mg/dl)						
Baseline	1163	229.63	41.21	1469	224.84	36.85
AV-1	1020	223.25	40.59	1365	215.84	35.23
AV-3	856	218.59	36.29	1165	214.97	35.37
AV-1 – Baseline	997	-6.04	29.85	1332	-8.79	28.18
AV-3 – Baseline	838	-10.90	34.20	1137	-8.82	31.99
LDL-C (mg/dl)						
Baseline	1139	142.06	36.82	1444	138.73	32.93
AV-1	998	128.48	35.85	1340	127.13	32.49
AV-3	838	126.86	34.57	1142	126.92	33.10
AV-1 – Baseline	966	-13.26	27.27	1298	-11.34	25.66
AV-3 – Baseline	811	-15.59	31.98	1100	-10.78	29.55
HDL-C (mg/dl)						
Baseline	1157	55.59	14.52	1464	56.92	14.38
AV-1	1018	59.92	16.83	1365	59.13	14.89
AV-3	851	58.49	16.59	1163	58.27	15.28
AV-1 – Baseline	993	4.11	9.36	1327	2.29	8.16
AV-3 – Baseline	830	3.05	10.24	1131	1.33	9.47
HDL-2 (mg/dl)						
Baseline	1133	16.92	7.52	1423	17.72	7.57
AV-1	995	19.35	8.80	1332	19.05	8.12
AV-3	838	16.44	6.82	1143	16.29	6.41
AV-1 – Baseline	952	2.05	5.05	1263	1.20	4.67
AV-3 – Baseline	804	-0.59	5.57	1082	-1.55	5.42
HDL-3 (mg/dl)						
Baseline	1134	38.75	8.41	1423	39.14	8.11
AV-1	997	40.86	9.49	1333	40.11	8.18
AV-3	838	41.97	10.67	1143	41.87	9.52
AV-1 – Baseline	954	2.10	5.77	1264	1.03	5.21
AV-3 – Baseline	805	3.60	7.33	1082	2.74	6.64
Lp(a) (mg/dl)						
Baseline	1141	26.81	26.19	1449	27.34	27.77
AV-1	1005	25.40	27.00	1351	25.25	27.27
AV-3	829	21.83	21.88	1129	21.72	22.16
AV-1 – Baseline	970	-1.12	10.84	1303	-2.01	10.88
AV-3 – Baseline	799	-4.75	15.21	1089	-4.87	14.82

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 2.9
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (μg/ml)						
Baseline	32	0.06	0.04	30	0.05	0.04
AV-1	27	0.07	0.08	25	0.05	0.03
AV-3	19	0.05	0.05	23	0.05	0.03
AV-1 - Baseline	27	0.01	0.06	24	-0.01	0.03
AV-3 - Baseline	19	-0.02	0.04	22	-0.01	0.04
Beta-Carotene (μg/ml)						
Baseline	32	0.33	0.38	30	0.25	0.20
AV-1	27	0.34	0.39	25	0.30	0.32
AV-3	19	0.30	0.26	23	0.25	0.29
AV-1 - Baseline	27	-0.02	0.24	24	0.03	0.17
AV-3 - Baseline	19	-0.06	0.27	22	0.01	0.20
Alpha-tocopherol (μg/ml)						
Baseline	32	18.70	9.89	30	13.04	4.96
AV-1	27	19.18	10.00	25	14.86	8.17
AV-3	19	18.92	7.17	23	13.00	4.00
AV-1 - Baseline	27	1.33	6.21	24	2.08	8.17
AV-3 - Baseline	19	1.66	7.37	22	0.19	3.22
Gamma-tocopherol (μg/ml)						
Baseline	32	2.47	1.64	30	3.06	1.80
AV-1	27	2.64	2.73	25	2.34	0.99
AV-3	19	2.08	1.72	23	2.16	0.80
AV-1 - Baseline	27	0.04	1.81	24	-0.76	1.95
AV-3 - Baseline	19	-0.50	1.21	22	-0.51	1.06
Beta-Cryptoxanthine (μg/ml)						
Baseline	32	0.09	0.11	30	0.06	0.03
AV-1	27	0.08	0.06	25	0.07	0.05
AV-3	19	0.09	0.07	23	0.08	0.06
AV-1 - Baseline	27	-0.01	0.10	24	0.01	0.04
AV-3 - Baseline	19	-0.01	0.11	22	0.02	0.06
Lycopene (μg/ml)						
Baseline	32	0.37	0.22	30	0.39	0.16
AV-1	27	0.40	0.21	25	0.42	0.18
AV-3	19	0.37	0.21	23	0.33	0.16
AV-1 - Baseline	27	0.03	0.21	24	0.05	0.16
AV-3 - Baseline	19	0.02	0.20	22	-0.03	0.19
Lutein and Zeaxanthin (μg/ml)						
Baseline	32	0.21	0.10	30	0.18	0.09
AV-1	27	0.25	0.15	25	0.18	0.09
AV-3	19	0.21	0.15	23	0.18	0.08
AV-1 - Baseline	27	0.03	0.09	24	0.00	0.05
AV-3 - Baseline	19	0.00	0.11	22	-0.01	0.05
Retinol (μg/ml)						
Baseline	32	0.62	0.20	30	0.52	0.12
AV-1	27	0.65	0.19	25	0.55	0.16
AV-3	19	0.63	0.14	23	0.57	0.15
AV-1 - Baseline	27	0.05	0.07	24	0.03	0.09
AV-3 - Baseline	19	0.06	0.12	22	0.04	0.12

(continues)

Table 2.9 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	30	144.43	37.09	27	118.30	32.15
AV-1	26	154.77	44.02	25	126.84	35.71
AV-3	19	145.26	47.09	24	122.75	30.44
AV-1 – Baseline	24	13.08	28.42	21	1.95	20.69
AV-3 – Baseline	18	10.00	29.57	21	3.10	23.59
Factor VII C (%)[1]						
Baseline	30	141.67	30.83	27	117.67	33.09
AV-1	25	141.24	30.15	25	126.44	32.24
AV-3	19	143.32	41.56	24	124.38	42.77
AV-1 – Baseline	23	6.70	16.45	21	3.90	23.09
AV-3 – Baseline	18	12.17	34.07	21	6.90	34.93
Fibrinogen (mg/dl)						
Baseline	30	325.93	67.56	27	312.41	79.21
AV-1	26	315.69	83.44	25	307.40	76.47
AV-3	19	313.26	52.91	24	283.08	58.72
AV-1 – Baseline	24	-9.04	75.45	21	-13.33	52.01
AV-3 – Baseline	18	-9.94	63.22	21	-34.71	57.48
Hormones / Other						
Glucose (mg/dl)						
Baseline	32	112.22	42.33	30	116.17	51.66
AV-1	27	112.30	42.55	25	113.44	60.34
AV-3	20	104.05	37.03	25	109.80	52.89
AV-1 – Baseline	27	-3.59	41.95	24	0.67	28.55
AV-3 – Baseline	20	-5.50	47.84	24	-2.50	31.91
Insulin (μIU/ml)						
Baseline	32	13.63	8.05	30	12.61	8.81
AV-1	27	13.22	7.68	24	12.52	7.35
AV-3	18	12.77	5.92	22	11.63	6.05
AV-1 – Baseline	27	-0.86	3.72	23	-0.26	2.88
AV-3 – Baseline	18	0.27	6.77	21	0.04	5.82

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.9 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	31	186.87	107.13	30	154.20	84.64
AV-1	27	214.63	159.36	25	161.12	100.16
AV-3	20	206.35	125.93	25	158.68	83.16
AV-1 – Baseline	26	35.85	98.82	24	10.88	56.74
AV-3 – Baseline	19	34.63	72.30	24	7.04	43.56
Total Cholesterol (mg/dl)						
Baseline	31	239.94	46.31	30	218.70	42.32
AV-1	27	230.78	47.19	25	208.32	41.70
AV-3	20	226.75	41.33	25	211.20	42.96
AV-1 – Baseline	26	-4.23	27.84	24	-2.83	19.24
AV-3 – Baseline	19	-3.11	27.32	24	-0.96	25.44
LDL-C (mg/dl)						
Baseline	28	143.11	28.19	30	133.93	38.98
AV-1	23	125.13	38.01	24	122.21	39.54
AV-3	18	133.39	39.21	25	123.88	41.47
AV-1 – Baseline	22	-15.77	25.61	23	-7.04	20.73
AV-3 – Baseline	18	-13.83	30.00	24	-3.25	25.32
HDL-C (mg/dl)						
Baseline	31	54.71	13.06	30	53.90	14.50
AV-1	27	59.44	15.82	25	56.28	13.48
AV-3	20	57.25	15.10	25	55.64	13.81
AV-1 – Baseline	26	5.04	7.68	24	2.67	7.85
AV-3 – Baseline	19	4.79	8.64	24	1.00	7.68
HDL-2 (mg/dl)						
Baseline	31	16.55	5.86	30	16.27	6.51
AV-1	26	19.42	7.17	25	16.76	5.80
AV-3	19	16.16	4.67	25	15.04	5.79
AV-1 – Baseline	25	2.68	3.67	24	0.50	4.31
AV-3 – Baseline	18	0.06	4.12	24	-1.63	3.56
HDL-3 (mg/dl)						
Baseline	32	38.06	7.75	30	37.63	8.72
AV-1	26	40.69	9.38	25	39.52	9.30
AV-3	19	41.16	11.30	25	40.60	8.96
AV-1 – Baseline	26	2.69	4.87	24	2.17	4.50
AV-3 – Baseline	19	3.84	6.60	24	2.63	6.00
Lp(a) (mg/dl)						
Baseline	31	35.90	39.11	30	21.83	32.28
AV-1	26	32.08	43.78	25	14.32	15.48
AV-3	19	26.05	28.02	23	18.87	26.63
AV-1 – Baseline	26	-0.50	14.62	24	-2.00	5.50
AV-3 – Baseline	18	-10.89	24.08	22	-5.59	12.85

(continues)

Table 2.9 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (μg/ml)						
Baseline	50	0.12	0.10	124	0.12	0.07
AV-1	45	0.09	0.07	115	0.11	0.08
AV-3	36	0.08	0.08	91	0.10	0.06
AV-1 - Baseline	45	-0.04	0.09	113	-0.01	0.07
AV-3 - Baseline	36	-0.04	0.07	89	-0.03	0.07
Beta-Carotene (μg/ml)						
Baseline	50	0.57	0.53	124	0.54	0.37
AV-1	45	0.40	0.33	115	0.44	0.27
AV-3	36	0.41	0.38	91	0.46	0.37
AV-1 - Baseline	45	-0.13	0.30	113	-0.10	0.30
AV-3 - Baseline	36	-0.10	0.29	89	-0.09	0.39
Alpha-tocopherol (μg/ml)						
Baseline	50	20.49	8.12	124	18.62	8.88
AV-1	45	21.30	8.68	115	19.55	10.14
AV-3	36	22.61	9.76	91	21.47	13.96
AV-1 - Baseline	45	0.90	5.79	113	0.69	6.09
AV-3 - Baseline	36	2.16	8.02	89	2.83	10.79
Gamma-tocopherol (μg/ml)						
Baseline	50	1.67	1.24	124	1.55	1.06
AV-1	45	1.36	1.15	115	1.26	0.99
AV-3	36	1.25	1.10	91	1.24	0.94
AV-1 - Baseline	45	-0.27	0.71	113	-0.26	0.76
AV-3 - Baseline	36	-0.38	1.07	89	-0.35	0.95
Beta-Cryptoxanthine (μg/ml)						
Baseline	50	0.16	0.14	124	0.24	0.37
AV-1	45	0.17	0.19	115	0.23	0.34
AV-3	36	0.20	0.26	91	0.24	0.25
AV-1 - Baseline	45	0.01	0.14	113	-0.02	0.25
AV-3 - Baseline	36	0.03	0.23	89	-0.02	0.30
Lycopene (μg/ml)						
Baseline	50	0.42	0.25	124	0.40	0.21
AV-1	45	0.35	0.19	115	0.36	0.19
AV-3	36	0.30	0.19	91	0.33	0.18
AV-1 - Baseline	45	-0.06	0.19	113	-0.04	0.19
AV-3 - Baseline	36	-0.11	0.18	89	-0.09	0.20
Lutein and Zeaxanthin (μg/ml)						
Baseline	50	0.30	0.14	124	0.29	0.11
AV-1	45	0.28	0.13	115	0.28	0.12
AV-3	36	0.25	0.12	91	0.28	0.14
AV-1 - Baseline	45	-0.03	0.08	113	-0.01	0.09
AV-3 - Baseline	36	-0.05	0.10	89	-0.01	0.12
Retinol (μg/ml)						
Baseline	50	0.62	0.13	124	0.60	0.15
AV-1	45	0.65	0.15	115	0.61	0.18
AV-3	36	0.65	0.15	91	0.60	0.16
AV-1 - Baseline	45	0.03	0.11	113	0.01	0.11
AV-3 - Baseline	36	0.04	0.14	89	0.00	0.12

(continues)

Table 2.9 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	47	127.23	23.78	122	122.39	27.53
AV-1	43	143.30	41.46	111	127.50	26.93
AV-3	33	126.30	24.90	90	129.29	29.99
AV-1 – Baseline	41	18.83	33.34	108	3.82	21.88
AV-3 – Baseline	32	5.34	27.30	87	5.99	22.35
Factor VII C (%)[1]						
Baseline	47	126.96	24.75	122	124.72	24.52
AV-1	43	134.42	24.89	111	123.19	27.23
AV-3	33	127.85	25.43	89	124.48	27.16
AV-1 – Baseline	41	9.29	19.47	108	-1.48	16.86
AV-3 – Baseline	32	9.47	25.49	86	-1.09	19.70
Fibrinogen (mg/dl)						
Baseline	47	290.96	62.19	122	298.55	57.06
AV-1	43	286.44	65.15	111	286.46	54.74
AV-3	33	258.52	51.22	90	280.60	62.35
AV-1 – Baseline	41	-5.37	57.30	108	-13.99	49.10
AV-3 – Baseline	32	-27.00	43.76	87	-21.06	60.99
Hormones / Other						
Glucose (mg/dl)						
Baseline	50	105.40	28.34	124	101.58	24.24
AV-1	45	105.78	36.28	115	100.99	22.78
AV-3	37	99.86	25.72	95	99.49	16.57
AV-1 – Baseline	45	-0.58	12.59	113	-0.92	12.16
AV-3 – Baseline	37	-6.86	14.67	93	-1.83	17.35
Insulin (μIU/ml)						
Baseline	49	12.06	8.12	116	10.70	7.71
AV-1	44	11.75	9.46	109	10.05	7.03
AV-3	34	14.24	11.86	90	11.59	6.83
AV-1 – Baseline	43	-0.88	5.54	107	-0.43	5.33
AV-3 – Baseline	33	1.04	5.62	84	1.66	7.66

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.9 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	50	176.18	84.55	124	146.48	71.67
AV-1	45	197.38	102.02	114	160.58	102.70
AV-3	37	183.19	91.74	95	162.34	137.11
AV-1 – Baseline	45	19.93	79.99	112	12.00	80.72
AV-3 – Baseline	37	10.22	77.03	93	11.19	116.78
Total Cholesterol (mg/dl)						
Baseline	50	231.80	32.71	124	222.26	33.71
AV-1	45	219.98	33.82	114	211.69	32.20
AV-3	37	202.54	33.18	95	211.80	32.96
AV-1 – Baseline	45	-14.82	21.84	112	-10.92	26.78
AV-3 – Baseline	37	-27.22	31.76	93	-9.11	27.56
LDL-C (mg/dl)						
Baseline	48	138.19	30.66	123	132.40	30.46
AV-1	44	118.75	35.98	111	120.50	29.88
AV-3	36	109.86	34.90	93	120.25	29.90
AV-1 – Baseline	42	-22.83	28.41	109	-12.96	27.33
AV-3 – Baseline	35	-29.43	35.07	91	-10.41	27.90
HDL-C (mg/dl)						
Baseline	50	58.50	17.42	124	59.96	16.19
AV-1	45	63.56	18.58	114	60.40	15.75
AV-3	37	58.78	15.63	95	60.18	14.19
AV-1 – Baseline	45	3.76	8.35	112	0.88	8.49
AV-3 – Baseline	37	0.51	6.85	93	0.56	9.54
HDL-2 (mg/dl)						
Baseline	49	17.73	9.38	123	18.96	8.87
AV-1	44	20.20	9.85	111	20.06	8.55
AV-3	37	15.92	6.54	92	17.20	5.89
AV-1 – Baseline	43	1.51	6.54	109	1.32	4.52
AV-3 – Baseline	36	-2.06	5.08	89	-1.72	5.73
HDL-3 (mg/dl)						
Baseline	49	40.43	9.13	123	40.78	8.42
AV-1	44	43.39	11.30	112	40.27	7.98
AV-3	37	42.86	9.68	92	43.20	8.83
AV-1 – Baseline	43	1.95	5.88	110	-0.39	5.94
AV-3 – Baseline	36	2.72	4.98	89	2.30	6.45
Lp(a) (mg/dl)						
Baseline	50	20.74	14.22	122	19.81	18.78
AV-1	45	16.62	14.70	114	17.31	17.67
AV-3	37	14.00	12.53	92	14.18	13.85
AV-1 – Baseline	45	-4.73	7.81	111	-3.04	12.22
AV-3 – Baseline	37	-5.89	11.29	90	-4.72	11.09

(continues)

Table 2.9 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	395	0.07	0.08	282	0.06	0.06
AV-1	343	0.06	0.08	262	0.06	0.07
AV-3	258	0.06	0.08	207	0.05	0.06
AV-1 - Baseline	334	0.00	0.06	257	0.00	0.05
AV-3 - Baseline	250	-0.01	0.08	203	0.00	0.06
Beta-Carotene (µg/ml)						
Baseline	394	0.36	0.38	282	0.30	0.25
AV-1	342	0.35	0.37	263	0.29	0.26
AV-3	258	0.34	0.42	207	0.27	0.22
AV-1 - Baseline	333	-0.01	0.21	258	-0.02	0.19
AV-3 - Baseline	249	-0.02	0.29	203	-0.03	0.22
Alpha-tocopherol (µg/ml)						
Baseline	395	14.36	6.52	282	14.39	6.35
AV-1	343	14.37	5.40	263	14.66	6.56
AV-3	258	14.55	5.85	207	15.38	6.68
AV-1 - Baseline	334	0.12	5.07	258	0.06	5.05
AV-3 - Baseline	250	0.82	5.74	203	1.06	6.28
Gamma-tocopherol (µg/ml)						
Baseline	395	2.50	1.38	282	2.53	1.42
AV-1	343	2.33	1.38	263	2.29	1.31
AV-3	258	2.16	1.33	207	2.20	1.55
AV-1 - Baseline	334	-0.17	0.91	258	-0.21	0.94
AV-3 - Baseline	250	-0.33	1.13	203	-0.35	1.12
Beta-Cryptoxanthine (µg/ml)						
Baseline	395	0.09	0.06	282	0.09	0.07
AV-1	343	0.09	0.07	263	0.09	0.06
AV-3	258	0.09	0.06	207	0.09	0.08
AV-1 - Baseline	334	0.00	0.06	258	0.00	0.06
AV-3 - Baseline	250	0.00	0.05	203	0.01	0.08
Lycopene (µg/ml)						
Baseline	395	0.39	0.21	282	0.40	0.21
AV-1	343	0.38	0.21	263	0.38	0.21
AV-3	258	0.34	0.22	207	0.35	0.20
AV-1 - Baseline	334	0.00	0.18	258	-0.02	0.19
AV-3 - Baseline	250	-0.04	0.22	203	-0.04	0.21
Lutein and Zeaxanthin (µg/ml)						
Baseline	395	0.24	0.12	282	0.23	0.11
AV-1	343	0.25	0.12	263	0.24	0.11
AV-3	258	0.22	0.11	207	0.22	0.09
AV-1 - Baseline	334	0.00	0.08	258	0.01	0.08
AV-3 - Baseline	250	-0.02	0.09	203	-0.01	0.08
Retinol (µg/ml)						
Baseline	395	0.56	0.16	282	0.56	0.16
AV-1	343	0.57	0.15	263	0.57	0.15
AV-3	258	0.54	0.13	207	0.57	0.18
AV-1 - Baseline	334	0.01	0.10	258	0.01	0.08
AV-3 - Baseline	250	-0.01	0.12	203	0.01	0.14

(continues)

Table 2.9 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	383	113.26	22.95	268	113.54	26.49
AV-1	334	119.15	28.31	254	118.29	30.43
AV-3	245	119.00	27.17	198	118.60	30.72
AV-1 – Baseline	317	5.64	20.62	239	4.70	18.58
AV-3 – Baseline	230	5.86	23.75	184	5.54	22.24
Factor VII C (%)[1]						
Baseline	373	117.99	28.00	262	116.98	29.20
AV-1	330	119.30	27.11	253	115.93	27.30
AV-3	245	118.07	26.60	197	118.37	30.96
AV-1 – Baseline	303	1.76	19.50	232	-1.88	20.49
AV-3 – Baseline	221	0.81	22.45	178	0.30	26.01
Fibrinogen (mg/dl)						
Baseline	382	328.07	66.21	268	318.81	65.87
AV-1	333	323.92	66.78	254	314.64	64.60
AV-3	245	310.20	69.56	197	304.05	63.94
AV-1 – Baseline	316	-2.01	52.20	239	-4.26	47.77
AV-3 – Baseline	229	-19.75	55.20	183	-12.24	68.17
Hormones / Other						
Glucose (mg/dl)						
Baseline	394	111.38	42.90	283	106.94	38.02
AV-1	343	108.62	40.78	261	109.82	41.39
AV-3	266	106.32	35.05	209	109.85	43.88
AV-1 – Baseline	333	-1.14	36.72	256	0.63	26.09
AV-3 – Baseline	258	-3.86	31.66	205	0.43	26.89
Insulin (μIU/ml)						
Baseline	386	15.99	25.09	279	13.16	8.24
AV-1	341	14.38	13.52	261	13.18	7.77
AV-3	255	17.01	26.86	201	14.60	9.79
AV-1 – Baseline	324	-0.86	8.40	253	-0.14	6.24
AV-3 – Baseline	242	-1.38	20.42	194	1.94	8.50

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.9 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	395	119.97	54.59	283	118.84	60.74
AV-1	343	122.01	50.37	263	119.79	59.57
AV-3	266	116.78	46.08	209	121.56	61.99
AV-1 – Baseline	334	4.30	38.53	258	-2.10	39.83
AV-3 – Baseline	258	0.93	43.88	205	-0.44	52.99
Total Cholesterol (mg/dl)						
Baseline	395	224.05	42.33	283	221.35	41.99
AV-1	343	220.02	41.01	263	214.95	38.34
AV-3	266	213.18	39.80	209	212.54	39.46
AV-1 – Baseline	334	-4.89	29.09	258	-6.82	24.91
AV-3 – Baseline	258	-10.38	35.49	205	-7.34	30.00
LDL-C (mg/dl)						
Baseline	394	143.33	40.35	281	140.54	38.87
AV-1	343	134.12	39.02	260	132.36	37.67
AV-3	266	130.35	37.40	207	132.20	39.19
AV-1 – Baseline	334	-9.86	27.40	255	-8.78	22.85
AV-3 – Baseline	257	-13.03	33.24	203	-6.74	28.25
HDL-C (mg/dl)						
Baseline	394	56.73	13.77	282	56.71	13.47
AV-1	343	61.44	15.73	263	59.24	14.51
AV-3	266	59.45	14.89	209	56.62	13.76
AV-1 – Baseline	334	4.08	9.64	257	2.60	8.37
AV-3 – Baseline	257	2.40	10.11	205	0.10	8.40
HDL-2 (mg/dl)						
Baseline	392	17.52	7.15	276	17.12	7.17
AV-1	341	20.25	8.62	261	18.81	8.19
AV-3	261	16.68	5.98	207	15.32	5.21
AV-1 – Baseline	330	2.25	5.46	250	1.58	5.16
AV-3 – Baseline	253	-1.16	5.74	199	-1.44	5.17
HDL-3 (mg/dl)						
Baseline	392	39.20	8.14	276	39.55	7.49
AV-1	343	41.26	9.00	261	40.23	7.78
AV-3	261	42.91	9.81	207	41.14	9.35
AV-1 – Baseline	331	1.80	5.81	250	0.74	4.84
AV-3 – Baseline	253	3.54	6.98	199	1.46	6.52
Lp(a) (mg/dl)						
Baseline	388	40.45	31.50	277	38.83	28.83
AV-1	341	38.48	31.37	262	37.15	27.76
AV-3	259	34.35	27.02	207	31.32	22.96
AV-1 – Baseline	327	-1.15	13.04	252	-2.08	10.95
AV-3 – Baseline	246	-4.97	22.13	197	-4.65	19.10

(continues)

Table 2.9 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (μg/ml)						
Baseline	177	0.09	0.11	222	0.10	0.09
AV-1	148	0.08	0.06	185	0.09	0.07
AV-3	123	0.06	0.07	158	0.07	0.07
AV-1 - Baseline	144	-0.02	0.11	183	-0.01	0.08
AV-3 - Baseline	121	-0.03	0.13	157	-0.03	0.10
Beta-Carotene (μg/ml)						
Baseline	177	0.32	0.49	222	0.32	0.31
AV-1	148	0.27	0.26	185	0.28	0.23
AV-3	123	0.23	0.25	158	0.28	0.28
AV-1 - Baseline	144	-0.07	0.38	183	-0.05	0.25
AV-3 - Baseline	121	-0.11	0.42	157	-0.07	0.36
Alpha-tocopherol (μg/ml)						
Baseline	177	15.52	7.30	222	15.78	6.81
AV-1	148	16.91	7.56	185	16.56	7.41
AV-3	123	16.27	7.11	158	17.29	8.43
AV-1 - Baseline	144	1.42	6.23	183	0.76	5.12
AV-3 - Baseline	121	0.20	6.68	157	1.38	6.74
Gamma-tocopherol (μg/ml)						
Baseline	177	2.29	1.37	222	2.23	1.37
AV-1	148	2.12	1.44	185	1.96	1.33
AV-3	123	1.97	1.22	158	1.92	1.49
AV-1 - Baseline	144	-0.22	0.98	183	-0.28	0.95
AV-3 - Baseline	121	-0.35	1.11	157	-0.36	1.17
Beta-Cryptoxanthine (μg/ml)						
Baseline	177	0.12	0.17	222	0.12	0.11
AV-1	148	0.11	0.11	185	0.12	0.11
AV-3	123	0.11	0.08	158	0.13	0.11
AV-1 - Baseline	144	-0.02	0.15	183	-0.01	0.09
AV-3 - Baseline	121	0.00	0.10	157	-0.01	0.10
Lycopene (μg/ml)						
Baseline	177	0.40	0.19	222	0.45	0.21
AV-1	148	0.38	0.18	185	0.40	0.19
AV-3	123	0.35	0.20	158	0.37	0.19
AV-1 - Baseline	144	-0.03	0.15	183	-0.05	0.17
AV-3 - Baseline	121	-0.05	0.19	157	-0.09	0.21
Lutein and Zeaxanthin (μg/ml)						
Baseline	177	0.19	0.09	222	0.22	0.10
AV-1	148	0.20	0.09	185	0.22	0.11
AV-3	123	0.18	0.08	158	0.20	0.09
AV-1 - Baseline	144	0.00	0.06	183	-0.01	0.08
AV-3 - Baseline	121	-0.01	0.07	157	-0.03	0.08
Retinol (μg/ml)						
Baseline	177	0.53	0.13	222	0.56	0.14
AV-1	148	0.55	0.13	185	0.56	0.15
AV-3	123	0.54	0.12	158	0.55	0.13
AV-1 - Baseline	144	0.02	0.08	183	0.00	0.09
AV-3 - Baseline	121	0.00	0.11	157	-0.01	0.11

(continues)

Table 2.9 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	170	122.91	25.34	209	124.94	27.93
AV-1	134	128.32	26.46	179	129.13	28.73
AV-3	123	130.59	28.74	147	131.42	28.79
AV-1 – Baseline	124	9.34	24.44	168	4.43	22.81
AV-3 – Baseline	117	7.26	28.49	140	5.26	28.42
Factor VII C (%)[1]						
Baseline	164	126.37	29.10	202	124.85	27.65
AV-1	131	126.92	24.66	174	123.49	26.08
AV-3	124	128.19	26.92	146	126.86	29.56
AV-1 – Baseline	118	3.15	26.69	158	-0.80	19.87
AV-3 – Baseline	113	2.55	28.53	134	0.51	26.75
Fibrinogen (mg/dl)						
Baseline	170	318.05	66.36	209	316.09	63.72
AV-1	134	311.28	60.61	178	315.65	61.87
AV-3	124	302.65	66.82	148	302.05	60.67
AV-1 – Baseline	124	-5.34	54.42	167	-6.71	52.31
AV-3 – Baseline	118	-16.12	56.05	141	-16.81	54.67
Hormones / Other						
Glucose (mg/dl)						
Baseline	176	104.09	30.87	222	106.05	35.26
AV-1	148	106.64	36.96	185	104.92	30.63
AV-3	127	106.45	29.46	161	108.14	37.73
AV-1 – Baseline	142	2.91	23.64	183	-1.09	17.83
AV-3 – Baseline	124	-0.05	26.54	160	-0.50	22.31
Insulin (μIU/ml)						
Baseline	174	14.00	8.69	220	13.60	7.88
AV-1	146	13.73	9.11	182	13.21	6.62
AV-3	118	15.07	8.32	154	13.97	7.45
AV-1 – Baseline	140	-0.39	6.26	180	-0.41	6.00
AV-3 – Baseline	115	1.61	7.22	152	0.00	8.14

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.9 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	178	162.16	67.43	222	166.98	86.24
AV-1	148	169.21	67.99	185	181.77	123.47
AV-3	126	169.68	66.86	161	192.13	144.12
AV-1 – Baseline	144	8.65	51.64	183	14.21	94.14
AV-3 – Baseline	124	0.69	65.66	160	27.31	110.22
Total Cholesterol (mg/dl)						
Baseline	178	219.26	37.88	222	224.51	37.44
AV-1	148	212.66	34.96	185	215.15	35.35
AV-3	126	208.44	33.04	161	215.30	35.20
AV-1 – Baseline	144	-6.39	27.28	183	-11.76	23.84
AV-3 – Baseline	124	-11.19	34.34	160	-11.58	29.47
LDL-C (mg/dl)						
Baseline	176	132.35	32.60	216	137.42	35.02
AV-1	147	122.43	31.51	178	127.15	33.73
AV-3	125	118.77	28.84	152	125.70	34.41
AV-1 – Baseline	141	-9.70	26.16	174	-14.01	24.32
AV-3 – Baseline	122	-13.18	30.87	148	-15.01	28.71
HDL-C (mg/dl)						
Baseline	177	54.01	12.96	222	53.64	14.08
AV-1	148	56.93	14.89	185	53.79	13.04
AV-3	125	55.57	14.36	161	54.37	13.62
AV-1 – Baseline	143	2.54	9.43	183	0.64	7.14
AV-3 – Baseline	123	1.94	10.08	160	0.89	8.88
HDL-2 (mg/dl)						
Baseline	177	15.97	6.45	218	15.61	6.68
AV-1	147	17.88	7.89	185	16.59	6.73
AV-3	124	15.24	6.03	160	15.18	5.70
AV-1 – Baseline	142	1.36	5.25	180	0.89	4.43
AV-3 – Baseline	122	-0.72	5.58	156	-0.59	5.34
HDL-3 (mg/dl)						
Baseline	177	38.03	7.75	218	37.58	7.65
AV-1	147	39.03	8.12	185	37.19	7.57
AV-3	124	40.19	9.22	160	39.23	8.71
AV-1 – Baseline	142	1.18	5.43	180	-0.31	4.77
AV-3 – Baseline	122	2.65	6.63	156	1.63	6.39
Lp(a) (mg/dl)						
Baseline	175	17.59	17.80	222	21.97	22.40
AV-1	145	16.40	17.78	184	19.75	20.96
AV-3	121	12.75	11.95	160	19.64	20.87
AV-1 – Baseline	140	-0.73	7.22	182	-1.79	10.78
AV-3 – Baseline	118	-1.40	8.15	159	-3.46	13.60

(continues)

Table 2.9 (continued)
Blood Specimen Analysis: White Women

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (μg/ml)						
Baseline	484	0.07	0.06	777	0.09	0.08
AV-1	436	0.06	0.05	749	0.08	0.08
AV-3	383	0.06	0.05	648	0.07	0.08
AV-1 - Baseline	427	-0.01	0.05	727	-0.01	0.06
AV-3 - Baseline	377	-0.01	0.05	629	-0.01	0.08
Beta-Carotene (μg/ml)						
Baseline	484	0.27	0.22	777	0.34	0.34
AV-1	436	0.24	0.22	749	0.31	0.31
AV-3	383	0.23	0.21	648	0.32	0.40
AV-1 - Baseline	427	-0.02	0.20	727	-0.04	0.21
AV-3 - Baseline	377	-0.04	0.22	629	-0.03	0.32
Alpha-tocopherol (μg/ml)						
Baseline	484	16.18	6.94	777	16.52	7.83
AV-1	436	18.04	9.19	749	17.02	7.36
AV-3	383	18.18	8.48	648	18.62	8.10
AV-1 - Baseline	427	1.86	6.39	727	0.54	5.80
AV-3 - Baseline	377	2.07	6.90	629	2.18	7.36
Gamma-tocopherol (μg/ml)						
Baseline	484	2.51	1.70	777	2.22	1.40
AV-1	436	2.23	1.91	749	1.80	1.21
AV-3	383	2.00	1.52	648	1.60	1.18
AV-1 - Baseline	427	-0.32	1.15	727	-0.40	0.92
AV-3 - Baseline	377	-0.60	1.20	629	-0.62	1.18
Beta-Cryptoxanthine (μg/ml)						
Baseline	484	0.08	0.07	777	0.09	0.07
AV-1	436	0.07	0.06	748	0.08	0.07
AV-3	383	0.08	0.06	648	0.09	0.08
AV-1 - Baseline	427	0.00	0.04	726	-0.01	0.06
AV-3 - Baseline	377	0.00	0.07	629	0.00	0.07
Lycopene (μg/ml)						
Baseline	484	0.40	0.20	777	0.41	0.19
AV-1	436	0.39	0.19	749	0.40	0.19
AV-3	383	0.35	0.18	648	0.39	0.21
AV-1 - Baseline	427	-0.01	0.17	727	-0.01	0.17
AV-3 - Baseline	377	-0.05	0.20	629	-0.02	0.22
Lutein and Zeaxanthin (μg/ml)						
Baseline	484	0.19	0.09	777	0.20	0.09
AV-1	436	0.20	0.09	749	0.21	0.09
AV-3	383	0.18	0.10	648	0.19	0.09
AV-1 - Baseline	427	0.00	0.06	727	0.00	0.06
AV-3 - Baseline	377	-0.01	0.07	629	-0.02	0.08
Retinol (μg/ml)						
Baseline	484	0.61	0.14	777	0.61	0.15
AV-1	436	0.64	0.15	749	0.62	0.14
AV-3	383	0.63	0.15	648	0.61	0.16
AV-1 - Baseline	427	0.03	0.11	727	0.01	0.10
AV-3 - Baseline	377	0.02	0.14	629	0.01	0.13

(continues)

Table 2.9 (continued)
Blood Specimen Analysis: White Women

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	466	130.54	29.03	756	124.77	28.36
AV-1	413	142.32	35.17	722	131.18	31.03
AV-3	367	138.56	34.18	613	129.74	31.78
AV-1 – Baseline	398	10.84	25.67	684	6.25	23.04
AV-3 – Baseline	351	8.69	31.75	581	5.40	28.42
Factor VII C (%)[1]						
Baseline	463	131.66	27.89	750	126.27	26.73
AV-1	409	139.00	32.05	717	126.12	27.93
AV-3	364	137.94	35.11	611	128.85	32.34
AV-1 – Baseline	392	6.86	24.44	673	-0.44	22.25
AV-3 – Baseline	347	8.15	29.68	574	2.94	27.62
Fibrinogen (mg/dl)						
Baseline	464	310.11	62.68	754	304.41	57.78
AV-1	412	298.22	59.62	720	296.60	58.17
AV-3	366	292.89	57.36	613	288.37	55.83
AV-1 – Baseline	395	-13.02	52.01	680	-8.11	53.98
AV-3 – Baseline	348	-17.56	63.14	579	-15.67	55.14
Hormones / Other						
Glucose (mg/dl)						
Baseline	483	104.40	34.60	773	99.20	23.96
AV-1	434	101.79	29.67	747	96.81	20.23
AV-3	388	101.43	31.74	653	96.75	22.28
AV-1 – Baseline	425	-3.37	18.03	721	-2.36	15.78
AV-3 – Baseline	382	-3.66	25.27	632	-2.85	19.72
Insulin (μIU/ml)						
Baseline	473	12.47	7.13	742	11.11	6.52
AV-1	423	11.81	7.05	712	11.09	7.10
AV-3	369	13.19	7.83	617	12.19	6.93
AV-1 – Baseline	407	-0.75	5.63	672	-0.06	5.49
AV-3 – Baseline	357	0.78	6.63	572	1.14	6.26

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.9 (continued)
Blood Specimen Analysis: White Women

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	484	167.85	104.44	776	148.16	75.10
AV-1	434	182.58	141.40	749	150.63	70.86
AV-3	388	176.29	84.03	651	153.91	76.43
AV-1 – Baseline	425	14.68	77.27	726	2.72	53.47
AV-3 – Baseline	381	7.51	86.62	631	6.42	61.65
Total Cholesterol (mg/dl)						
Baseline	484	230.56	41.19	776	225.46	36.16
AV-1	434	224.01	40.78	749	216.14	34.82
AV-3	388	220.06	35.73	651	215.36	34.84
AV-1 – Baseline	425	-6.00	30.26	726	-8.92	28.82
AV-3 – Baseline	381	-10.63	34.07	631	-8.92	32.57
LDL-C (mg/dl)						
Baseline	469	142.35	36.70	760	138.85	31.99
AV-1	418	128.17	35.47	738	126.68	31.58
AV-3	374	127.11	34.28	641	126.54	32.13
AV-1 – Baseline	405	-13.65	27.27	708	-11.57	25.97
AV-3 – Baseline	360	-15.71	31.76	610	-11.14	29.77
HDL-C (mg/dl)						
Baseline	480	55.47	14.64	772	57.06	14.40
AV-1	432	59.82	17.04	749	59.41	14.94
AV-3	384	58.54	16.97	649	58.63	15.54
AV-1 – Baseline	422	4.19	9.38	722	2.40	8.18
AV-3 – Baseline	375	3.22	10.33	625	1.49	9.64
HDL-2 (mg/dl)						
Baseline	459	16.89	7.60	743	17.89	7.59
AV-1	415	19.30	8.87	721	19.21	8.14
AV-3	378	16.48	6.99	635	16.45	6.58
AV-1 – Baseline	390	2.06	4.96	672	1.17	4.63
AV-3 – Baseline	356	-0.49	5.56	591	-1.64	5.45
HDL-3 (mg/dl)						
Baseline	459	38.70	8.48	743	39.14	8.18
AV-1	415	40.84	9.58	721	40.26	8.24
AV-3	378	41.94	10.88	635	42.06	9.57
AV-1 – Baseline	390	2.17	5.79	672	1.19	5.26
AV-3 – Baseline	356	3.68	7.47	591	2.96	6.66
Lp(a) (mg/dl)						
Baseline	472	25.65	25.24	764	26.46	27.75
AV-1	426	24.39	26.22	737	24.41	27.46
AV-3	375	20.94	21.12	625	20.86	21.99
AV-1 – Baseline	410	-1.06	10.74	705	-1.96	10.81
AV-3 – Baseline	362	-4.83	14.40	599	-4.96	14.40

(continues)

Table 2.9 (continued)
Blood Specimen Analysis: Unknown Race/Ethnicity

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (μg/ml)						
Baseline	25	0.10	0.05	33	0.11	0.13
AV-1	23	0.10	0.09	29	0.09	0.10
AV-3	19	0.09	0.07	24	0.07	0.08
AV-1 - Baseline	23	0.00	0.07	28	-0.03	0.05
AV-3 - Baseline	19	-0.01	0.06	23	-0.05	0.08
Beta-Carotene (μg/ml)						
Baseline	25	0.35	0.32	33	0.42	0.45
AV-1	23	0.35	0.25	29	0.35	0.31
AV-3	19	0.36	0.45	24	0.36	0.34
AV-1 - Baseline	23	-0.03	0.16	28	-0.07	0.29
AV-3 - Baseline	19	0.01	0.22	23	-0.03	0.21
Alpha-tocopherol (μg/ml)						
Baseline	25	17.48	8.26	33	16.71	7.64
AV-1	23	18.94	11.06	29	17.21	6.22
AV-3	19	19.93	10.62	24	18.16	6.99
AV-1 - Baseline	23	0.97	5.11	28	0.09	5.64
AV-3 - Baseline	19	1.50	5.54	23	0.03	5.27
Gamma-tocopherol (μg/ml)						
Baseline	25	2.19	1.14	33	1.90	1.08
AV-1	23	2.00	0.87	29	1.73	1.06
AV-3	19	1.65	1.06	24	1.48	0.96
AV-1 - Baseline	23	-0.14	0.99	28	-0.08	0.70
AV-3 - Baseline	19	-0.43	1.36	23	-0.43	0.79
Beta-Cryptoxanthine (μg/ml)						
Baseline	25	0.09	0.08	33	0.11	0.12
AV-1	23	0.11	0.07	29	0.08	0.06
AV-3	19	0.09	0.08	24	0.09	0.08
AV-1 - Baseline	23	0.01	0.05	28	-0.02	0.08
AV-3 - Baseline	19	0.01	0.04	23	-0.03	0.09
Lycopene (μg/ml)						
Baseline	25	0.48	0.21	33	0.36	0.21
AV-1	23	0.44	0.23	29	0.33	0.22
AV-3	19	0.30	0.12	24	0.29	0.20
AV-1 - Baseline	23	-0.06	0.24	28	0.00	0.16
AV-3 - Baseline	19	-0.15	0.18	23	-0.03	0.15
Lutein and Zeaxanthin (μg/ml)						
Baseline	25	0.20	0.10	33	0.20	0.14
AV-1	23	0.20	0.11	29	0.22	0.12
AV-3	19	0.20	0.11	24	0.18	0.09
AV-1 - Baseline	23	-0.01	0.07	28	0.01	0.10
AV-3 - Baseline	19	0.00	0.10	23	-0.03	0.11
Retinol (μg/ml)						
Baseline	25	0.59	0.14	33	0.58	0.13
AV-1	23	0.64	0.19	29	0.60	0.13
AV-3	19	0.59	0.12	24	0.60	0.14
AV-1 - Baseline	23	0.06	0.13	28	0.00	0.12
AV-3 - Baseline	19	0.02	0.11	23	0.03	0.13

(continues)

Table 2.9 (continued)
Blood Specimen Analysis: Unknown Race/Ethnicity

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	25	124.88	22.36	33	120.91	21.99
AV-1	23	133.00	26.98	28	130.21	27.60
AV-3	18	133.94	22.92	23	131.96	28.21
AV-1 – Baseline	23	8.43	26.66	28	8.82	16.06
AV-3 – Baseline	18	12.06	23.28	23	8.43	22.78
Factor VII C (%)[1]						
Baseline	24	123.79	22.90	33	123.64	21.38
AV-1	23	130.57	20.25	28	127.11	27.36
AV-3	18	146.94	30.04	23	130.39	32.67
AV-1 – Baseline	22	7.41	19.63	28	3.71	18.73
AV-3 – Baseline	17	23.35	20.64	23	5.13	29.63
Fibrinogen (mg/dl)						
Baseline	25	317.08	55.39	33	324.70	71.74
AV-1	23	294.04	64.72	28	307.32	59.63
AV-3	18	293.56	77.70	23	292.65	72.59
AV-1 – Baseline	23	-24.48	53.87	28	-23.04	51.03
AV-3 – Baseline	18	-20.67	73.91	23	-34.96	52.58
Hormones / Other						
Glucose (mg/dl)						
Baseline	25	98.32	19.88	34	100.62	26.89
AV-1	23	103.04	28.07	29	99.59	19.11
AV-3	19	103.37	26.24	24	100.92	19.67
AV-1 – Baseline	23	4.17	14.54	29	-2.83	14.46
AV-3 – Baseline	19	8.58	15.90	24	-3.08	17.55
Insulin (μIU/ml)						
Baseline	25	10.15	6.58	34	10.24	4.97
AV-1	23	10.90	7.41	29	10.97	6.59
AV-3	19	12.14	6.86	23	11.93	3.80
AV-1 – Baseline	23	0.61	6.25	29	0.11	3.45
AV-3 – Baseline	19	2.98	5.27	23	1.24	4.19

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 2.9 (continued)
Blood Specimen Analysis: Unknown Race/Ethnicity

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	25	155.40	89.00	34	157.29	73.88
AV-1	23	168.13	68.18	29	161.72	75.02
AV-3	19	155.11	63.58	24	156.17	61.65
AV-1 – Baseline	23	11.57	62.43	29	2.21	38.74
AV-3 – Baseline	19	8.42	31.67	24	-10.21	52.33
Total Cholesterol (mg/dl)						
Baseline	25	238.76	41.89	34	221.15	35.46
AV-1	23	236.48	36.92	29	220.34	38.73
AV-3	19	219.95	38.86	24	219.42	33.09
AV-1 – Baseline	23	-4.96	28.61	29	-1.17	29.84
AV-3 – Baseline	19	-12.16	34.25	24	-7.67	26.22
LDL-C (mg/dl)						
Baseline	24	152.25	37.79	34	135.24	33.35
AV-1	23	143.65	35.75	29	132.62	41.10
AV-3	19	131.05	31.86	24	129.71	32.45
AV-1 – Baseline	22	-10.27	23.25	29	-2.62	29.46
AV-3 – Baseline	19	-17.58	30.37	24	-11.46	30.71
HDL-C (mg/dl)						
Baseline	25	55.32	12.58	34	54.47	14.86
AV-1	23	59.17	13.34	29	55.31	15.06
AV-3	19	57.89	13.27	24	58.50	16.08
AV-1 – Baseline	23	4.61	7.45	29	0.93	4.78
AV-3 – Baseline	19	3.63	10.58	24	5.88	7.81
HDL-2 (mg/dl)						
Baseline	25	16.48	6.76	33	16.03	8.12
AV-1	22	18.73	7.25	29	17.00	9.21
AV-3	19	16.42	6.27	24	16.88	6.29
AV-1 – Baseline	22	1.91	5.08	28	0.57	4.14
AV-3 – Baseline	19	0.47	5.83	23	1.43	5.53
HDL-3 (mg/dl)						
Baseline	25	38.84	7.11	33	38.00	7.80
AV-1	22	41.50	6.84	29	38.31	7.28
AV-3	19	41.47	7.76	24	41.63	10.72
AV-1 – Baseline	22	3.00	4.86	28	0.18	3.38
AV-3 – Baseline	19	3.16	6.78	23	4.39	5.66
Lp(a) (mg/dl)						
Baseline	25	20.64	22.31	34	27.41	25.20
AV-1	22	20.23	23.22	29	23.00	19.88
AV-3	18	15.28	12.95	22	25.86	22.36
AV-1 – Baseline	22	-0.55	3.20	29	-3.55	15.82
AV-3 – Baseline	18	-1.67	3.83	22	-5.27	12.56

Table 2.10
Bone Mineral Density[1] Analysis: HRT Participants

Data as of: August 31, 2002

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan						
Baseline	930	1.01	0.11	1017	0.99	0.10
AV1	838	1.01	0.11	926	1.00	0.10
AV3	766	1.03	0.12	854	1.02	0.10
AV6	422	1.03	0.12	471	1.03	0.11
AV1 % Change from baseline BMD[2]	833	0.41	2.79	921	0.26	2.35
AV3 % Change from baseline BMD[3]	761	2.08	4.28	846	1.97	3.79
AV6 % Change from baseline BMD[4]	419	2.19	5.27	465	2.76	5.51
Spine Scan						
Baseline	906	0.97	0.16	991	0.95	0.16
AV1	818	0.99	0.16	896	0.97	0.16
AV3	753	1.00	0.17	834	0.99	0.17
AV6	410	1.01	0.17	460	1.00	0.17
AV1 % Change from baseline BMD[2]	814	1.91	4.55	892	2.06	4.34
AV3 % Change from baseline BMD[3]	749	3.53	6.16	828	4.09	6.04
AV6 % Change from baseline BMD[4]	407	4.48	7.75	458	5.22	7.60
Hip Scan						
Baseline	934	0.86	0.14	1024	0.84	0.13
AV1	841	0.86	0.14	928	0.84	0.13
AV3	774	0.88	0.15	860	0.86	0.14
AV6	429	0.88	0.14	481	0.86	0.13
AV1 % Change from baseline BMD[2]	838	0.72	3.31	925	0.63	3.17
AV3 % Change from baseline BMD[3]	768	2.22	4.86	854	2.17	4.78
AV6 % Change from baseline BMD[4]	426	0.84	5.59	473	1.36	5.74

[1] Measured in (g/cm^2).
[2] AV1 % Change from baseline BMD is defined as ((AV1-Baseline)/Baseline)x100.
[3] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[4] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 2.13
Locally Verified Outcomes (Annualized Percentages) by Age for Hormone Replacement Therapy

Data as of: August 31, 2002

Outcomes	Total	Age 50-54	Age 55-59	Age 60-69	Age 70-79
Number randomized	27347	3425	5408	12364	6150
Mean follow-up (months)	66.4	71.5	68.6	65.5	63.6
Cardiovascular					
CHD[1]	568 (0.38%)	34 (0.17%)	48 (0.16%)	255 (0.38%)	231 (0.71%)
CHD death[2]	133 (0.09%)	7 (0.03%)	13 (0.04%)	49 (0.07%)	64 (0.20%)
Total MI[3]	479 (0.32%)	29 (0.14%)	37 (0.12%)	220 (0.33%)	193 (0.59%)
Clinical MI	462 (0.31%)	28 (0.14%)	37 (0.12%)	211 (0.31%)	186 (0.57%)
Evolving Q-wave MI[4]	17 (0.01%)	1 (<0.01%)	0 (0.00%)	9 (0.01%)	7 (0.02%)
Possible evolving Q-wave MI[4]	95 (0.06%)	11 (0.05%)	11 (0.04%)	35 (0.05%)	38 (0.12%)
Angina	771 (0.51%)	32 (0.16%)	95 (0.31%)	359 (0.53%)	285 (0.87%)
CABG/PTCA	765 (0.51%)	31 (0.15%)	83 (0.27%)	371 (0.55%)	280 (0.86%)
Carotid artery disease	131 (0.09%)	2 (0.01%)	14 (0.05%)	72 (0.11%)	43 (0.13%)
Congestive heart failure	440 (0.29%)	24 (0.12%)	47 (0.15%)	180 (0.27%)	189 (0.58%)
Stroke	458 (0.30%)	14 (0.07%)	43 (0.14%)	211 (0.31%)	190 (0.58%)
Non-disabling stroke	267 (0.18%)	11 (0.05%)	24 (0.08%)	127 (0.19%)	105 (0.32%)
Fatal/disabling stroke	111 (0.07%)	2 (0.01%)	6 (0.02%)	46 (0.07%)	57 (0.17%)
Unknown status from stroke	80 (0.05%)	1 (<0.01%)	13 (0.04%)	38 (0.06%)	28 (0.09%)
PVD	124 (0.08%)	6 (0.03%)	12 (0.04%)	62 (0.09%)	44 (0.13%)
DVT	261 (0.17%)	15 (0.07%)	38 (0.12%)	115 (0.17%)	93 (0.29%)
Pulmonary embolism	164 (0.11%)	8 (0.04%)	26 (0.08%)	74 (0.11%)	56 (0.17%)
CHD[1]/Possible evolving Q-wave MI	658 (0.43%)	45 (0.22%)	59 (0.19%)	288 (0.43%)	266 (0.82%)
Coronary disease[5]	1692 (1.12%)	95 (0.47%)	186 (0.60%)	769 (1.14%)	642 (1.97%)
DVT/PE	346 (0.23%)	17 (0.08%)	50 (0.16%)	161 (0.24%)	118 (0.36%)
Total cardiovascular disease	2543 (1.68%)	129 (0.63%)	279 (0.90%)	1188 (1.76%)	947 (2.90%)
Cancer					
Breast cancer[6]	597 (0.39%)	55 (0.27%)	101 (0.33%)	291 (0.43%)	150 (0.46%)
Invasive breast cancer	478 (0.32%)	44 (0.22%)	82 (0.27%)	229 (0.34%)	123 (0.38%)
Non-invasive breast cancer	121 (0.08%)	11 (0.05%)	19 (0.06%)	64 (0.09%)	27 (0.08%)
Ovarian cancer	60 (0.04%)	2 (0.01%)	11 (0.04%)	34 (0.05%)	13 (0.04%)
Endometrial cancer[7]	50 (0.05%)	1 (0.01%)	10 (0.05%)	24 (0.06%)	15 (0.08%)
Colorectal cancer	218 (0.14%)	10 (0.05%)	24 (0.08%)	107 (0.16%)	77 (0.24%)
Other cancer[8]	766 (0.51%)	57 (0.28%)	107 (0.35%)	356 (0.53%)	246 (0.75%)
Total cancer	1645 (1.09%)	125 (0.61%)	247 (0.80%)	787 (1.17%)	486 (1.49%)
Fractures					
Hip fracture	176 (0.12%)	3 (0.01%)	4 (0.01%)	57 (0.08%)	112 (0.34%)
Vertebral fracture	187 (0.12%)	6 (0.03%)	20 (0.06%)	78 (0.12%)	83 (0.25%)
Other fracture[8]	2233 (1.47%)	253 (1.24%)	343 (1.11%)	1056 (1.56%)	581 (1.78%)
Total fracture	2509 (1.66%)	259 (1.27%)	362 (1.17%)	1153 (1.71%)	735 (2.25%)
Deaths					
Cardiovascular deaths	259 (0.17%)	10 (0.05%)	23 (0.07%)	99 (0.15%)	127 (0.39%)
Cancer deaths	377 (0.25%)	19 (0.09%)	37 (0.12%)	181 (0.27%)	140 (0.43%)
Other known cause	124 (0.08%)	9 (0.04%)	17 (0.05%)	45 (0.07%)	53 (0.16%)
Unknown cause	51 (0.03%)	4 (0.02%)	6 (0.02%)	21 (0.03%)	20 (0.06%)
Not yet adjudicated	72 (0.05%)	2 (0.01%)	7 (0.02%)	34 (0.05%)	29 (0.09%)
Total death	883 (0.58%)	44 (0.22%)	90 (0.29%)	380 (0.56%)	369 (1.13%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Excludes four cases with borderline malignancy.
[7] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[8] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 2.13 (continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Hormone Replacement Therapy

Data as of: August 31, 2002

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	130	527	2738	1537	22030	385
Mean follow-up (months)	64.1	63.0	65.5	63.6	66.9	62.7
Cardiovascular						
CHD[1]	3 (0.43%)	7 (0.25%)	51 (0.34%)	17 (0.21%)	477 (0.39%)	13 (0.65%)
CHD death[2]	2 (0.29%)	3 (0.11%)	22 (0.15%)	4 (0.05%)	99 (0.08%)	3 (0.15%)
Total MI[3]	2 (0.29%)	6 (0.22%)	37 (0.25%)	14 (0.17%)	409 (0.33%)	11 (0.55%)
Clinical MI	2 (0.29%)	6 (0.22%)	36 (0.24%)	14 (0.17%)	394 (0.32%)	10 (0.50%)
Evolving Q-wave MI[4]	0 (0.00%)	0 (0.00%)	1 (0.01%)	0 (0.00%)	15 (0.01%)	1 (0.05%)
Possible evolving Q-wave MI[4]	0 (0.00%)	1 (0.04%)	11 (0.07%)	4 (0.05%)	78 (0.06%)	1 (0.05%)
Angina	4 (0.58%)	12 (0.43%)	79 (0.53%)	34 (0.42%)	635 (0.52%)	7 (0.35%)
CABG/PTCA	5 (0.72%)	7 (0.25%)	66 (0.44%)	30 (0.37%)	648 (0.53%)	9 (0.45%)
Carotid artery disease	1 (0.14%)	1 (0.04%)	5 (0.03%)	0 (0.00%)	124 (0.10%)	0 (0.00%)
Congestive heart failure	3 (0.43%)	6 (0.22%)	64 (0.43%)	11 (0.14%)	351 (0.29%)	5 (0.25%)
Stroke	3 (0.43%)	8 (0.29%)	58 (0.39%)	14 (0.17%)	370 (0.30%)	5 (0.25%)
Non-disabling stroke	2 (0.29%)	5 (0.18%)	28 (0.19%)	10 (0.12%)	219 (0.18%)	3 (0.15%)
Fatal/disabling stroke	1 (0.14%)	2 (0.07%)	15 (0.10%)	2 (0.02%)	90 (0.07%)	1 (0.05%)
Unknown status from stroke	0 (0.00%)	1 (0.04%)	15 (0.10%)	2 (0.02%)	61 (0.05%)	1 (0.05%)
PVD	2 (0.29%)	0 (0.00%)	11 (0.07%)	2 (0.02%)	109 (0.09%)	0 (0.00%)
DVT	1 (0.14%)	1 (0.04%)	23 (0.15%)	4 (0.05%)	231 (0.19%)	1 (0.05%)
Pulmonary embolism	3 (0.43%)	1 (0.04%)	16 (0.11%)	1 (0.01%)	142 (0.12%)	1 (0.05%)
CHD[1]/Possible evolving Q-wave MI	3 (0.43%)	8 (0.29%)	61 (0.41%)	21 (0.26%)	551 (0.45%)	14 (0.70%)
Coronary disease[5]	9 (1.30%)	22 (0.80%)	188 (1.26%)	64 (0.79%)	1386 (1.13%)	23 (1.14%)
DVT/PE	4 (0.58%)	1 (0.04%)	29 (0.19%)	4 (0.05%)	307 (0.25%)	1 (0.05%)
Total cardiovascular disease	15 (2.16%)	32 (1.16%)	273 (1.83%)	80 (0.98%)	2114 (1.72%)	29 (1.44%)
Cancer						
Breast cancer[6]	0 (0.00%)	14 (0.51%)	51 (0.34%)	21 (0.26%)	507 (0.41%)	4 (0.20%)
Invasive breast cancer	0 (0.00%)	10 (0.36%)	40 (0.27%)	15 (0.18%)	409 (0.33%)	4 (0.20%)
Non-invasive breast cancer	0 (0.00%)	4 (0.14%)	11 (0.07%)	6 (0.07%)	100 (0.08%)	0 (0.00%)
Ovarian cancer	0 (0.00%)	0 (0.00%)	5 (0.03%)	0 (0.00%)	54 (0.04%)	1 (0.05%)
Endometrial cancer[7]	1 (0.34%)	0 (0.00%)	0 (0.00%)	1 (0.02%)	48 (0.06%)	0 (0.00%)
Colorectal cancer	0 (0.00%)	7 (0.25%)	22 (0.15%)	12 (0.15%)	174 (0.14%)	3 (0.15%)
Other cancer[8]	5 (0.72%)	12 (0.43%)	64 (0.43%)	26 (0.32%)	648 (0.53%)	11 (0.55%)
Total cancer	6 (0.86%)	33 (1.19%)	136 (0.91%)	58 (0.71%)	1394 (1.13%)	18 (0.89%)
Fractures						
Hip fracture	0 (0.00%)	2 (0.07%)	7 (0.05%)	3 (0.04%)	163 (0.13%)	1 (0.05%)
Vertebral fracture	0 (0.00%)	2 (0.07%)	2 (0.01%)	2 (0.02%)	179 (0.15%)	2 (0.10%)
Other fracture[8]	11 (1.58%)	29 (1.05%)	115 (0.77%)	74 (0.91%)	1983 (1.61%)	21 (1.04%)
Total fracture	11 (1.58%)	32 (1.16%)	124 (0.83%)	77 (0.95%)	2243 (1.83%)	22 (1.09%)
Deaths						
Cardiovascular deaths	2 (0.29%)	5 (0.18%)	43 (0.29%)	4 (0.05%)	201 (0.16%)	4 (0.20%)
Cancer deaths	1 (0.14%)	11 (0.40%)	39 (0.26%)	10 (0.12%)	311 (0.25%)	5 (0.25%)
Other known cause	2 (0.29%)	1 (0.04%)	12 (0.08%)	0 (0.00%)	109 (0.09%)	0 (0.00%)
Unknown cause	1 (0.14%)	0 (0.00%)	7 (0.05%)	1 (0.01%)	41 (0.03%)	1 (0.05%)
Not yet adjudicated	1 (0.14%)	0 (0.00%)	6 (0.04%)	2 (0.02%)	62 (0.05%)	1 (0.05%)
Total death	7 (1.01%)	17 (0.61%)	107 (0.72%)	17 (0.21%)	724 (0.59%)	11 (0.55%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Excludes four cases with borderline malignancy.
[7] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[8] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 2.14
Locally Verified Outcomes (Annualized Percentages) for HRT Participants Without and With Uterus

Data as of: August 31, 2002

Outcomes	Without Uterus		With Uterus	
Number randomized	10739		16608	
Mean follow-up (months)	65.2		67.2	
Cardiovascular				
CHD[1]	258	(0.44%)	310	(0.33%)
CHD death[2]	70	(0.12%)	63	(0.07%)
Total MI[3]	213	(0.36%)	266	(0.29%)
Clinical MI	205	(0.35%)	257	(0.28%)
Evolving Q-wave MI[4]	8	(0.01%)	9	(0.01%)
Possible evolving Q-wave MI[4]	36	(0.06%)	59	(0.06%)
Angina	418	(0.72%)	353	(0.38%)
CABG/PTCA	370	(0.63%)	395	(0.42%)
Carotid artery disease	70	(0.12%)	61	(0.07%)
Congestive heart failure	239	(0.41%)	201	(0.22%)
Stroke	221	(0.38%)	237	(0.25%)
Non-disabling stroke	127	(0.22%)	140	(0.15%)
Fatal/disabling stroke	49	(0.08%)	62	(0.07%)
Unknown status from stroke	45	(0.08%)	35	(0.04%)
PVD	63	(0.11%)	61	(0.07%)
DVT	81	(0.14%)	180	(0.19%)
Pulmonary embolism	50	(0.09%)	114	(0.12%)
CHD[1]/Possible evolving Q-wave MI	293	(0.50%)	365	(0.39%)
Coronary disease[5]	835	(1.43%)	857	(0.92%)
DVT/PE	109	(0.19%)	237	(0.25%)
Total cardiovascular disease	1198	(2.05%)	1345	(1.45%)
Cancer				
Breast cancer[6]	204	(0.35%)	393	(0.42%)
Invasive breast cancer	161	(0.28%)	317	(0.34%)
Non-invasive breast cancer	44	(0.08%)	77	(0.08%)
Ovarian cancer	20	(0.03%)	40	(0.04%)
Endometrial cancer[7]	0	N/A	50	(0.05%)
Colorectal cancer	98	(0.17%)	120	(0.13%)
Other cancer[8]	294	(0.50%)	472	(0.51%)
Total cancer	601	(1.03%)	1044	(1.12%)
Fractures				
Hip fracture	63	(0.11%)	113	(0.12%)
Vertebral fracture	69	(0.12%)	118	(0.13%)
Other fracture[8]	858	(1.47%)	1375	(1.48%)
Total fracture	956	(1.64%)	1553	(1.67%)
Deaths				
Cardiovascular deaths	128	(0.22%)	131	(0.14%)
Cancer deaths	160	(0.27%)	217	(0.23%)
Other known cause	42	(0.07%)	82	(0.09%)
Unknown cause	29	(0.05%)	22	(0.02%)
Not yet adjudicated	27	(0.05%)	45	(0.05%)
Total death	386	(0.66%)	497	(0.53%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Excludes four cases with borderline malignancy.
[7] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[8] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 2.15
Frequency (%)[1] of Various Subcategories of Stroke Diagnosis: HRT Participants

Data as of: August 31, 2002

	Without Uterus		With Uterus	
Number randomized	10739		16608	
Stroke Diagnosis				
Subarachoid hemorrhage	8	3.6%	11	4.6%
Intracerebral hemorrhage	26	11.8%	34	14.3%
Other intracranial hemorrhage	2	0.9%	2	0.8%
Occlusion of cerebral arteries with infarction	126	57.0%	135	57.0%
Acute cerebrovascular disease	42	19.0%	34	14.3%
Central nervous system complications	11	5.0%	8	3.4%
Report of cerebrovascular death only	6	2.7%	12	5.1%
Missing	0	0.0%	1	0.4%
Total	221	100%	237	100%

[1] Percentages are relative to the total number of stroke diagnoses.

Table 2.16
Frequency (%)[1] of Disability Levels Following Stroke – Glasgow Scale: HRT Participants

Data as of: August 31, 2002

	Without Uterus		With Uterus	
Number randomized	10739		16608	
Glasgow scale				
Good recovery	69	31.2%	76	32.1%
Moderately disabled	58	26.2%	64	27.0%
Severely disabled	21	9.5%	25	10.5%
Vegetative survival	0	0.0%	4	1.7%
Death or death within 1 month	28	12.7%	33	13.9%
Unable to categorize stroke	15	6.8%	14	5.9%
Not yet categorized	30	13.6%	21	8.9%
Total	221	100%	237	100%

[1] Percentages are relative to the total number of stroke diagnoses.

Table 2.17
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for HRT Participants who did not report a prevalent condition at baseline

Data as of: August 31, 2002

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	27347	3425	5408	12364	6150
Mean follow-up (months)	66.4	71.5	68.6	65.5	63.6
Hospitalizations					
Ever	10832 (7.15%)	955 (4.68%)	1710 (5.53%)	5027 (7.45%)	3140 (9.63%)
Two or more	5186 (3.42%)	402 (1.97%)	728 (2.35%)	2409 (3.57%)	1647 (5.05%)
Other					
Diabetes (treated)	1522 (1.06%)	206 (1.05%)	308 (1.05%)	690 (1.08%)	318 (1.04%)
Gallbladder disease[1]	1525 (1.21%)	210 (1.19%)	322 (1.22%)	716 (1.28%)	277 (1.05%)
Hysterectomy	496 (0.53%)	41 (0.34%)	91 (0.45%)	251 (0.60%)	113 (0.59%)
Glaucoma	2130 (1.47%)	180 (0.90%)	347 (1.15%)	1023 (1.58%)	580 (1.92%)
Osteoporosis	4224 (2.94%)	297 (1.48%)	623 (2.07%)	2034 (3.18%)	1270 (4.31%)
Osteoarthritis[2]	3507 (3.76%)	434 (2.84%)	690 (3.23%)	1597 (3.98%)	786 (4.75%)
Rheumatoid arthritis	1176 (0.81%)	159 (0.81%)	263 (0.88%)	501 (0.78%)	253 (0.82%)
Intestinal polyps	2619 (1.86%)	261 (1.32%)	441 (1.49%)	1343 (2.14%)	574 (1.99%)
Lupus	200 (0.13%)	27 (0.13%)	43 (0.14%)	93 (0.14%)	37 (0.11%)
Kidney stones[2]	466 (0.38%)	54 (0.35%)	89 (0.36%)	214 (0.39%)	109 (0.41%)
Cataracts[2]	6178 (5.76%)	304 (1.93%)	839 (3.46%)	3319 (6.78%)	1716 (9.39%)
Pills for hypertension	5376 (5.00%)	569 (3.45%)	1011 (4.23%)	2454 (5.24%)	1342 (6.56%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	130	527	2738	1537	22030	385
Mean follow-up (months)	64.1	63.0	65.5	63.6	66.9	62.7
Hospitalizations						
Ever	57 (8.20%)	136 (4.92%)	1114 (7.45%)	476 (5.84%)	8913 (7.25%)	136 (6.76%)
Two or more	30 (4.32%)	53 (1.92%)	557 (3.73%)	184 (2.26%)	4309 (3.51%)	53 (2.63%)
Other						
Diabetes (treated)	11 (1.84%)	33 (1.31%)	266 (2.03%)	136 (1.82%)	1057 (0.90%)	19 (1.02%)
Gallbladder disease[1]	9 (1.69%)	22 (0.87%)	132 (0.98%)	81 (1.33%)	1260 (1.23%)	21 (1.27%)
Hysterectomy	2 (0.68%)	2 (0.10%)	28 (0.45%)	24 (0.51%)	434 (0.55%)	6 (0.48%)
Glaucoma	10 (1.53%)	40 (1.50%)	273 (1.98%)	132 (1.68%)	1644 (1.39%)	31 (1.65%)
Osteoporosis	20 (3.04%)	92 (3.46%)	209 (1.45%)	207 (2.73%)	3633 (3.12%)	63 (3.31%)
Osteoarthritis[2]	23 (4.88%)	67 (3.45%)	364 (4.04%)	247 (4.39%)	2742 (3.66%)	64 (4.95%)
Rheumatoid arthritis	8 (1.30%)	21 (0.79%)	199 (1.46%)	168 (2.17%)	757 (0.64%)	23 (1.21%)
Intestinal polyps	11 (1.72%)	38 (1.50%)	258 (1.85%)	128 (1.64%)	2163 (1.89%)	21 (1.13%)
Lupus	1 (0.14%)	3 (0.11%)	25 (0.17%)	13 (0.16%)	157 (0.13%)	1 (0.05%)
Kidney stones[2]	5 (0.96%)	17 (0.75%)	47 (0.40%)	29 (0.45%)	363 (0.37%)	5 (0.30%)
Cataracts[2]	30 (5.94%)	98 (4.92%)	555 (5.23%)	319 (5.09%)	5102 (5.90%)	74 (5.16%)
Pills for hypertension	33 (6.73%)	103 (5.32%)	504 (6.81%)	320 (5.24%)	4353 (4.82%)	63 (4.83%)

[1] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[2] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 2.18
Baseline Characteristics of HRT Participants Enrolled in WHIMS

Data as of: August 31, 2002

	HRT Participants			
	Without Uterus		With Uterus	
Total HRT Participants	10739		16608	
Eligible HRT Population	4999		7415	
Enrolled in WHIMS	2970		4556	
% Enrolled of Total HRT		27.7%		27.4%
% Enrolled of Eligible		59.4%		61.4%
WHIMS Participants	**(N = 2970)**		**(N = 4556)**	
Age at Screening				
< 70	1424	(47.9%)	2293	(50.3%)
70-74	1062	(35.8%)	1540	(33.8%)
75+	484	(16.3%)	723	(15.9%)
Education				
Missing	8	(0.3%)	16	(0.4%)
0-8 years	68	(2.3%)	68	(1.5%)
Some high school	213	(7.2%)	231	(5.1%)
High school diploma/GED	706	(23.8%)	947	(20.8%)
School after high school	1246	(42.0%)	1775	(39.0%)
College degree or higher	729	(24.5%)	1519	(33.3%)
Ethnicity				
American Indian	16	(0.5%)	10	(0.2%)
Asian/Pacific Islander	37	(1.2%)	91	(2.0%)
Black	326	(11.0%)	216	(4.7%)
Hispanic	84	(2.8%)	105	(2.3%)
White	2457	(82.7%)	4065	(89.2%)
Unknown	50	(1.7%)	69	(1.5%)
Family Income				
Missing	182	(6.1%)	274	(6.0%)
< $10,000	226	(7.6%)	197	(4.3%)
$10,000 - $19,999	649	(21.9%)	789	(17.3%)
$20,000 - $34,999	897	(30.2%)	1325	(29.1%)
$35,000 - $49,999	516	(17.4%)	931	(20.4%)
$50,000 - $74,999	324	(10.9%)	660	(14.5%)
$75,000 +	176	(5.9%)	380	(8.3%)

3. DM Component

3.1 Recruitment

Age and race/ethnicity-specific DM recruitment data are presented in *Table 3.1*. The age-specific enrollment exceeded the design assumptions for ages 50-54, 55-59, and 60-69. For the age category 70-79, recruitment was lower than designed.

3.2 Adherence

Nutrient intake data for adherence monitoring are presented in *Table 3.2* and *Figure 3.1*. Studywide, the Food Frequency Questionnaire (FFQ) mean difference between Intervention and Control women is 10.9% energy from fat at AV-1 decreasing to 7.7% at AV-8. This report presents nutrient intake comparisons for each racial/ethnic group separately (*Table 3.3*). Because of sparse numbers, some of these results are highly variable. The C-I value in minority women is roughly 1-3 percentage points lower compared to white women. All C-I analyses are based on only those women providing a food frequency questionnaire at the designated visit. For example, missing data account for 11.5% of our sample at AV-1 and 15.2% at AV-3. The overall C-I percent energy from fat is approximately 2 to 3 percentage points lower than the design assumptions. Refer to *Section 3.7* for a discussion of the impact of the C-I on study power and of the adherence initiatives that are underway.

For fruit and vegetable intake, the mean difference between the arms of the trial remains consistently in excess of 1 more serving per day for Intervention vs. Control women. Compared to Control women, Intervention women consumed almost 1 more serving per day of grains at AV-1, decreasing to one-half servings from AV-4 to AV-7, with a recent decrease to one-third at AV-8. Generally, the C-I for fruit and vegetables intake, as well as grain intake, are similar across race/ethnicity groups.

Multivariate analyses were conducted to identify factors associated with C-I differences in percent energy from fat based on FFQs collected in the past year and controlling for visit year and clinic effect (*Table 3.4*). The only participant characteristics that are consistently associated with a lower C-I difference was being older than age 60-69 ($p<0.05$) or being Black compared to White ($p<0.05$). DM Participants randomized to HRT were also significantly more adherent than non-HRT participants. Separate analyses were conducted to examine session attendance, completion, and fat score provision variables in relation to C-I because these measures are highly correlated. For example, self-monitoring scores are almost always provided at sessions, and therefore session attendance (and completion) is closely associated with self-monitoring. Session attendance, completion, and self-monitoring are all significantly associated with much higher (i.e., better) C-I values.

Body weight data are presented in *Table 3.5*. The difference in body weight between Control and Intervention participants at AV-1 was almost 2 kg ($p<0.01$). The body weight C-I has steadily decreased and there is no statistically significant difference at AV-8, although the mean intervention body weight is less than in control women. From a trend perspective, these results are consistent with changes in energy intake estimated with the FFQ. The body weight data by race/ethnicity show that American Indians on the Intervention have maintained the same mean weight for four years,

while the control arm has gained 4-5 kg, producing marginally significant differences at AV-3 through AV-6.

Tables 3.6-3.7 give reasons for stopping DM categorized by general type and stratified by age and race/ethnicity. Overall, the major reasons for stopping given by participants were family responsibilities (12.4%), demands of work (10.3%), and issues of interest in the study (9.8%). Issues specifically related to the DM intervention were seldom mentioned. The age and race/ethnicity stratified analyses have sparse numbers and may be confounded by other factors, and therefore should be interpreted cautiously. These data suggest that older participants were less likely to indicate that they were stopping due the demands of work, but were also less likely to stop the DM intervention because it was "Too far to the CC." Compared to the other race/ethnicity groups, Hispanic/Latino women were most likely to indicate that they were stopping intervention because of family demands, but least likely to stop intervention because of interest in the study. Black/African American women were most likely to stop DM because of demands of work and/or issues of interest in the study.

3.3 Blood Specimen and Bone Density Analyses

Tables 3.8-3.9 present the results of blinded blood specimen analyses from a small (4.3%) cohort of DM women selected randomly at baseline for these prospective analyses. This subsample incorporated oversampling of minorities. The results shown in *Table 3.8* are weighted to reflect the overall WHI distribution of race/ethnicity. *Table 3.9* presents analysis by race/ethnicity. Differences between baseline and AV-1 are mostly modest, with reductions of approximately 5% in LDL cholesterol and about 3% in total cholesterol for Intervention and Control women combined. There are no substantial changes in HDL-cholesterol or triglycerides in the combined groups. Blood specimen analyses are presented by race/ethnicity group and appear to be consistent with the dietary data. For example, LDL cholesterol reductions averaged 7% in Asian/Pacific Islander women and 5% in white women but are slightly lower among other groups (about 4% in Hispanic/Latinas and American Indian/Alaskan Native women and 3% in Blacks/African American). Note that baseline and AV-1 specimens were batched together for concurrent analyses by Medical Research Labs.

Tables 3.10-3.11 present blinded bone mineral density data from the DM bone density subsample overall and by race/ethnicity. Changes from baseline to AV-1, AV-3, and AV-6 are interesting with increases in mean bone mineral density in the whole body scan as well as the spine and hip scan. An increase in BMD was not expected from this intervention. There were, generally, similar trends by race/ethnicity. Possible reasons for this observation include use of calcium supplements and/or HRT, selection of health-conscious women, incomplete BMD data (e.g., 12.6% missing at AV-3), or measurement issues.

3.4 Adherence to Follow-up

Table 3.12 summarizes adherence to follow-up contacts by treatment arm and contact type. Follow-up participation has been roughly equivalent in the two arms. The acceptable adherence rates specified by the Steering Committee for collection of outcome data are 90% at AV-1, with a decline of no more than 1% per year, going no lower than 85%. WHI adherence rates are above those rates for all annual visits.

3.5 Vital Status

Table 3.13 presents data on the vital status and the participation status of participants in the DM trial. A detailed description of CCC and clinic activities to actively locate participants who do not complete their periodic visits is given in *Section 6 – Outcomes Processing*. For operational purposes, we define CT participants to have an "unknown" participation status if there is no outcomes information from the participant for 18 months and no other contacts for 6 months. Currently, about 3.7% of the DM participants are lost-to-follow-up or have stopped follow-up (an increase of 0.1% compared to the Spring 2002 report), and 2.6% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. The design assumed that 3% per year would be lost-to-follow-up or death. Currently, the average follow-up for DM participants is about 5.7 years, suggesting that approximately 15.9% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

3.6 Outcomes

Table 3.14 contains counts of the number of locally verified major WHI outcomes for DM participants by race/ethnicity and age. Approximately 4% of the self-reported outcomes have not yet been verified, so the numbers in this table can be seen as a lower bound to the actual number of outcomes that have occurred. Compared to the design assumptions, we have observed almost 110% of the expected number of breast cancers, 75% of the expected number of colorectal cancers, about 60% of the expected number of CHD events, and about 30% of the expected number hip fractures.

Table 3.15 contains counts of the number of self-reports for some outcomes that are not locally verified in WHI. As most of the locally verified outcomes are somewhat over reported (see *Section 6.3 – Outcomes Data Quality)*, the number in this table should be taken as an upper bound to the number of events that have occurred in DM participants.

3.7 Issues

As noted above, the C-I difference is less than the design assumptions. The WHI investigators and staff have undertaken a number of activities addressing adherence. In summer 1999, the DM Intervention incorporated an Intensive Intervention Program (IIP) that consisted of interviews using motivational enhancement techniques. Nutritionists targeted "medium adherers," defined as women who are attending some sessions but not meeting their fat gram goal or not self-monitoring (about 40% of intervention women). This protocol was completed on March 30, 2001. A preliminary evaluation of the IIP among intervention participants indicated that these contacts had a positive effect on adherence to fat intake goals among medium adherers. Specifically, when examining change (increases) in fat intake from AV-1 to most recent data collection, participants who received IIP contact had an increase in fat intake that was 0.75 percentage points less (i.e., had less slippage) than intervention women who did not receive IIP ($p<0.05$).

The second major DM initiative was called the Targeted Message Campaign (TMC). The campaign began with a 2000 Fall/Winter Kickoff Newsletter to raise awareness and excitement. Starting in January 2001, participants received a mailing introducing five themes to help them rediscover their intrinsic motivation(s) for participating in WHI. This first mailing was followed by a motivational enhancement phone call that supports participants in the process of identifying their primary

motivation. Finally, based on information collected on the call, a second targeted mailing allowed a woman to select an action consistent with her readiness to enhance her intervention adherence. This campaign was completed at the end of 2001.

A Dietary Modification Working Group developed a third initiative called the Personalized Evaluation of Fat Intake (PEFI). This intervention uses tailored, food-based, feedback to facilitate dietary goal re-setting for participants. The dietary assessment is performed using a specially designed instrument that focuses on usual fat-intake over the past 4 weeks. After scanning, computerized algorithms provide printed, individualized feedback on estimated grams of fat consumed (by foods) and food-specific behavioral change suggestions. The dietary questionnaire was administered during Summer 2002 group sessions. The written feedback is provided and reinforced in Fall 2002 group sessions. CCs are conducting individual follow-up of group non-attenders by phone and mail.

Table 3.1
Dietary Modification Component Age – and Race/Ethnicity – Specific Recruitment

Data as of: August 31, 2002

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**48,835**			
50-54	6961	149%	14%	10
55-59	11043	118%	23%	20
60-69	22713	108%	47%	45
70-79	8118	70%	17%	25
Race/Ethnicity	**48,835**			
American Indian	202		<1%	
Asian	1105		2%	
Black	5262		11%	
Hispanic	1845		4%	
White	39762		81%	
Unknown	659		1%	

Table 3.2
Nutrient Intake Monitoring

Data as of: August 31, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	19541	38.8	5.0	29294	38.8	5.0	0.0	0.0	0.83
FFQ Year 1[3]	18098	25.2	7.5	26772	36.1	6.9	10.9	0.1	<.01
FFQ Year 2[4]	5923	26.3	7.6	8667	36.3	7.0	9.9	0.1	<.01
FFQ Year 3[5]	3241	27.7	7.9	4892	37.3	7.1	9.6	0.2	<.01
FFQ Year 4[6]	5025	28.5	8.1	7834	37.6	7.1	9.1	0.1	<.01
FFQ Year 5[7]	4908	28.9	8.2	7519	37.8	7.3	8.9	0.1	<.01
FFQ Year 6[8]	3741	29.4	8.2	5716	37.6	7.1	8.2	0.2	<.01
FFQ Year 7[9]	1521	30.0	8.0	2303	37.6	7.1	7.6	0.2	<.01
FFQ Year 8[10]	366	29.7	8.1	619	37.5	7.3	7.7	0.5	<.01
4DFR Baseline	892	32.8	6.4	1351	33.0	6.8	0.2	0.3	0.54
4DFR Year 1	805	21.7	7.3	1171	32.9	6.8	11.3	0.3	<.01
24 Hr Recall, Post-baseline	226	23.0	9.2	262	32.1	7.6	9.2	0.8	<.01
24 Hr Recall, Year 1	221	22.4	7.8	268	32.6	7.7	10.2	0.7	<.01
24 Hr Recall, Year 2	214	23.8	9.7	244	32.5	8.0	8.7	0.8	<.01
24 Hr Recall, Year 3	209	25.1	9.2	249	33.3	8.6	8.2	0.8	<.01
24 Hr Recall, Year 3 Cohort	787	24.8	8.5	1183	33.0	7.6	8.3	0.4	<.01
24 Hr Recall, Year 4	195	25.7	9.4	220	33.2	8.5	7.5	0.9	<.01
24 Hr Recall, Year 5	102	27.3	9.5	159	34.5	8.2	7.2	1.1	<.01
24 Hr Recall, Year 6	59	26.9	9.8	74	34.0	7.9	7.1	1.5	<.01
24 Hr Recall, Year 6 Cohort	309	26.5	8.7	511	33.5	7.5	7.0	0.6	<.01
24 Hr Recall, Year 7	17	27.7	11.5	23	35.4	9.0	7.7	3.2	0.03
Total Energy (kcal)									
FFQ Baseline	19541	1789.1	713.3	29294	1789.4	706.6	0.3	6.6	0.93
FFQ Year 1	18098	1473.9	534.4	26772	1584.3	641.5	110.4	5.8	<.01
FFQ Year 2	5923	1479.6	534.9	8667	1575.5	625.4	95.9	10.0	<.01
FFQ Year 3	3241	1476.7	539.0	4892	1571.9	644.3	95.2	13.7	<.01
FFQ Year 4	5025	1443.1	536.4	7834	1562.1	634.4	118.9	10.8	<.01
FFQ Year 5	4908	1465.5	541.1	7519	1560.7	640.2	95.2	11.1	<.01
FFQ Year 6	3741	1455.8	548.5	5716	1539.0	635.6	83.3	12.7	<.01
FFQ Year 7	1521	1455.0	528.0	2303	1545.4	632.7	90.4	19.6	<.01
FFQ Year 8	366	1425.5	512.1	619	1542.5	625.9	117.0	38.7	0.02
4DFR Baseline	892	1707.2	454.3	1351	1712.9	459.4	5.7	19.7	0.79
4DFR Year 1	805	1422.8	355.7	1171	1627.0	446.9	204.2	18.9	<.01
24 Hr Recall, Post-baseline	226	1519.8	418.2	262	1652.8	516.5	133.0	43.0	<.01
24 Hr Recall, Year 1	221	1482.1	417.8	268	1635.8	477.0	153.6	41.0	<.01
24 Hr Recall, Year 2	214	1436.4	430.0	244	1603.8	523.4	167.4	45.1	<.01
24 Hr Recall, Year 3	209	1443.3	427.8	249	1589.2	504.2	145.9	44.2	<.01
24 Hr Recall, Year 3 Cohort	787	1431.8	391.6	1183	1589.9	489.3	158.1	20.8	<.01
24 Hr Recall, Year 4	195	1447.7	398.9	220	1525.9	469.3	78.2	43.0	0.15
24 Hr Recall, Year 5	102	1460.3	473.3	159	1613.4	530.2	153.0	64.5	0.02
24 Hr Recall, Year 6	59	1375.5	411.3	74	1582.3	512.5	206.8	82.1	0.01
24 Hr Recall, Year 6 Cohort	309	1432.4	395.2	511	1547.5	482.5	115.2	32.5	<.01
24 Hr Recall, Year 7	17	1292.5	241.6	23	1514.0	477.0	221.5	126.5	0.18

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 4953 (27%) Intervention women had <=20% energy from fat at year 1.
[4] 1268 (21%) Intervention women had <=20% energy from fat at year 2.
[5] 566 (17%) Intervention women had <=20% energy from fat at year 3.
[6] 769 (15%) Intervention women had <=20% energy from fat at year 4.
[7] 685 (14%) Intervention women had <=20% energy from fat at year 5.
[8] 419 (11%) Intervention women had <=20% energy from fat at year 6.
[9] 146 (10%) Intervention women had <=20% energy from fat at year 7.
[10] 43 (12%) Intervention women had <=20% energy from fat at year 8.

Table 3.2 (continued)
Nutrient Intake Monitoring

Data as of: August 31, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Total Fat (g)									
FFQ Baseline	19541	77.9	35.3	29294	77.8	34.7	0.0	0.3	0.87
FFQ Year 1	18098	41.5	21.8	26772	64.5	31.7	23.0	0.3	<.01
FFQ Year 2	5923	43.5	22.3	8667	64.5	31.3	21.0	0.5	<.01
FFQ Year 3	3241	45.9	23.8	4892	66.0	32.5	20.2	0.7	<.01
FFQ Year 4	5025	46.2	23.9	7834	66.2	32.2	20.0	0.5	<.01
FFQ Year 5	4908	47.5	24.5	7519	66.6	32.9	19.1	0.5	<.01
FFQ Year 6	3741	47.8	24.0	5716	65.1	32.2	17.3	0.6	<.01
FFQ Year 7	1521	48.8	24.6	2303	65.5	32.3	16.8	1.0	<.01
FFQ Year 8	366	47.2	23.0	619	65.2	32.5	18.0	1.9	<.01
4DFR Baseline	892	63.0	23.6	1351	63.8	24.6	0.8	1.0	0.71
4DFR Year 1	805	34.1	14.5	1171	60.4	23.5	26.3	0.9	<.01
24 Hr Recall, Post-baseline	226	39.6	21.9	262	60.5	26.9	20.9	2.2	<.01
24 Hr Recall, Year 1	221	36.9	17.1	268	60.6	25.1	23.7	2.0	<.01
24 Hr Recall, Year 2	214	38.8	22.6	244	59.3	27.2	20.5	2.4	<.01
24 Hr Recall, Year 3	209	40.9	21.2	249	60.3	27.9	19.4	2.4	<.01
24 Hr Recall, Year 3 Cohort	787	39.8	18.7	1183	59.9	25.6	20.0	1.1	<.01
24 Hr Recall, Year 4	195	41.9	20.9	220	58.1	26.1	16.2	2.3	<.01
24 Hr Recall, Year 5	102	44.6	22.4	159	63.8	29.0	19.2	3.4	<.01
24 Hr Recall, Year 6	59	41.1	19.4	74	61.0	27.3	19.9	4.2	<.01
24 Hr Recall, Year 6 Cohort	309	42.6	20.3	511	59.3	26.3	16.7	1.7	<.01
24 Hr Recall, Year 7	17	41.9	23.1	23	59.5	26.2	17.6	8.0	0.02
Saturated Fat (g)									
FFQ Baseline	19541	27.4	13.4	29294	27.3	13.2	0.1	0.1	0.85
FFQ Year 1	18098	14.2	8.1	26772	22.5	11.9	8.4	0.1	<.01
FFQ Year 2	5923	14.8	8.2	8667	22.5	11.7	7.7	0.2	<.01
FFQ Year 3	3241	15.5	9.0	4892	22.9	12.2	7.4	0.2	<.01
FFQ Year 4	5025	15.7	8.9	7834	23.2	12.2	7.5	0.2	<.01
FFQ Year 5	4908	16.2	9.1	7519	23.3	12.5	7.1	0.2	<.01
FFQ Year 6	3741	16.2	8.8	5716	22.8	12.3	6.6	0.2	<.01
FFQ Year 7	1521	16.8	9.2	2303	23.1	12.5	6.3	0.4	<.01
FFQ Year 8	366	16.4	9.1	619	23.1	13.3	6.7	0.8	<.01
4DFR Baseline	892	20.6	8.9	1351	20.9	9.3	0.3	0.4	0.72
4DFR Year 1	805	10.6	5.2	1171	19.5	8.3	9.0	0.3	<.01
24 Hr Recall, Post-baseline	226	12.9	7.9	262	20.1	9.6	7.2	0.8	<.01
24 Hr Recall, Year 1	221	11.7	6.2	268	20.1	10.1	8.4	0.8	<.01
24 Hr Recall, Year 2	214	12.3	8.2	244	19.5	9.9	7.2	0.9	<.01
24 Hr Recall, Year 3	209	13.4	7.7	249	20.3	10.8	6.9	0.9	<.01
24 Hr Recall, Year 3 Cohort	787	12.4	6.8	1183	19.7	9.3	7.3	0.4	<.01
24 Hr Recall, Year 4	195	13.5	7.8	220	19.4	10.2	5.9	0.9	<.01
24 Hr Recall, Year 5	102	14.3	7.4	159	21.8	10.7	7.5	1.2	<.01
24 Hr Recall, Year 6	59	13.1	6.0	74	20.2	10.4	7.1	1.5	<.01
24 Hr Recall, Year 6 Cohort	309	13.6	7.4	511	19.7	9.9	6.2	0.7	<.01
24 Hr Recall, Year 7	17	13.0	9.1	23	20.4	10.2	7.4	3.1	0.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.2 (continued)
Nutrient Intake Monitoring

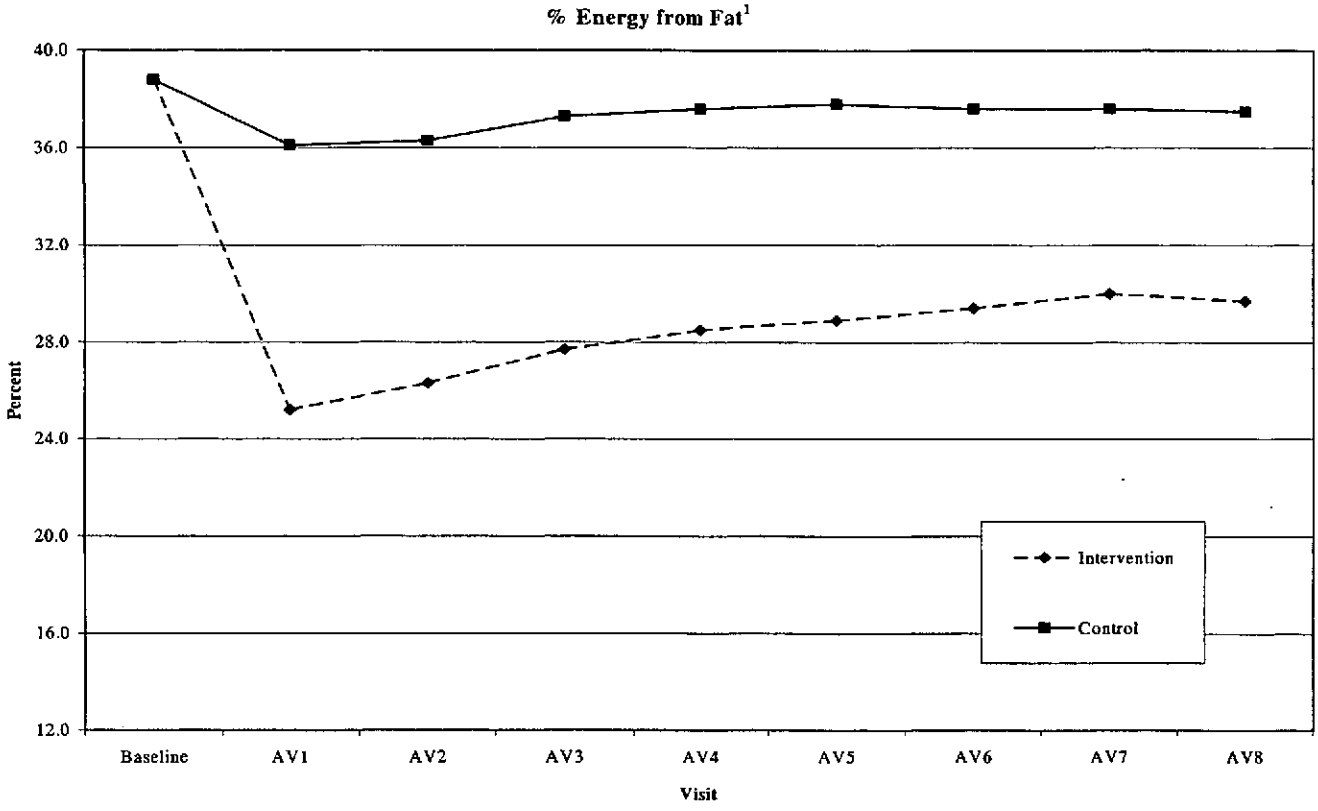
Data as of: August 31, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Polyunsaturated Fat (g)									
FFQ Baseline	19541	15.3	7.6	29294	15.3	7.6	0.0	0.1	0.79
FFQ Year 1	18098	7.9	4.4	26772	12.5	6.7	4.6	0.1	<.01
FFQ Year 2	5923	8.3	4.5	8667	12.4	6.5	4.1	0.1	<.01
FFQ Year 3	3241	8.8	4.7	4892	12.8	6.8	4.0	0.1	<.01
FFQ Year 4	5025	9.0	4.9	7834	12.8	6.7	3.8	0.1	<.01
FFQ Year 5	4908	9.2	5.0	7519	12.9	6.9	3.7	0.1	<.01
FFQ Year 6	3741	9.4	5.1	5716	12.6	6.5	3.2	0.1	<.01
FFQ Year 7	1521	9.4	5.1	2303	12.6	6.5	3.2	0.2	<.01
FFQ Year 8	366	9.0	4.4	619	12.3	6.1	3.3	0.4	<.01
4DFR Baseline	892	13.1	5.8	1351	13.5	6.1	0.3	0.3	0.40
4DFR Year 1	805	7.4	3.4	1171	12.7	6.2	5.3	0.2	<.01
24 Hr Recall, Post-baseline	226	8.3	5.0	262	12.6	7.3	4.3	0.6	<.01
24 Hr Recall, Year 1	221	7.8	4.4	268	12.4	6.3	4.6	0.5	<.01
24 Hr Recall, Year 2	214	8.3	5.7	244	12.5	7.6	4.2	0.6	<.01
24 Hr Recall, Year 3	209	8.5	5.5	249	12.2	6.6	3.8	0.6	<.01
24 Hr Recall, Year 3 Cohort	787	8.7	4.6	1183	12.2	6.9	3.6	0.3	<.01
24 Hr Recall, Year 4	195	8.8	5.1	220	11.7	7.0	2.9	0.6	<.01
24 Hr Recall, Year 5	102	9.4	6.7	159	12.6	8.3	3.1	1.0	<.01
24 Hr Recall, Year 6	59	8.7	5.3	74	13.0	6.9	4.3	1.1	<.01
24 Hr Recall, Year 6 Cohort	309	9.0	4.8	511	12.0	6.0	3.0	0.4	<.01
24 Hr Recall, Year 7	17	9.2	5.4	23	11.8	5.9	2.5	1.8	0.08
Fruits and Vegetables (servings)									
FFQ Baseline	19470	3.6	1.8	29216	3.6	1.8	0.0	0.0	0.69
FFQ Year 1	18017	5.0	2.3	26690	3.8	2.0	1.2	0.0	<.01
FFQ Year 2	5900	5.1	2.4	8635	3.9	2.0	1.2	0.0	<.01
FFQ Year 3	3235	5.2	2.5	4878	3.9	2.0	1.3	0.1	<.01
FFQ Year 4	5015	5.1	2.4	7820	3.8	2.0	1.3	0.0	<.01
FFQ Year 5	4886	5.1	2.5	7494	3.8	2.1	1.3	0.0	<.01
FFQ Year 6	3719	5.1	2.5	5693	3.8	2.0	1.3	0.0	<.01
FFQ Year 7	1510	5.0	2.4	2294	3.8	2.0	1.1	0.1	<.01
FFQ Year 8	364	5.1	2.4	618	3.8	2.0	1.3	0.1	<.01
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	19468	4.7	2.5	29214	4.8	2.5	0.0	0.0	0.42
FFQ Year 1	18013	5.1	2.7	26680	4.2	2.3	0.8	0.0	<.01
FFQ Year 2	5899	4.9	2.5	8629	4.1	2.2	0.7	0.0	<.01
FFQ Year 3	3234	4.6	2.5	4873	4.0	2.2	0.7	0.1	<.01
FFQ Year 4	5011	4.4	2.4	7808	3.9	2.2	0.5	0.0	<.01
FFQ Year 5	4882	4.3	2.3	7486	3.9	2.2	0.5	0.0	<.01
FFQ Year 6	3719	4.3	2.4	5690	3.8	2.1	0.5	0.0	<.01
FFQ Year 7	1510	4.2	2.3	2293	3.8	2.0	0.5	0.1	<.01
FFQ Year 8	364	4.0	2.1	618	3.7	2.0	0.3	0.1	0.03

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.

Figure 3.1
Nutrient Intake

Data as of: August 31, 2002

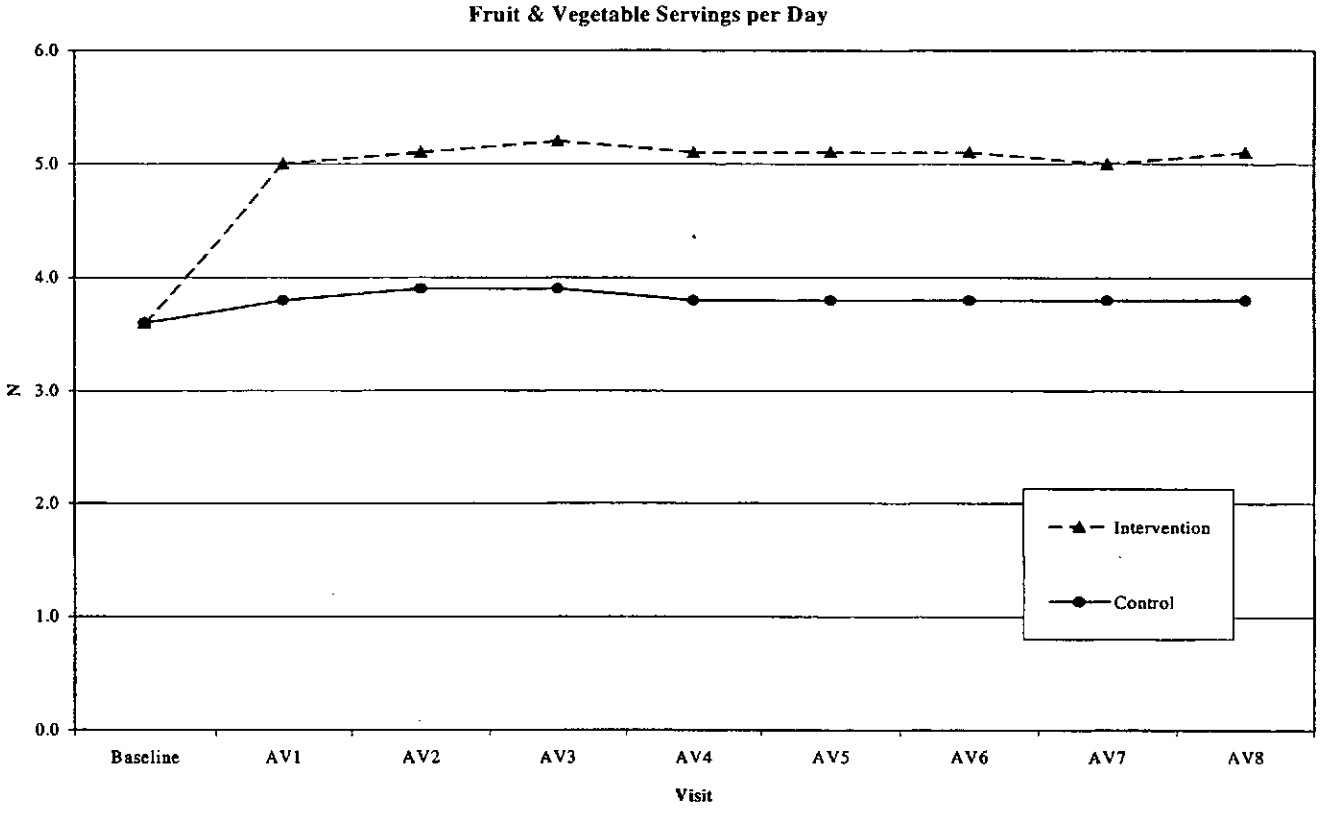


(continues)

[1] Baseline % energy from fat values are about 3% higher in both groups due to the use of FFQ % energy from fat as an exclusionary criterion during screening.

Figure 3.1 (continued)
Nutrient Intake

Data as of: August 31, 2002



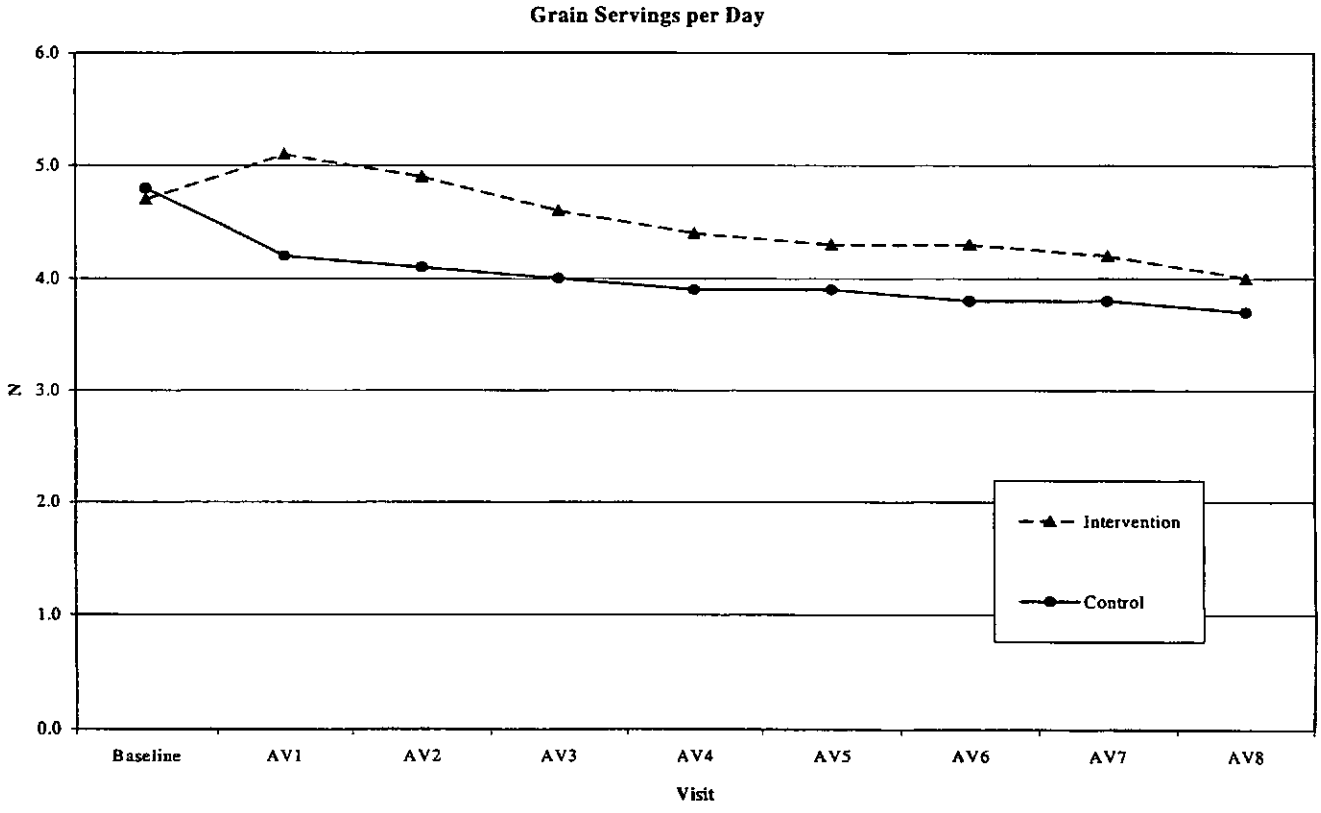


Table 3.3
Nutrient Intake Monitoring in American Indian/Alaskan Native Women[1]

Data as of: August 31, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[2]	SE	p-value[3]
% Energy from Fat									
FFQ Baseline	88	39.5	5.7	114	40.0	5.2	0.5	0.8	0.49
FFQ Year 1[4]	73	27.5	8.9	96	38.0	8.0	10.5	1.3	<.01
FFQ Year 2[5]	28	26.9	8.8	32	38.2	6.8	11.3	2.0	<.01
FFQ Year 3[6]	18	31.3	8.9	41	38.0	7.0	6.7	2.1	<.01
FFQ Year 4[7]	23	30.3	9.3	28	39.9	7.6	9.6	2.4	<.01
FFQ Year 5[8]	19	27.6	7.6	16	39.9	7.8	12.3	2.6	<.01
FFQ Year 6[9]	17	33.0	8.0	21	41.6	8.5	8.6	2.7	<.01
FFQ Year 7[10]	8	26.0	8.1	6	38.7	11.0	12.7	5.1	0.04
4DFR Baseline	24	34.0	6.7	44	33.4	7.8	0.6	1.9	0.73
4DFR Year 1	18	20.5	6.2	32	34.6	7.4	14.2	2.1	<.01
Total Energy (kcal)									
FFQ Baseline	88	1717.5	795.9	114	1771.7	718.2	54.3	106.8	0.42
FFQ Year 1	73	1631.3	689.6	96	1545.5	753.4	85.8	112.8	0.52
FFQ Year 2	28	1508.4	565.8	32	1554.0	706.9	45.6	166.9	0.95
FFQ Year 3	18	1520.0	614.4	41	1589.0	704.1	69.0	191.9	0.83
FFQ Year 4	23	1441.3	478.9	28	1821.1	932.9	379.7	214.8	0.09
FFQ Year 5	19	1673.2	661.5	16	1366.0	724.8	307.2	234.5	0.10
FFQ Year 6	17	1097.9	455.0	21	1734.5	464.2	636.6	150.1	<.01
FFQ Year 7	8	1719.4	334.4	6	1532.9	604.8	186.5	252.0	0.40
4DFR Baseline	24	1524.3	426.0	44	1672.0	606.8	147.7	139.7	0.47
4DFR Year 1	18	1283.9	418.7	32	1631.9	613.0	348.1	162.7	0.04
Total Fat (g)									
FFQ Baseline	88	76.5	40.3	114	79.3	35.6	2.8	5.4	0.34
FFQ Year 1	73	50.3	29.6	96	67.1	43.6	16.8	5.9	<.01
FFQ Year 2	28	45.8	29.0	32	68.5	40.0	22.7	9.1	<.01
FFQ Year 3	18	56.6	35.4	41	68.6	35.7	11.9	10.1	0.22
FFQ Year 4	23	48.9	21.7	28	81.3	44.5	32.4	10.2	<.01
FFQ Year 5	19	52.1	26.7	16	63.6	43.0	11.5	11.9	0.46
FFQ Year 6	17	39.4	17.5	21	80.0	24.7	40.5	7.1	<.01
FFQ Year 7	8	49.6	19.1	6	65.1	29.8	15.5	13.0	0.25
4DFR Baseline	24	57.4	17.5	44	63.8	30.8	6.4	6.8	0.83
4DFR Year 1	18	29.4	12.9	32	64.9	33.0	35.5	8.1	<.01

(continues)

[1] Insufficient sample size for FFQ Year 8.
[2] Absolute difference.
[3] P-values based on testing in the natural log scale except for % Energy from fat.
[4] 14 (19%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 1.
[5] 6 (21%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 2.
[6] 1 (5%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 3.
[7] 5 (22%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 4.
[8] 3 (16%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 5.
[9] 2 (12%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 6.
[10] 2 (25%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 7.

Table 3.3 (continued)
Nutrient Intake Monitoring in American Indian/Alaskan Native Women[1]

Data as of: August 31, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[2]	SE	p-value[3]
Saturated Fat (g)									
FFQ Baseline	88	26.9	14.2	114	27.9	14.1	1.0	2.0	0.42
FFQ Year 1[4]	73	17.4	11.0	96	23.7	18.0	6.2	2.4	<.01
FFQ Year 2[5]	28	15.5	9.9	32	23.3	14.9	7.8	3.3	<.01
FFQ Year 3[6]	18	19.8	13.9	41	22.9	11.9	3.0	3.5	0.27
FFQ Year 4[7]	23	17.2	8.4	28	28.3	16.6	11.2	3.8	<.01
FFQ Year 5[8]	19	18.3	11.6	16	22.0	17.0	3.7	4.8	0.50
FFQ Year 6[9]	17	13.6	7.1	21	27.7	10.9	14.1	3.1	<.01
FFQ Year 7[10]	8	17.0	6.7	6	22.1	13.3	5.1	5.4	0.41
4DFR Baseline	24	19.1	6.9	44	21.4	12.3	2.4	2.7	0.87
4DFR Year 1	18	9.0	4.2	32	21.0	10.9	12.0	2.7	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	88	15.2	9.5	114	15.3	7.6	0.1	1.2	0.48
FFQ Year 1	73	9.4	6.3	96	12.7	8.5	3.3	1.2	<.01
FFQ Year 2	28	8.9	6.6	32	14.0	8.8	5.1	2.0	<.01
FFQ Year 3	18	10.2	5.8	41	14.0	7.9	3.8	2.1	0.10
FFQ Year 4	23	9.3	4.7	28	15.6	8.9	6.3	2.1	<.01
FFQ Year 5	19	9.7	3.9	16	11.8	8.2	2.0	2.1	0.64
FFQ Year 6	17	7.6	3.9	21	15.8	5.8	8.2	1.6	<.01
FFQ Year 7	8	9.0	3.9	6	13.2	5.4	4.2	2.5	0.12
4DFR Baseline	24	11.5	4.6	44	12.2	6.2	0.7	1.5	0.92
4DFR Year 1	18	6.9	3.8	32	13.6	9.6	6.7	2.4	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	88	3.5	1.9	114	3.0	1.6	0.4	0.2	0.23
FFQ Year 1	73	5.1	2.9	96	3.5	2.1	1.6	0.4	<.01
FFQ Year 2	28	5.2	3.3	32	3.3	1.6	1.9	0.7	0.05
FFQ Year 3	18	4.9	2.0	41	3.8	2.3	1.0	0.6	0.03
FFQ Year 4	23	5.1	3.1	28	4.0	2.1	1.1	0.7	0.25
FFQ Year 5	19	5.6	2.4	16	2.7	1.4	2.8	0.7	<.01
FFQ Year 6	17	4.7	3.2	21	3.7	2.3	1.0	0.9	0.42
FFQ Year 7	8	7.0	3.5	6	4.1	1.3	2.9	1.5	0.08
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	88	4.5	2.5	114	4.7	2.7	0.2	0.4	0.49
FFQ Year 1	73	5.5	3.4	96	4.2	2.3	1.3	0.4	0.02
FFQ Year 2	28	5.5	3.0	32	4.2	2.9	1.3	0.8	0.15
FFQ Year 3	18	4.2	2.6	41	4.2	2.5	0.0	0.7	0.76
FFQ Year 4	23	4.2	2.2	28	4.5	2.8	0.3	0.7	0.72
FFQ Year 5	19	4.6	2.4	16	3.8	2.2	0.8	0.8	0.26
FFQ Year 6	17	3.1	2.1	21	4.6	2.4	1.5	0.8	0.08
FFQ Year 7	8	5.2	2.7	6	3.4	1.8	1.7	1.3	0.23

(continues)

[1] Insufficient sample size for FFQ Year 8.
[2] Absolute difference.
[3] P-values based on testing in the natural log scale except for % Energy from fat.
[4] 14 (19%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 1.
[5] 6 (21%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 2.
[6] 1 (5%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 3.
[7] 5 (22%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 4.
[8] 3 (16%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 5.
[9] 2 (12%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 6.
[10] 2 (25%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 7.

Table 3.3 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women

Data as of: August 31, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	431	37.7	4.4	674	38.4	4.7	0.7	0.3	0.02
FFQ Year 1[3]	409	25.8	7.3	629	36.1	6.6	10.3	0.4	<.01
FFQ Year 2[4]	147	27.2	7.4	213	36.1	6.9	8.9	0.8	<.01
FFQ Year 3[5]	107	28.1	7.5	152	36.3	6.4	8.2	0.9	<.01
FFQ Year 4[6]	106	29.6	8.3	188	37.4	6.7	7.8	0.9	<.01
FFQ Year 5[7]	118	28.6	8.0	189	37.1	7.2	8.5	0.9	<.01
FFQ Year 6[8]	63	28.9	7.4	111	38.2	6.3	9.3	1.1	<.01
FFQ Year 7[9]	11	26.7	8.5	18	38.2	6.9	11.5	2.9	<.01
FFQ Year 8[10]	2	31.6	8.2	4	36.9	9.4	5.3	7.9	0.54
4DFR Baseline	70	30.2	5.4	104	31.4	6.8	1.2	1.0	0.18
4DFR Year 1	68	21.5	7.6	88	31.6	5.8	10.1	1.1	<.01
Total Energy (kcal)									
FFQ Baseline	431	1699.9	722.7	674	1674.9	711.3	25.0	44.1	0.50
FFQ Year 1	409	1501.7	587.0	629	1523.7	635.3	22.0	39.2	0.94
FFQ Year 2	147	1512.0	636.7	213	1500.3	777.2	11.7	77.6	0.24
FFQ Year 3	107	1496.2	630.5	152	1414.8	582.8	81.5	76.1	0.28
FFQ Year 4	106	1475.7	616.6	188	1507.6	613.6	31.9	74.7	0.98
FFQ Year 5	118	1531.6	631.9	189	1515.2	834.4	16.4	89.5	0.24
FFQ Year 6	63	1458.7	521.7	111	1517.8	611.4	59.1	91.6	0.72
FFQ Year 7	11	1497.4	396.7	18	1352.1	443.6	145.3	163.4	0.26
FFQ Year 8	2	1539.9	473.9	4	882.7	301.8	657.2	305.5	0.16
4DFR Baseline	70	1683.3	400.1	104	1732.3	387.9	48.9	60.7	0.38
4DFR Year 1	68	1524.9	374.1	88	1619.6	397.2	94.7	62.5	0.12
Total Fat (g)									
FFQ Baseline	431	71.9	34.1	674	72.2	34.8	0.4	2.1	0.99
FFQ Year 1	409	43.5	23.5	629	62.3	31.4	18.9	1.8	<.01
FFQ Year 2	147	46.1	24.6	213	61.1	35.6	15.0	3.4	<.01
FFQ Year 3	107	47.3	28.0	152	57.7	28.0	10.3	3.5	<.01
FFQ Year 4	106	49.5	28.8	188	63.3	29.7	13.8	3.6	<.01
FFQ Year 5	118	50.1	29.5	189	63.3	39.8	13.1	4.3	<.01
FFQ Year 6	63	46.6	20.3	111	64.6	27.7	18.0	4.0	<.01
FFQ Year 7	11	46.4	26.2	18	59.3	28.7	12.9	10.6	0.15
FFQ Year 8	2	56.2	30.6	4	36.9	17.2	19.3	18.5	0.47
4DFR Baseline	70	57.1	19.1	104	61.8	23.4	4.7	3.4	0.24
4DFR Year 1	68	36.6	17.4	88	57.6	19.9	21.0	3.0	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 99 (24%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 1.
[4] 24 (16%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 2.
[5] 18 (17%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 3.
[6] 12 (11%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 4.
[7] 15 (13%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 5.
[8] 5 (8%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 6.
[9] 3 (27%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 7.
[10] 0 (0%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 8.

Table 3.3 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women

Data as of: August 31, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	431	22.8	12.0	674	22.9	12.0	0.1	0.7	0.94
FFQ Year 1[3]	409	13.5	8.0	629	19.5	10.8	6.0	0.6	<.01
FFQ Year 2[4]	147	14.3	8.5	213	19.2	11.9	5.0	1.1	<.01
FFQ Year 3[5]	107	14.8	10.1	152	18.1	9.8	3.3	1.3	<.01
FFQ Year 4[6]	106	15.4	10.1	188	19.9	9.6	4.5	1.2	<.01
FFQ Year 5[7]	118	15.7	10.0	189	19.9	13.7	4.2	1.5	<.01
FFQ Year 6[8]	63	14.3	7.2	111	20.2	9.5	5.9	1.4	<.01
FFQ Year 7[9]	11	14.6	9.8	18	19.3	11.2	4.7	4.1	0.15
FFQ Year 8[10]	2	16.8	9.8	4	11.0	5.0	5.8	5.6	0.51
4DFR Baseline	70	17.2	7.1	104	18.8	8.4	1.7	1.2	0.26
4DFR Year 1	68	10.5	5.5	88	17.7	7.2	7.2	1.0	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	431	15.6	7.4	674	15.7	7.8	0.0	0.5	0.54
FFQ Year 1	409	9.1	5.0	629	13.6	7.2	4.5	0.4	<.01
FFQ Year 2	147	9.8	5.5	213	13.0	8.0	3.2	0.8	<.01
FFQ Year 3	107	10.1	5.7	152	12.1	6.1	2.0	0.7	<.01
FFQ Year 4	106	10.8	6.2	188	13.4	6.5	2.6	0.8	<.01
FFQ Year 5	118	10.7	7.4	189	13.5	8.2	2.8	0.9	<.01
FFQ Year 6	63	10.1	5.2	111	14.0	6.0	3.9	0.9	<.01
FFQ Year 7	11	9.8	5.2	18	11.5	5.2	1.6	2.0	0.37
FFQ Year 8	2	11.5	5.4	4	6.3	3.1	5.2	3.3	0.27
4DFR Baseline	70	13.1	5.3	104	14.6	6.5	1.5	0.9	0.12
4DFR Year 1	68	8.8	4.4	88	12.9	5.9	4.1	0.9	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	429	3.4	1.7	674	3.3	1.9	0.1	0.1	0.26
FFQ Year 1	407	4.7	2.4	629	3.5	1.9	1.2	0.1	<.01
FFQ Year 2	146	4.8	2.7	213	3.4	1.9	1.4	0.2	<.01
FFQ Year 3	107	5.0	2.5	152	3.4	2.1	1.5	0.3	<.01
FFQ Year 4	105	4.7	2.4	188	3.2	1.9	1.5	0.3	<.01
FFQ Year 5	118	5.1	2.3	189	3.5	2.0	1.5	0.3	<.01
FFQ Year 6	63	5.0	2.4	111	3.6	2.0	1.4	0.3	<.01
FFQ Year 7	11	5.3	1.8	18	2.9	1.4	2.4	0.6	<.01
FFQ Year 8	2	7.0	0.6	4	2.0	1.0	5.0	0.8	0.01
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	429	5.0	2.6	674	4.8	2.3	0.2	0.1	0.43
FFQ Year 1	407	5.8	2.7	629	4.5	2.1	1.3	0.2	<.01
FFQ Year 2	146	5.4	2.7	213	4.3	2.4	1.1	0.3	<.01
FFQ Year 3	107	5.1	2.4	152	4.2	2.2	0.9	0.3	<.01
FFQ Year 4	105	5.1	2.4	188	4.4	2.2	0.6	0.3	<.01
FFQ Year 5	118	5.1	2.3	189	4.5	3.1	0.6	0.3	<.01
FFQ Year 6	63	5.0	2.4	111	4.3	2.2	0.7	0.4	0.06
FFQ Year 7	11	5.9	2.4	18	3.6	1.2	2.3	0.7	<.01
FFQ Year 8	2	5.5	0.5	4	2.5	1.2	2.9	0.9	0.06

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 99 (24%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 1.
[4] 24 (16%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 2.
[5] 18 (17%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 3.
[6] 12 (11%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 4.
[7] 15 (13%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 5.
[8] 5 (8%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 6.
[9] 3 (27%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 7.
[10] 0 (0%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 8.

Table 3.3 (continued)
Nutrient Intake Monitoring in Black/African American Women

Data as of: August 31, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	2135	39.7	5.3	3127	39.9	5.2	0.1	0.1	0.41
FFQ Year 1[3]	1860	28.0	8.4	2628	36.9	7.4	8.8	0.2	<.01
FFQ Year 2[4]	612	29.4	8.0	829	36.4	7.3	7.0	0.4	<.01
FFQ Year 3[5]	351	29.4	7.9	514	38.2	7.2	8.8	0.5	<.01
FFQ Year 4[6]	483	30.7	8.3	766	37.6	7.4	6.9	0.4	<.01
FFQ Year 5[7]	481	31.2	8.5	715	37.5	7.6	6.3	0.5	<.01
FFQ Year 6[8]	427	30.9	8.1	651	37.3	7.6	6.5	0.5	<.01
FFQ Year 7[9]	103	31.7	7.5	178	37.1	6.5	5.4	0.9	<.01
FFQ Year 8[10]	17	33.2	8.5	28	36.2	7.3	3.1	2.4	0.22
4DFR Baseline	243	34.0	6.7	371	34.2	6.9	0.2	0.6	0.76
4DFR Year 1	219	23.5	7.9	307	34.2	7.0	10.8	0.7	<.01
Total Energy (kcal)									
FFQ Baseline	2135	1744.4	826.9	3127	1739.4	834.9	5.0	23.3	0.72
FFQ Year 1	1860	1382.7	633.4	2628	1492.6	774.7	109.9	21.8	<.01
FFQ Year 2	612	1392.3	717.6	829	1449.0	724.7	56.6	38.5	0.35
FFQ Year 3	351	1391.5	636.9	514	1537.1	791.3	145.5	50.7	0.02
FFQ Year 4	483	1341.1	623.0	766	1439.8	745.9	98.7	40.7	0.07
FFQ Year 5	481	1387.2	644.7	715	1368.9	688.9	18.2	39.6	0.59
FFQ Year 6	427	1306.3	561.9	651	1383.1	812.6	76.9	45.1	0.51
FFQ Year 7	103	1296.7	536.6	178	1349.1	727.8	52.4	82.2	0.99
FFQ Year 8	17	1338.9	852.7	28	1469.6	839.9	130.7	259.7	0.66
4DFR Baseline	243	1704.3	526.0	371	1651.0	478.3	53.4	41.1	0.32
4DFR Year 1	219	1345.6	341.6	307	1584.5	481.8	239.0	38.0	<.01
Total Fat (g)									
FFQ Baseline	2135	77.7	40.7	3127	77.8	41.3	0.1	1.2	0.92
FFQ Year 1	1860	43.6	26.8	2628	62.3	37.2	18.7	1.0	<.01
FFQ Year 2	612	46.4	32.5	829	60.1	36.0	13.7	1.8	<.01
FFQ Year 3	351	46.4	27.3	514	66.3	38.6	19.9	2.4	<.01
FFQ Year 4	483	46.1	26.7	766	61.1	35.8	15.0	1.9	<.01
FFQ Year 5	481	48.4	27.3	715	58.3	34.8	9.9	1.9	<.01
FFQ Year 6	427	45.4	24.9	651	58.6	40.5	13.2	2.2	<.01
FFQ Year 7	103	45.9	24.0	178	57.0	34.8	11.0	3.9	0.01
FFQ Year 8	17	50.3	36.8	28	60.7	42.0	10.4	12.3	0.39
4DFR Baseline	243	65.1	25.7	371	63.9	26.3	1.2	2.2	0.54
4DFR Year 1	219	34.9	14.7	307	61.5	25.7	26.6	1.9	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 323 (17%) Black/African American Intervention women had <=20% energy from fat at year 1.
[4] 80 (13%) Black/African American Intervention women had <=20% energy from fat at year 2.
[5] 46 (13%) Black/African American Intervention women had <=20% energy from fat at year 3.
[6] 54 (11%) Black/African American Intervention women had <=20% energy from fat at year 4.
[7] 38 (8%) Black/African American Intervention women had <=20% energy from fat at year 5.
[8] 37 (9%) Black/African American Intervention women had <=20% energy from fat at year 6.
[9] 4 (4%) Black/African American Intervention women had <=20% energy from fat at year 7.
[10] 1 (6%) Black/African American Intervention women had <=20% energy from fat at year 8.

Table 3.3 (continued)
Nutrient Intake Monitoring in Black/African American Women

Data as of: August 31, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	2135	25.8	14.3	3127	25.9	14.7	0.1	0.4	0.91
FFQ Year 1[3]	1860	14.3	9.2	2628	20.5	12.8	6.2	0.3	<.01
FFQ Year 2[4]	612	15.3	11.8	829	19.8	12.3	4.5	0.6	<.01
FFQ Year 3[5]	351	15.1	9.6	514	21.8	13.4	6.7	0.8	<.01
FFQ Year 4[6]	483	14.8	9.2	766	20.1	12.5	5.3	0.7	<.01
FFQ Year 5[7]	481	15.6	9.3	715	19.0	12.2	3.4	0.7	<.01
FFQ Year 6[8]	427	14.6	8.4	651	19.2	14.1	4.6	0.8	<.01
FFQ Year 7[9]	103	14.9	8.9	178	19.0	12.3	4.1	1.4	<.01
FFQ Year 8[10]	17	16.6	13.6	28	19.7	14.3	3.0	4.3	0.46
4DFR Baseline	243	20.3	9.3	371	20.2	9.1	0.1	0.8	0.96
4DFR Year 1	219	10.6	5.2	307	18.7	8.2	8.1	0.6	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	2135	16.0	8.9	3127	16.0	8.9	0.0	0.3	0.98
FFQ Year 1	1860	8.7	5.6	2628	12.7	8.0	4.0	0.2	<.01
FFQ Year 2	612	9.1	6.2	829	12.1	7.5	2.9	0.4	<.01
FFQ Year 3	351	9.3	5.6	514	13.4	8.0	4.1	0.5	<.01
FFQ Year 4	483	9.5	5.7	766	12.4	7.6	3.0	0.4	<.01
FFQ Year 5	481	9.8	5.7	715	12.1	7.8	2.3	0.4	<.01
FFQ Year 6	427	9.3	5.6	651	12.0	8.2	2.7	0.5	<.01
FFQ Year 7	103	9.5	5.1	178	11.4	6.9	1.9	0.8	0.04
FFQ Year 8	17	10.2	7.9	28	12.4	8.6	2.2	2.6	0.32
4DFR Baseline	243	14.5	6.7	371	13.8	6.7	0.7	0.6	0.15
4DFR Year 1	219	7.6	3.2	307	13.7	6.9	6.1	0.5	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	2132	3.3	1.9	3123	3.2	1.9	0.0	0.1	0.73
FFQ Year 1	1854	4.5	2.6	2622	3.4	2.1	1.1	0.1	<.01
FFQ Year 2	611	4.5	2.6	824	3.5	2.2	1.0	0.1	<.01
FFQ Year 3	351	4.8	2.7	514	3.7	2.3	1.0	0.2	<.01
FFQ Year 4	483	4.8	2.7	766	3.4	2.2	1.3	0.1	<.01
FFQ Year 5	479	4.7	2.8	714	3.4	2.1	1.3	0.1	<.01
FFQ Year 6	427	4.6	2.6	649	3.5	2.1	1.1	0.1	<.01
FFQ Year 7	103	4.6	2.6	177	3.5	2.1	1.1	0.3	<.01
FFQ Year 8	17	4.8	2.6	28	3.3	2.0	1.6	0.7	0.13
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	2132	4.5	2.7	3122	4.4	2.8	0.1	0.1	0.32
FFQ Year 1	1853	4.4	2.8	2620	3.8	2.5	0.6	0.1	<.01
FFQ Year 2	611	4.2	2.6	823	3.7	2.4	0.4	0.1	<.01
FFQ Year 3	351	4.2	2.7	514	3.8	2.5	0.4	0.2	0.01
FFQ Year 4	483	4.0	2.5	764	3.6	2.4	0.4	0.1	<.01
FFQ Year 5	478	4.0	2.6	713	3.4	2.2	0.6	0.1	<.01
FFQ Year 6	427	3.7	2.2	648	3.3	2.2	0.4	0.1	<.01
FFQ Year 7	103	3.5	1.7	177	3.4	2.3	0.1	0.3	0.26
FFQ Year 8	17	3.2	1.5	28	3.8	2.6	0.6	0.7	0.75

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 323 (17%) Black/African American Intervention women had <=20% energy from fat at year 1.
[4] 80 (13%) Black/African American Intervention women had <=20% energy from fat at year 2.
[5] 46 (13%) Black/African American Intervention women had <=20% energy from fat at year 3.
[6] 54 (11%) Black/African American Intervention women had <=20% energy from fat at year 4.
[7] 38 (8%) Black/African American Intervention women had <=20% energy from fat at year 5.
[8] 37 (9%) Black/African American Intervention women had <=20% energy from fat at year 6.
[9] 4 (4%) Black/African American Intervention women had <=20% energy from fat at year 7.
[10] 1 (6%) Black/African American Intervention women had <=20% energy from fat at year 8.

Table 3.3 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women

Data as of: August 31, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	751	39.3	5.1	1094	39.0	5.1	0.4	0.2	0.13
FFQ Year 1[3]	617	27.9	8.0	914	36.1	7.4	8.2	0.4	<.01
FFQ Year 2[4]	226	27.7	8.3	304	36.9	7.5	9.2	0.7	<.01
FFQ Year 3[5]	131	29.9	8.9	195	37.2	7.3	7.3	0.9	<.01
FFQ Year 4[6]	162	30.7	8.1	292	36.9	7.1	6.2	0.7	<.01
FFQ Year 5[7]	160	29.5	8.4	260	36.4	7.4	7.0	0.8	<.01
FFQ Year 6[8]	106	29.7	8.4	186	37.2	6.2	7.4	0.9	<.01
FFQ Year 7[9]	31	30.9	9.8	47	37.0	6.6	6.1	1.9	<.01
FFQ Year 8[10]	7	25.3	4.4	17	34.8	5.6	9.5	2.4	<.01
4DFR Baseline	96	32.4	5.7	134	32.4	6.5	0.1	0.8	0.95
4DFR Year 1	82	23.1	7.4	110	32.0	7.3	8.9	1.1	<.01
Total Energy (kcal)									
FFQ Baseline	751	1846.5	836.1	1094	1859.3	870.7	12.8	40.6	0.86
FFQ Year 1	617	1418.6	665.0	914	1569.9	862.5	151.2	41.1	<.01
FFQ Year 2	226	1411.2	614.8	304	1625.8	772.1	214.6	62.3	<.01
FFQ Year 3	131	1534.3	638.4	195	1576.7	710.7	42.4	77.1	0.80
FFQ Year 4	162	1382.2	652.6	292	1531.8	759.0	149.6	70.8	0.03
FFQ Year 5	160	1400.6	678.6	260	1566.3	878.8	165.7	81.2	0.08
FFQ Year 6	106	1333.9	718.3	186	1508.6	762.7	174.7	90.9	0.03
FFQ Year 7	31	1203.9	373.4	47	1419.4	571.3	215.4	116.3	0.12
FFQ Year 8	7	1583.6	817.8	17	1442.7	693.8	141.0	327.7	0.70
4DFR Baseline	96	1643.3	446.4	134	1748.5	460.0	105.2	60.8	0.06
4DFR Year 1	82	1399.8	412.1	110	1627.1	448.8	227.3	63.3	<.01
Total Fat (g)									
FFQ Baseline	751	81.6	41.0	1094	80.8	40.5	0.8	1.9	0.56
FFQ Year 1	617	44.5	27.2	914	64.3	41.2	19.8	1.9	<.01
FFQ Year 2	226	43.7	24.3	304	68.3	38.6	24.5	2.9	<.01
FFQ Year 3	131	52.3	31.8	195	66.1	34.8	13.8	3.8	<.01
FFQ Year 4	162	47.6	27.4	292	63.7	35.6	16.1	3.2	<.01
FFQ Year 5	160	47.1	30.7	260	65.4	42.9	18.3	3.9	<.01
FFQ Year 6	106	44.1	27.4	186	62.9	35.3	18.8	4.0	<.01
FFQ Year 7	31	40.9	17.0	47	58.3	25.9	17.4	5.3	<.01
FFQ Year 7	7	43.2	21.0	17	55.9	28.6	12.8	12.0	0.33
4DFR Baseline	96	59.6	20.1	134	64.1	25.6	4.5	3.1	0.22
4DFR Year 1	82	36.4	17.7	110	58.9	24.5	22.5	3.2	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 106 (17%) Hispanic/Latino Intervention women had <=20% energy from fat at year 1.
[4] 45 (20%) Hispanic/Latino Intervention women had <=20% energy from fat at year 2.
[5] 14 (11%) Hispanic/Latino Intervention women had <=20% energy from fat at year 3.
[6] 16 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 4.
[7] 21 (13%) Hispanic/Latino Intervention women had <=20% energy from fat at year 5.
[8] 12 (11%) Hispanic/Latino Intervention women had <=20% energy from fat at year 6.
[9] 3 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 7.
[10] 0 (0%) Hispanic/Latino Intervention women had <=20% energy from fat at year 8.

Table 3.3 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women

Data as of: August 31, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	751	27.8	14.9	1094	27.7	15.1	0.1	0.7	0.65
FFQ Year 1[3]	617	15.0	9.8	914	21.7	14.3	6.7	0.7	<.01
FFQ Year 2[4]	226	14.4	8.4	304	23.1	14.2	8.7	1.1	<.01
FFQ Year 3[5]	131	17.4	12.0	195	22.1	12.5	4.8	1.4	<.01
FFQ Year 4[6]	162	15.6	9.8	292	21.2	12.4	5.7	1.1	<.01
FFQ Year 5[7]	160	15.7	10.7	260	22.2	15.1	6.5	1.4	<.01
FFQ Year 6[8]	106	14.3	9.8	186	21.4	13.1	7.0	1.5	<.01
FFQ Year 7[9]	31	13.1	5.5	47	19.2	8.5	6.1	1.7	<.01
FFQ Year 8[10]	7	14.7	9.1	17	18.6	8.6	3.9	3.9	0.29
4DFR Baseline	96	19.8	7.6	134	20.9	10.0	1.1	1.2	0.57
4DFR Year 1	82	11.5	6.7	110	19.4	8.9	7.9	1.2	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	751	15.9	8.4	1094	15.7	8.2	0.2	0.4	0.48
FFQ Year 1	617	8.6	5.5	914	12.7	8.6	4.2	0.4	<.01
FFQ Year 2	226	8.7	5.3	304	13.4	8.2	4.7	0.6	<.01
FFQ Year 3	131	10.4	6.5	195	12.9	7.4	2.5	0.8	<.01
FFQ Year 4	162	9.3	5.5	292	12.5	7.2	3.2	0.6	<.01
FFQ Year 5	160	9.2	6.7	260	12.6	8.9	3.4	0.8	<.01
FFQ Year 6	106	8.9	5.6	186	12.1	6.9	3.2	0.8	<.01
FFQ Year 7	31	8.6	4.6	47	11.4	6.0	2.8	1.3	0.02
FFQ Year 8	7	8.1	4.0	17	10.4	6.4	2.4	2.6	0.44
4DFR Baseline	96	11.5	4.6	134	13.4	6.2	1.9	0.7	0.02
4DFR Year 1	82	7.8	4.1	110	12.0	6.3	4.2	0.8	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	748	3.0	1.9	1094	2.9	1.8	0.1	0.1	0.27
FFQ Year 1	614	4.2	2.3	914	3.1	1.9	1.0	0.1	<.01
FFQ Year 2	224	4.4	2.4	304	3.2	1.7	1.2	0.2	<.01
FFQ Year 3	130	4.6	2.9	195	3.4	2.0	1.3	0.3	<.01
FFQ Year 4	162	4.7	2.7	292	3.1	2.1	1.6	0.2	<.01
FFQ Year 5	159	4.5	2.4	260	3.3	2.2	1.1	0.2	<.01
FFQ Year 6	105	4.6	2.6	186	3.1	2.0	1.6	0.3	<.01
FFQ Year 7	31	4.1	3.0	47	3.2	2.1	0.9	0.6	0.11
FFQ Year 8	7	5.8	3.3	17	3.0	1.7	2.8	1.0	0.02
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	748	5.5	3.3	1094	5.7	3.5	0.2	0.2	0.54
FFQ Year 1	614	5.1	3.3	914	4.8	3.4	0.3	0.2	0.06
FFQ Year 2	224	5.0	3.5	304	4.9	3.1	0.0	0.3	0.48
FFQ Year 3	130	5.1	3.0	195	4.7	2.9	0.4	0.3	0.32
FFQ Year 4	162	4.3	2.9	292	4.6	2.9	0.3	0.3	0.16
FFQ Year 5	159	4.3	3.0	260	4.8	3.4	0.5	0.3	0.17
FFQ Year 6	105	4.6	3.5	186	4.7	3.3	0.1	0.4	0.55
FFQ Year 7	31	3.9	2.4	47	4.5	2.6	0.6	0.6	0.22
FFQ Year 8	7	5.4	3.8	17	5.1	3.8	0.3	1.7	0.72

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 106 (17%) Hispanic/Latino Intervention women had <=20% energy from fat at year 1.
[4] 45 (20%) Hispanic/Latino Intervention women had <=20% energy from fat at year 2.
[5] 14 (11%) Hispanic/Latino Intervention women had <=20% energy from fat at year 3.
[6] 16 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 4.
[7] 21 (13%) Hispanic/Latino Intervention women had <=20% energy from fat at year 5.
[8] 12 (11%) Hispanic/Latino Intervention women had <=20% energy from fat at year 6.
[9] 3 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 7.
[10] 0 (0%) Hispanic/Latino Intervention women had <=20% energy from fat at year 8.

Table 3.3 (continued)
Nutrient Intake Monitoring in White Women

Data as of: August 31, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	15871	38.7	5.0	23891	38.7	4.9	0.0	0.1	0.93
FFQ Year 1[3]	14899	24.6	7.3	22151	36.0	6.8	11.3	0.1	<.01
FFQ Year 2[4]	4831	25.8	7.5	7166	36.2	7.0	10.3	0.1	<.01
FFQ Year 3[5]	2588	27.3	7.8	3931	37.2	7.1	9.9	0.2	<.01
FFQ Year 4[6]	4180	28.1	8.0	6449	37.6	7.0	9.5	0.1	<.01
FFQ Year 5[7]	4074	28.7	8.1	6259	37.9	7.3	9.3	0.2	<.01
FFQ Year 6[8]	3092	29.2	8.1	4677	37.6	7.0	8.4	0.2	<.01
FFQ Year 7[9]	1358	29.8	8.0	2036	37.6	7.1	7.8	0.3	<.01
FFQ Year 8[10]	337	29.6	8.1	562	37.7	7.3	8.0	0.5	<.01
4DFR Baseline	442	32.6	6.5	669	32.6	6.7	0.1	0.4	0.88
4DFR Year 1	405	20.4	6.7	610	32.5	6.6	12.1	0.4	<.01
Total Energy (kcal)									
FFQ Baseline	15871	1795.1	687.8	23891	1797.1	677.4	2.0	7.0	0.62
FFQ Year 1	14899	1485.5	509.0	22151	1599.0	611.3	113.5	6.1	<.01
FFQ Year 2	4831	1493.0	497.0	7166	1590.4	597.6	97.4	10.4	<.01
FFQ Year 3	2588	1484.5	512.1	3931	1583.5	618.6	99.0	14.6	<.01
FFQ Year 4	4180	1457.4	515.8	6449	1579.5	610.2	122.2	11.4	<.01
FFQ Year 5	4074	1474.7	516.5	6259	1586.0	612.2	111.4	11.6	<.01
FFQ Year 6	3092	1480.2	536.6	4677	1561.9	599.4	81.8	13.3	<.01
FFQ Year 7	1358	1471.8	528.3	2036	1564.5	620.0	92.7	20.5	<.01
FFQ Year 8	337	1424.0	482.9	562	1560.3	612.0	136.4	39.1	<.01
4DFR Baseline	442	1744.2	422.9	669	1740.7	447.9	3.6	26.9	0.68
4DFR Year 1	405	1461.2	331.5	610	1652.6	428.1	191.4	25.2	<.01
Total Fat (g)									
FFQ Baseline	15871	77.8	34.1	23891	77.9	33.4	0.0	0.3	0.65
FFQ Year 1	14899	40.9	20.6	22151	64.8	30.5	23.9	0.3	<.01
FFQ Year 2	4831	43.0	20.2	7166	64.9	30.1	21.9	0.5	<.01
FFQ Year 3	2588	45.3	22.5	3931	66.3	31.5	21.0	0.7	<.01
FFQ Year 4	4180	46.0	23.2	6449	67.0	31.5	21.0	0.6	<.01
FFQ Year 5	4074	47.3	23.6	6259	67.8	31.9	20.4	0.6	<.01
FFQ Year 6	3092	48.3	23.8	4677	66.0	30.8	17.8	0.7	<.01
FFQ Year 7	1358	49.2	24.9	2036	66.4	32.0	17.2	1.0	<.01
FFQ Year 8	337	47.0	22.3	562	66.2	32.1	19.2	2.0	<.01
4DFR Baseline	442	64.1	23.9	669	64.0	23.5	0.2	1.5	0.81
4DFR Year 1	405	33.0	13.0	610	60.5	22.3	27.5	1.2	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 4373 (29%) White Intervention women had <=20% energy from fat at year 1.
[4] 1097 (23%) White Intervention women had <=20% energy from fat at year 2.
[5] 482 (19%) White Intervention women had <=20% energy from fat at year 3.
[6] 671 (16%) White Intervention women had <=20% energy from fat at year 4.
[7] 597 (15%) White Intervention women had <=20% energy from fat at year 5.
[8] 359 (12%) White Intervention women had <=20% energy from fat at year 6.
[9] 134 (10%) White Intervention women had <=20% energy from fat at year 7.
[10] 42 (12%) White Intervention women had <=20% energy from fat at year 8.

Table 3.3 (continued)
Nutrient Intake Monitoring in White Women

Data as of: August 31, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	15871	27.7	13.2	23891	27.6	12.8	0.1	0.1	0.95
FFQ Year 1[3]	14899	14.1	7.8	22151	22.9	11.6	8.8	0.1	<.01
FFQ Year 2[4]	4831	14.7	7.5	7166	22.9	11.4	8.1	0.2	<.01
FFQ Year 3[5]	2588	15.5	8.6	3931	23.4	12.0	7.8	0.3	<.01
FFQ Year 4[6]	4180	15.8	8.8	6449	23.7	12.1	7.9	0.2	<.01
FFQ Year 5[7]	4074	16.3	9.0	6259	24.0	12.2	7.7	0.2	<.01
FFQ Year 6[8]	3092	16.5	8.8	4677	23.4	12.0	6.8	0.3	<.01
FFQ Year 7[9]	1358	17.0	9.3	2036	23.5	12.5	6.5	0.4	<.01
FFQ Year 8[10]	337	16.4	8.9	562	23.6	13.4	7.2	0.8	<.01
4DFR Baseline	442	21.7	9.2	669	21.6	9.1	0.1	0.6	0.64
4DFR Year 1	405	10.4	4.7	610	20.2	8.3	9.8	0.5	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	15871	15.2	7.4	23891	15.2	7.3	0.0	0.1	0.48
FFQ Year 1	14899	7.7	4.1	22151	12.4	6.4	4.7	0.1	<.01
FFQ Year 2	4831	8.1	4.1	7166	12.3	6.2	4.2	0.1	<.01
FFQ Year 3	2588	8.6	4.4	3931	12.7	6.5	4.1	0.1	<.01
FFQ Year 4	4180	8.8	4.6	6449	12.8	6.5	4.0	0.1	<.01
FFQ Year 5	4074	9.1	4.8	6259	13.0	6.6	3.9	0.1	<.01
FFQ Year 6	3092	9.3	5.0	4677	12.6	6.2	3.2	0.1	<.01
FFQ Year 7	1358	9.4	5.1	2036	12.7	6.4	3.3	0.2	<.01
FFQ Year 8	337	8.9	4.2	562	12.5	5.9	3.5	0.4	<.01
4DFR Baseline	442	12.9	5.5	669	13.2	5.7	0.3	0.3	0.51
4DFR Year 1	405	7.1	3.1	610	12.4	5.6	5.3	0.3	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	15809	3.7	1.8	23818	3.7	1.8	0.0	0.0	0.17
FFQ Year 1	14830	5.2	2.3	22076	3.9	2.0	1.2	0.0	<.01
FFQ Year 2	4813	5.2	2.3	7139	4.0	2.0	1.2	0.0	<.01
FFQ Year 3	2583	5.3	2.4	3917	4.0	2.0	1.3	0.1	<.01
FFQ Year 4	4172	5.2	2.4	6435	3.9	2.0	1.3	0.0	<.01
FFQ Year 5	4055	5.2	2.4	6235	3.9	2.1	1.3	0.0	<.01
FFQ Year 6	3072	5.2	2.4	4656	3.9	2.0	1.3	0.1	<.01
FFQ Year 7	1347	5.0	2.4	2028	3.8	1.9	1.2	0.1	<.01
FFQ Year 8	335	5.1	2.4	561	3.8	2.0	1.2	0.1	<.01
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	15807	4.7	2.4	23817	4.8	2.4	0.0	0.0	0.21
FFQ Year 1	14827	5.1	2.6	22068	4.2	2.2	0.9	0.0	<.01
FFQ Year 2	4812	5.0	2.4	7134	4.1	2.1	0.8	0.0	<.01
FFQ Year 3	2582	4.6	2.5	3912	3.9	2.1	0.7	0.1	<.01
FFQ Year 4	4168	4.4	2.3	6425	3.9	2.1	0.6	0.0	<.01
FFQ Year 5	4052	4.4	2.2	6228	3.9	2.0	0.5	0.0	<.01
FFQ Year 6	3072	4.4	2.4	4654	3.8	2.0	0.6	0.1	<.01
FFQ Year 7	1347	4.3	2.3	2027	3.8	2.0	0.5	0.1	<.01
FFQ Year 8	335	4.0	2.1	561	3.7	1.9	0.3	0.1	0.10

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 4373 (29%) White Intervention women had <=20% energy from fat at year 1.
[4] 1097 (23%) White Intervention women had <=20% energy from fat at year 2.
[5] 482 (19%) White Intervention women had <=20% energy from fat at year 3.
[6] 671 (16%) White Intervention women had <=20% energy from fat at year 4.
[7] 597 (15%) White Intervention women had <=20% energy from fat at year 5.
[8] 359 (12%) White Intervention women had <=20% energy from fat at year 6.
[9] 134 (10%) White Intervention women had <=20% energy from fat at year 7.
[10] 42 (12%) White Intervention women had <=20% energy from fat at year 8.

Table 3.3 (continued)
Nutrient Intake Monitoring in Unknown Race/Ethnicity

Data as of: August 31, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	265	39.1	5.3	394	39.2	5.1	0.1	0.4	0.79
FFQ Year 1[3]	240	27.7	8.0	354	35.9	7.7	8.3	0.7	<.01
FFQ Year 2[4]	79	27.2	7.9	123	37.3	6.9	10.2	1.1	<.01
FFQ Year 3[5]	46	29.1	7.4	59	37.8	8.2	8.6	1.5	<.01
FFQ Year 4[6]	71	29.2	8.2	111	37.0	7.1	7.8	1.1	<.01
FFQ Year 5[7]	56	29.0	8.9	80	38.2	7.7	9.3	1.4	<.01
FFQ Year 6[8]	36	30.3	8.3	70	39.0	6.6	8.6	1.5	<.01
FFQ Year 7[9]	10	32.6	7.8	18	37.9	7.8	5.3	3.1	0.10
FFQ Year 8[10]	2	32.9	10.8	6	32.0	7.7	0.9	6.8	0.92
4DFR Baseline	17	32.2	5.5	29	32.8	5.6	0.6	1.7	0.71
4DFR Year 1	13	22.8	8.9	24	33.6	6.5	10.8	2.6	<.01
Total Energy (kcal)									
FFQ Baseline	265	1796.2	774.8	394	1726.3	769.8	70.0	61.3	0.23
FFQ Year 1	240	1505.5	628.2	354	1501.5	639.0	4.1	53.1	0.66
FFQ Year 2	79	1463.9	583.5	123	1571.6	674.2	107.8	92.3	0.33
FFQ Year 3	46	1463.7	598.3	59	1477.1	725.4	13.4	132.3	1.00
FFQ Year 4	71	1388.5	616.5	111	1497.3	660.1	108.8	97.8	0.31
FFQ Year 5	56	1445.1	562.6	80	1419.5	572.1	25.6	99.0	0.59
FFQ Year 6	36	1653.8	533.8	70	1511.4	629.2	142.4	122.8	0.13
FFQ Year 7	10	1330.4	618.6	18	1849.1	924.2	518.7	327.8	0.11
FFQ Year 8	2	1599.1	1010.1	6	1035.9	456.6	563.2	478.8	0.55
4DFR Baseline	17	1504.1	288.3	29	1693.4	404.8	189.3	112.0	0.10
4DFR Year 1	13	1334.5	469.5	24	1541.7	334.5	207.2	133.0	0.13
Total Fat (g)									
FFQ Baseline	265	79.0	39.4	394	75.9	38.4	3.1	3.1	0.31
FFQ Year 1	240	46.7	28.0	354	60.7	31.5	14.0	2.5	<.01
FFQ Year 2	79	44.9	29.0	123	66.7	35.1	21.8	4.7	<.01
FFQ Year 3	46	46.2	21.0	59	62.8	35.9	16.6	6.0	<.01
FFQ Year 4	71	46.2	30.4	111	63.0	33.3	16.8	4.9	<.01
FFQ Year 5	56	47.5	27.5	80	60.9	28.4	13.4	4.9	<.01
FFQ Year 6	36	55.7	25.1	70	66.2	33.8	10.5	6.4	0.08
FFQ Year 7	10	44.2	11.9	18	77.7	42.2	33.5	13.7	<.01
FFQ Year 8	2	52.4	17.8	6	39.5	26.2	12.9	20.4	0.30
4DFR Baseline	17	54.4	16.8	29	61.8	17.4	7.4	5.2	0.18
4DFR Year 1	13	33.7	19.1	24	57.9	17.3	24.2	6.2	<.01

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 38 (16%) Unknown Intervention women had <=20% energy from fat at year 1.
[4] 16 (20%) Unknown Intervention women had <=20% energy from fat at year 2.
[5] 5 (11%) Unknown Intervention women had <=20% energy from fat at year 3.
[6] 11 (15%) Unknown Intervention women had <=20% energy from fat at year 4.
[7] 11 (20%) Unknown Intervention women had <=20% energy from fat at year 5.
[8] 4 (11%) Unknown Intervention women had <=20% energy from fat at year 6.
[9] 0 (0%) Unknown Intervention women had <=20% energy from fat at year 7.
[10] 0 (0%) Unknown Intervention women had <=20% energy from fat at year 8.

Table 3.3 (continued)
Nutrient Intake Monitoring in Unknown Race/Ethnicity

Data as of: August 31, 2002

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	265	27.2	14.6	394	26.3	14.2	0.9	1.1	0.47
FFQ Year 1[3]	240	15.4	9.4	354	20.9	11.7	5.5	0.9	<.01
FFQ Year 2[4]	79	15.3	10.7	123	23.2	12.6	7.9	1.7	<.01
FFQ Year 3[5]	46	15.3	7.9	59	20.9	13.0	5.6	2.2	0.01
FFQ Year 4[6]	71	15.2	10.3	111	21.8	12.3	6.6	1.8	<.01
FFQ Year 5[7]	56	15.6	9.2	80	20.8	10.5	5.2	1.7	<.01
FFQ Year 6[8]	36	18.2	9.7	70	22.3	12.4	4.1	2.4	0.04
FFQ Year 7[9]	10	15.7	4.7	18	28.3	16.5	12.6	5.4	0.01
FFQ Year 8[10]	2	16.6	7.8	6	13.1	8.9	3.5	7.2	0.48
4DFR Baseline	17	17.6	6.7	29	21.0	7.2	3.4	2.1	0.10
4DFR Year 1	13	11.3	8.7	24	18.9	5.7	7.6	2.4	<.01
Polyunsaturated Fat (g)									
FFQ Baseline	265	15.9	8.7	394	15.0	8.6	0.9	0.7	0.19
FFQ Year 1	240	9.0	6.0	354	11.9	6.8	2.8	0.5	<.01
FFQ Year 2	79	8.4	5.6	123	12.8	7.8	4.5	1.0	<.01
FFQ Year 3	46	9.0	4.1	59	13.1	7.9	4.1	1.3	<.01
FFQ Year 4	71	9.3	6.5	111	12.4	7.4	3.1	1.1	<.01
FFQ Year 5	56	9.5	5.7	80	12.0	6.2	2.4	1.0	0.02
FFQ Year 6	36	11.5	5.7	70	13.3	6.9	1.9	1.3	0.15
FFQ Year 7	10	7.7	2.2	18	14.5	8.9	6.8	2.9	<.01
FFQ Year 8	2	10.1	2.9	6	6.2	3.8	3.8	3.0	0.13
4DFR Baseline	17	11.7	3.7	29	12.5	4.4	0.8	1.3	0.59
4DFR Year 1	13	6.6	3.1	24	11.8	4.3	5.2	1.4	<.01
Fruits and Vegetables (servings)									
FFQ Baseline	264	3.7	2.0	393	3.4	2.0	0.2	0.2	0.04
FFQ Year 1	239	4.9	2.4	353	3.6	2.0	1.3	0.2	<.01
FFQ Year 2	78	5.0	2.2	123	3.9	2.3	1.1	0.3	<.01
FFQ Year 3	46	5.0	2.6	59	3.7	1.9	1.3	0.4	<.01
FFQ Year 4	70	5.1	2.7	111	4.0	2.1	1.1	0.4	0.02
FFQ Year 5	56	4.8	2.6	80	3.5	2.2	1.4	0.4	<.01
FFQ Year 6	35	5.7	2.4	70	4.1	2.1	1.6	0.5	<.01
FFQ Year 7	10	4.3	2.9	18	6.2	3.7	2.0	1.3	0.19
FFQ Year 8	2	4.4	3.1	6	5.1	2.9	0.7	2.4	0.88
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	264	4.8	2.7	393	4.7	2.7	0.1	0.2	0.71
FFQ Year 1	239	5.0	3.0	353	4.2	2.4	0.8	0.2	<.01
FFQ Year 2	78	4.7	2.4	123	4.2	2.3	0.4	0.3	0.31
FFQ Year 3	46	4.7	3.0	59	4.2	2.8	0.5	0.6	0.41
FFQ Year 4	70	4.2	2.5	111	3.9	2.1	0.3	0.3	0.65
FFQ Year 5	56	4.6	2.3	80	3.8	2.3	0.8	0.4	0.04
FFQ Year 6	35	5.1	2.5	70	3.5	1.9	1.6	0.4	<.01
FFQ Year 7	10	4.5	3.3	18	4.1	2.3	0.3	1.1	0.87
FFQ Year 8	2	6.0	4.1	6	1.9	1.1	4.1	1.6	0.15

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 38 (16%) Unknown Intervention women had <=20% energy from fat at year 1.
[4] 16 (20%) Unknown Intervention women had <=20% energy from fat at year 2.
[5] 5 (11%) Unknown Intervention women had <=20% energy from fat at year 3.
[6] 11 (15%) Unknown Intervention women had <=20% energy from fat at year 4.
[7] 11 (20%) Unknown Intervention women had <=20% energy from fat at year 5.
[8] 4 (11%) Unknown Intervention women had <=20% energy from fat at year 6.
[9] 0 (0%) Unknown Intervention women had <=20% energy from fat at year 7.
[10] 0 (0%) Unknown Intervention women had <=20% energy from fat at year 8.

Table 3.4
Control - Intervention Difference in % Energy from Fat in WHI DM Participants
Study Subject Characteristics and Session Participation from FFQs Collected in the Last Year[1]

Data as of: August 31, 2002

	Model Including Attendance				Model Including Completion				Model Including Fat Scores			
	N	C – I (%)	R^2	(ΔR^2) for Inclusion	N	C – I (%)	R^2	(ΔR^2) for Inclusion	N	C – I (%)	R^2	(ΔR^2) for Inclusion
Demographics			20.0%				20.0%				20.0%	
Age												
60-69	5922				5922				5922			
50-54 vs. 60-69	2011	0.27			2011	0.39			2011	0.45		
55-59 vs. 60-69	3116	0.21			3116	0.19			3116	0.11		
70-79 vs. 60-69	1993	-0.99 *			1993	-0.73			1993	-0.87 *		
Ethnicity												
White	10810				10810				10810			
American Indian vs. White	38	5.09 *			38	5.74 *			38	6.35 **		
Asian/Pacific Islander vs. White	285	-1.46			285	-1.51			285	-1.66		
Black vs. White	1318	-1.61 **			1318	-1.72 **			1318	-1.27 *		
Hispanic vs. White	425	-1.49			425	-1.36			425	-1.37		
Unknown vs. White	166	0.53			166	0.32			166	0.47		
Education												
Post H.S.	10354				10354				10354			
0-8 Years vs. Post H.S.	139	-0.40			139	-0.05			139	0.15		
Some H.S. or Diploma vs. Post H.S.	2549	-0.17			2549	0.03			2549	-0.16		
Family Income												
≥75K	2317				2317				2317			
<20K vs. ≥75K	2242	0.10			2242	0.07			2242	0.10		
20-35K vs. ≥75K	2975	0.46			2975	0.43			2975	0.46		
35-50K vs. ≥75K	2790	0.39			2790	0.47			2790	0.28		
50-75K vs. ≥75K	2718	0.16			2718	0.09			2718	0.00		
HRT Randomized												
No	10916				10916				10916			
Yes vs. No	2126	0.34			2126	0.36			2126	0.46		
Visit			21.0%	(1.0%)			21.0%	(1.0%)			21.0%	(1.0%)
Visit Year												
AV-4	1823				1823				1823			
AV-3 vs. AV-4	69	-2.06			69	-2.04			69	-1.80		
AV-5 vs. AV-4	3928	-0.05			3928	-0.32			3928	-0.24		
AV-6 vs. AV-4	4179	-0.15			4179	-0.51			4179	-0.27		
AV-7 vs. AV-4	2081	-0.80 *			2081	-1.08 **			2081	-0.96 *		
AV-8 vs. AV-4	957	-0.07			957	-0.40			957	-0.33		
Clinic Effect			24.9%	(3.9%)			24.9%	(3.9%)			24.9%	(3.9%)
Intervention Participation												
# Sessions Attended in Previous 12 Months			29.3%	(4.3%)								
None	9576											
1 vs. None	631	4.13 **										
2 vs. None	916	4.87 **										
3 vs. None	1070	6.23 **										
4+ vs. None	849	7.56 **										
# Sessions Completed in Previous 12 Months							29.4%	(4.5%)				
None					8827							
1 vs. None					330	2.47 **						
2 vs. None					408	4.08 **						
3 vs. None					786	5.43 **						
4+ vs. None					2691	7.78 **						
# Fat Scores Provided in Previous 12 Months											30.1%	(5.2%)
None									9728			
1 vs. None									509	3.25 **		
2 vs. None									551	4.46 **		
3 vs. None									702	6.02 **		
4+ vs. None									1552	7.68 **		

[1] Model adjusted for clinic effects.
* P-value <0.05 from a two-sided test.
** P-value <0.01 from a two-sided test.

Table 3.5
Body Weight

Data as of: August 31, 2002

Body Weight (kg)[1]	Intervention			Control			Difference		
	N	Mean	S.D.	N	Mean	S.D.	Mean[2]	S.E.	p-value
All Participants									
Baseline	19523	76.8	16.7	29271	76.7	16.5	-0.1	0.2	0.36
Year 1	18149	74.4	16.8	26681	76.3	16.8	1.9	0.2	<.01
Year 2	16706	75.3	17.2	25053	76.7	16.9	1.4	0.2	<.01
Year 3	16670	75.7	17.1	25388	76.8	16.8	1.1	0.2	<.01
Year 4	15747	76.0	17.1	24311	76.7	16.7	0.7	0.2	<.01
Year 5	12462	76.0	17.0	19244	76.7	16.8	0.7	0.2	<.01
Year 6	7846	76.1	16.7	12102	76.6	16.4	0.5	0.2	0.04
Year 7	3492	75.9	16.6	5352	75.9	16.0	0.1	0.4	0.88
Year 8	1040	74.9	16.1	1692	75.3	15.4	0.4	0.6	0.57
Participants Aged 70-79									
Baseline	3246	73.0	14.7	4870	72.9	14.5	-0.1	0.3	0.82
Year 1	3010	70.7	15.2	4486	72.6	15.4	1.9	0.4	<.01
Year 2	2787	71.0	15.0	4172	72.6	15.3	1.6	0.4	<.01
Year 3	2754	71.1	15.4	4197	72.2	14.8	1.1	0.4	<.01
Year 4	2550	71.0	15.1	3913	71.7	14.4	0.7	0.4	0.07
Year 5	1834	70.4	14.5	2846	71.2	14.4	0.8	0.4	0.06
Year 6	978	69.7	14.4	1541	70.5	13.9	0.7	0.6	0.20
Year 7	414	69.8	14.9	668	69.9	13.6	0.2	0.9	0.86
Year 8	107	68.6	13.8	192	69.7	15.6	1.2	1.8	0.50

[1] Shown for 30 <= weight (kg) <= 220.
[2] Control – Intervention.

Table 3.5 (continued)
Body Weight by Race/Ethnicity

Data as of: August 31, 2002

Body Weight (kg)[1]	Intervention N	Intervention Mean	Intervention S.D.	Control N	Control Mean	Control S.D.	Difference Mean[2]	Difference S.E.	Difference p-value
American Indian/ Alaskan Native									
Baseline	87	77.8	14.4	114	80.9	17.0	3.1	2.3	0.17
Year 1	74	75.6	15.0	93	81.3	16.9	5.7	2.5	0.02
Year 2	66	76.9	18.7	91	83.5	18.1	6.6	3.0	0.03
Year 3	67	75.5	15.5	95	83.6	17.5	8.1	2.7	<.01
Year 4	65	76.2	15.6	88	84.1	18.7	7.9	2.9	<.01
Year 5	57	77.4	15.4	65	85.0	17.4	7.6	3.0	0.01
Year 6	37	74.6	14.9	43	84.9	15.8	10.3	3.5	<.01
Year 7	14	76.1	16.8	16	78.0	12.9	1.9	5.4	0.73
Year 8	5	70.2	8.4	2	72.3	8.8	2.1	7.1	0.80
Asian/Pacific Islander									
Baseline	431	63.4	13.2	674	63.4	14.4	-0.1	0.9	0.93
Year 1	414	62.5	14.7	636	62.8	12.9	0.3	0.9	0.78
Year 2	392	62.7	14.1	615	63.0	12.4	0.3	0.8	0.73
Year 3	392	63.1	13.5	614	63.9	14.7	0.7	0.9	0.43
Year 4	366	63.2	12.6	608	63.8	13.8	0.5	0.9	0.54
Year 5	280	62.7	13.5	453	63.5	12.6	0.8	1.0	0.44
Year 6	141	61.7	12.5	240	62.2	13.3	0.6	1.4	0.67
Year 7	34	64.0	21.0	45	64.2	17.1	0.2	4.3	0.96
Year 8	9	62.6	7.8	6	59.1	7.9	-3.5	4.1	0.42
Black/African American									
Baseline	2133	85.3	18.2	3126	85.1	18.5	-0.1	0.5	0.79
Year 1	1891	84.3	19.3	2662	84.9	19.0	0.6	0.6	0.27
Year 2	1715	84.9	18.8	2503	85.2	19.0	0.4	0.6	0.51
Year 3	1698	85.3	19.4	2509	85.2	18.8	-0.1	0.6	0.90
Year 4	1578	85.4	19.1	2364	85.5	18.3	0.1	0.6	0.91
Year 5	1228	85.8	19.4	1845	85.8	19.1	0.0	0.7	0.98
Year 6	781	84.6	18.4	1182	85.2	18.4	0.6	0.8	0.49
Year 7	321	83.8	18.7	449	84.5	18.2	0.7	1.3	0.62
Year 8	50	80.9	14.8	88	82.1	15.9	1.2	2.8	0.67
Hispanic/Latino									
Baseline	750	75.2	16.0	1094	73.7	15.2	-1.5	0.7	0.05
Year 1	638	74.2	16.6	935	73.2	15.5	-1.0	0.8	0.22
Year 2	570	74.4	16.1	864	73.9	15.8	-0.4	0.9	0.63
Year 3	545	75.3	16.9	866	74.3	16.5	-1.0	0.9	0.28
Year 4	512	75.6	16.8	831	73.8	15.2	-1.7	0.9	0.06
Year 5	418	75.1	16.5	659	74.2	14.5	-0.9	1.0	0.34
Year 6	239	76.2	17.6	376	74.8	14.2	-1.4	1.3	0.29
Year 7	80	74.2	15.5	124	70.9	14.4	-3.2	2.1	0.13
Year 8	25	75.0	12.6	43	69.9	14.9	-5.1	3.6	0.14

[1] Shown for 30 <= weight (kg) <= 220.
[2] Control – Intervention.

Table 3.5 (continued)
Body Weight by Race/Ethnicity

Data as of: August 31, 2002

Body Weight (kg)[1]	Intervention			Control			Difference		
	N	Mean	S.D.	N	Mean	S.D.	Mean[2]	S.E.	p-value
White									
Baseline	15857	76.1	16.1	23869	76.1	15.9	-0.0	0.2	0.87
Year 1	14893	73.5	15.9	22010	75.8	16.2	2.3	0.2	<.01
Year 2	13757	74.5	16.6	20656	76.2	16.3	1.6	0.2	<.01
Year 3	13762	74.9	16.5	20983	76.2	16.2	1.3	0.2	<.01
Year 4	13031	75.2	16.5	20104	76.2	16.2	1.0	0.2	<.01
Year 5	10344	75.3	16.3	16002	76.1	16.2	0.8	0.2	<.01
Year 6	6580	75.4	16.1	10134	75.9	15.8	0.6	0.3	0.02
Year 7	3019	75.2	16.0	4669	75.3	15.5	0.2	0.4	0.62
Year 8	944	74.7	16.2	1537	75.1	15.3	0.4	0.6	0.56
Unknown									
Baseline	265	78.3	18.4	394	76.4	16.8	-1.9	1.4	0.18
Year 1	239	77.6	20.4	345	77.0	18.0	-0.6	1.6	0.71
Year 2	206	76.2	18.7	324	77.3	18.5	1.1	1.7	0.52
Year 3	206	77.0	17.6	321	77.1	18.2	0.1	1.6	0.93
Year 4	195	76.4	18.2	316	76.6	16.3	0.2	1.6	0.90
Year 5	135	75.7	16.3	220	77.3	19.6	1.6	2.0	0.42
Year 6	68	78.4	18.6	127	76.5	19.3	-1.9	2.9	0.49
Year 7	24	82.3	17.6	49	76.6	16.4	-5.7	4.2	0.19
Year 8	7	81.0	17.8	16	77.5	17.9	-3.5	8.1	0.68

[1] Shown for 30 <= weight (kg) <= 220.
[2] Control – Intervention.

Table 3.6
Reasons for Stopping DM[1]

Data as of: August 31, 2002

Reasons[2]	(N = 2331)	
Personal/family		
Demands of work	241	10.3%
Family illness, emergency, or other family demands[3]	288	12.4%
Financial problems	9	0.4%
Lack of cooperation/support from family/friends[4]	39	1.7%
Living in nursing home	23	1.0%
Issues of interest in study[5]	229	9.8%
Travel		
Too far to CC	113	4.8%
Moved out of area or refuses to be followed at another CC	17	0.7%
Other Travel Issues[6]	63	2.7%
Visits & Procedures		
Doesn't like visits/calls	44	1.9%
Doesn't like required forms or safety procedures[7]	44	1.9%
Problems with other procedures[8]	9	0.4%
Worried about health effects of medical tests/procedures	3	0.1%
Wants test results[9]	0	0.0%
Problems with the CC[10]	32	1.4%

(continues)

[1] Does not include reasons reported by women who stopped and later restarted DM Intervention.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Family illness, emergency or other family demands", "Death in the family or of a close friend", and "Caregiver responsibilities demanding time, effort, lifestyle changes".
[4] Combines "Lack of cooperation/support from family and/or friends" and "Family/friends request that she withdraw".
[5] Combines "Conflicting priorities other than work or family", "Feels discouraged regarding participation overall", "Loss of interest, boredom", "Feels it is not an important study", and "In another study in conflict with WHI intervention".
[6] Combines "Transportation problems (other than distance)", "Traffic", "Parking at CC", and "CC neighborhood/safety".
[7] Combines "Doesn't like filling out forms (other than those required for safety)", and "Doesn't like required safety forms and/or procedures".
[8] Combines "Doesn't like mammograms", "Cost of mammograms", "Doesn't like having blood drawn", "Doesn't like ECG", "Doesn't like gynecologic procedures" and "Doesn't like other procedures (other than those required for safety)".
[9] Combines "Wants results of blood analyses", and "Wants results of bone mineral density measurement".
[10] Combines "Problem with the CC", "Problem with CC staff person (other than DM Group Nutritionist)", and "Staff change/turnover".

Table 3.6 (continued)
Reasons for Stopping DM[1]

Data as of: August 31, 2002

Reasons[2]	(N = 2331)	
Symptoms		
GI Problems[3]	2	< 0.1%
Hair/Skin Changes	1	< 0.1%
Weight loss/gain	5	0.2%
HRT Related Symptoms[4]	4	0.2%
Other[5]	7	0.3%
Health Conditions		
Disease and/or health conditions[6]	81	3.5%
Communication difficulties[7]	47	2.0%
Intervention		
Doesn't like randomized nature of intervention	11	0.5%
Expected some benefit from intervention	32	1.4%
Feels guilty/unhappy or like a failure for not meeting study goals	19	0.8%
Pill Issues[8]	5	0.2%
CaD Issues[9]	1	< 0.1%
HRT Issues[10]	3	0.1%
Problem with DM group nutritionist or group members	31	1.3%
Doesn't like attending DM intervention classes	63	2.7%
Doesn't like self-monitoring	43	1.8%
Doesn't like budgeting fat grams	4	0.2%
Health concerns regarding long-term risk/benefits of low fat diet	17	0.7%
Unhappy that not losing weight	17	0.7%
Not in control of meal preparation	11	0.5%
Too difficult to meet or maintain dietary goals	41	1.8%
Doesn't like eating low fat diet	29	1.2%
Doesn't like eating 5 vegetables/fruits per day	2	< 0.1%
Doesn't like eating 6 grains per day	7	0.3%
Feels fat gram goal is unrealistic	6	0.3%
Eating pattern conflicts with personal health beliefs	26	1.1%
Other Health Issues		
Worried about costs if adverse effects occur	1	< 0.1%
Expected more health care	14	0.6%
Advised not to participate by health care provider[11]	21	0.9%
Study conflicts with other health issues[12]	29	1.2%
Other		
Other reasons not listed above	459	19.7%
Refuses to give a reason	93	4.0%

[1] Does not include reasons reported by women who stopped and later restarted DM Intervention.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Bloating/Gas", "Constipation", and "Other gastrointestinal problems".
[4] Combines "Vaginal bleeding", "Breast tenderness", "Other breast changes", "Vaginal changes (e.g., dryness)", and "Hot flashes/night sweats".
[5] Combines "Headaches", "Low energy/too tired", "Possible allergic reaction", and "Other symptoms not listed above".
[6] Combines "Breast cancer", "Complex or atypical hyperplasia", "Endometrial cancer", "Deep vein thrombosis", "Pulmonary embolism", "Gallbladder disease", "Hypercalcemia", "Kidney failure/dialysis", "Renal calculi", "High triglycerides (> 1000 mg/dl)", "Malignant melanoma", "Meningioma", "Heart attack", "Stroke", "Arthritis", "Diabetes", "Depression", "Cholesterol (high or concern about levels)", "Osteoporosis", and "Other health conditions not listed above".
[7] Combines "Communication problem", "Loss of vision and/or hearing", and "Cognitive/memory changes".
[8] Combines "Doesn't like taking pills", "Doesn't like taste of pills", "Unable to swallow pills", and "Takes too many pills".
[9] Combines "Wants to take her own calcium", "Feels diet is already sufficient in calcium/Vitamin D", "Taking more than the maximum allowable IU of Vit D", and "Taking Calcitriol".
[10] Combines "Has made a personal decision to go on active HRT", "Has made a personal decision that she does not want to be on HRT", "Advised to go on active HRT by health care provider", "Advised to not be on active HRT by health care provider", "Has made a personal decision to go on SERM (e.g., Evista/raloxifene, tamoxifen)", "Advised to go on SERM (e.g., Evista/raloxifene, tamoxifen) by health care provider", and "Taking testosterone medications".
[11] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason".
[12] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues".

Table 3.7
Reasons for Stopping DM by Age at Screening and Race/Ethnicity[1]

Data as of August 31, 2002

	All (N = 19,541)		Age at Screening: 50 – 54 (N = 2,783)		55 –59 (N = 4,424)		60 –69 (N = 9,086)		70 –79 (N = 3,248)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping Intervention	2331	11.9%	370	13.3%	528	11.9%	948	10.4%	485	14.9%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	288	12.4%	47	12.7%	71	13.4%	114	12.0%	56	11.5%
Demands of work	241	10.3%	76	20.5%	71	13.4%	78	8.2%	16	3.3%
Issues of interest in study[6]	229	9.8%	35	9.5%	58	11.0%	92	9.7%	44	9.1%
Too far to CC	113	4.8%	25	6.8%	33	6.3%	41	4.3%	14	2.9%
Other ("Other reasons not listed above")	459	19.7%	77	20.8%	129	24.4%	180	19.0%	73	15.1%

	Race/Ethnicity: American Indian/ Alaskan (N = 88)		Asian/Pacific Islander (N = 431)		Black/African American (N = 2,135)		Hispanic/Latino (N = 751)		White (N = 15,871)		Unknown (N = 265)	
	N	%[7]	N	%[7]	N	%[7]	N	%[7]	N	%[7]	N	%[7]
Women Stopping Intervention	21	23.9%	52	12.1%	323	15.1%	163	21.7%	1725	10.9%	47	17.7%
REASONS FOR STOPPING[3]	N	%[8]	N	%[8]	N	%[8]	N	%[8]	N	%[8]	N	%[8]
Family illness, emergency, or other family demands[5]	2	9.5%	3	5.8%	34	10.5%	25	15.3%	218	12.6%	6	12.8%
Demands of work	1	4.8%	5	9.6%	47	14.6%	17	10.4%	167	9.7%	4	8.5%
Issues of interest in study[6]	3	14.3%	5	9.6%	36	11.1%	7	4.3%	175	10.1%	3	6.4%
Too far to CC	2	9.5%	2	3.8%	6	1.9%	6	3.7%	96	5.6%	1	2.1%
Other ("Other reasons not listed above")	5	23.8%	8	15.4%	50	15.5%	49	30.1%	339	19.7%	8	17.0%

[1] Does not include reasons reported by women who stopped and later restarted DM intervention.
[2] Percentages are of DM intervention participants in the same age category.
[3] Multiple reasons may be reported for a woman.
[4] Percentages are of DM intervention participants in the same age category who stopped DM intervention.
[5] Combines "Family illness, emergency or other family demands", "Death in the family or of a close friend", and "Caregiver responsibilities demanding time, effort, lifestyle changes".
[6] Combines "Conflicting priorities other than work or family", "Feels discouraged regarding participation overall", "Loss of interest, boredom", "Feels it is not an important study", and "In another study in conflict with WHI intervention".
[7] Percentages are of DM intervention participants in the same race/ethnicity category.
[8] Percentages are of DM intervention participants in the same race/ethnicity category who stopped DM intervention.

Table 3.8
Blood Specimen Analysis: DM Participants

Data as of: August 31, 2002

	N	Mean[1]	S.D.[1]
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	2731	0.08	0.08
AV-1	2501	0.08	0.07
AV-3	2129	0.07	0.07
AV-1 – Baseline	2426	0.00	0.06
AV-3 – Baseline	2059	-0.01	0.07
Beta-Carotene (µg/ml)			
Baseline	2731	0.30	0.28
AV-1	2501	0.30	0.29
AV-3	2129	0.29	0.29
AV-1 – Baseline	2426	0.00	0.22
AV-3 – Baseline	2059	0.00	0.26
Alpha-tocopherol (µg/ml)			
Baseline	2731	16.28	7.30
AV-1	2501	16.96	7.52
AV-3	2129	18.16	7.74
AV-1 – Baseline	2426	0.76	5.49
AV-3 – Baseline	2059	1.95	6.73
Gamma-tocopherol (µg/ml)			
Baseline	2731	2.21	1.42
AV-1	2500	1.85	1.31
AV-3	2129	1.69	1.32
AV-1 – Baseline	2425	-0.36	0.92
AV-3 – Baseline	2059	-0.55	1.13
Beta-Cryptoxanthine (µg/ml)			
Baseline	2731	0.09	0.07
AV-1	2500	0.09	0.07
AV-3	2129	0.10	0.08
AV-1 – Baseline	2425	0.00	0.06
AV-3 – Baseline	2059	0.01	0.07
Lycopene (µg/ml)			
Baseline	2731	0.41	0.19
AV-1	2501	0.41	0.19
AV-3	2129	0.38	0.20
AV-1 – Baseline	2426	-0.01	0.16
AV-3 – Baseline	2059	-0.03	0.20
Lutein and Zeaxanthin (µg/ml)			
Baseline	2731	0.21	0.10
AV-1	2501	0.22	0.10
AV-3	2129	0.20	0.10
AV-1 – Baseline	2426	0.00	0.07
AV-3 – Baseline	2059	-0.02	0.08
Retinol (µg/ml)			
Baseline	2731	0.61	0.15
AV-1	2501	0.62	0.15
AV-3	2129	0.61	0.15
AV-1 – Baseline	2426	0.00	0.10
AV-3 – Baseline	2059	0.00	0.13

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 3.8 (continued)
Blood Specimen Analysis: DM Participants

Data as of: August 31, 2002

	N	Mean[1]	S.D.[1]
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	2640	130.69	32.41
AV-1	2399	130.70	32.64
AV-3	2033	132.25	33.27
AV-1 – Baseline	2276	-0.23	22.36
AV-3 – Baseline	1910	0.96	28.18
Factor VII C (%)[2]			
Baseline	2595	129.82	30.74
AV-1	2368	127.30	30.37
AV-3	2025	131.06	33.88
AV-1 – Baseline	2211	-2.82	22.49
AV-3 – Baseline	1865	0.85	28.35
Fibrinogen (mg/dl)			
Baseline	2630	299.80	60.77
AV-1	2392	297.57	60.62
AV-3	2034	289.37	59.12
AV-1 – Baseline	2264	-2.56	49.77
AV-3 – Baseline	1903	-10.72	52.91
Hormones/Other			
Glucose (mg/dl)			
Baseline	2729	100.17	26.76
AV-1	2493	98.81	26.23
AV-3	2155	99.36	26.86
AV-1 – Baseline	2418	-1.33	18.98
AV-3 – Baseline	2083	-1.00	21.12
Insulin (μIU/ml)			
Baseline	2661	11.69	8.77
AV-1	2431	11.30	10.33
AV-3	2066	12.79	10.10
AV-1 – Baseline	2320	-0.31	8.54
AV-3 – Baseline	1950	1.08	8.42

(continues)

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.
[2] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.8 (continued)
Blood Specimen Analysis: DM Participants

Data as of: August 31, 2002

	N	Mean[1]	S.D.[1]
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	2730	157.45	86.55
AV-1	2499	159.31	86.45
AV-3	2155	160.15	90.01
AV-1 – Baseline	2424	2.51	54.98
AV-3 – Baseline	2083	2.06	74.72
Total Cholesterol (mg/dl)			
Baseline	2730	224.13	38.13
AV-1	2499	217.41	37.32
AV-3	2155	215.56	35.67
AV-1 – Baseline	2424	-6.61	26.66
AV-3 – Baseline	2083	-8.33	32.09
LDL-C (mg/dl)			
Baseline	2680	133.82	35.18
AV-1	2454	126.49	34.05
AV-3	2121	125.45	33.69
AV-1 – Baseline	2360	-6.91	23.78
AV-3 – Baseline	2022	-7.69	29.33
HDL-C (mg/dl)			
Baseline	2722	59.05	15.68
AV-1	2497	59.28	15.30
AV-3	2155	58.82	15.68
AV-1 – Baseline	2416	-0.08	8.79
AV-3 – Baseline	2077	-0.40	9.95
HDL-2 (mg/dl)			
Baseline	2662	18.29	8.17
AV-1	2456	18.84	8.36
AV-3	2127	16.45	6.64
AV-1 – Baseline	2329	0.31	4.97
AV-3 – Baseline	2009	-1.90	5.63
HDL-3 (mg/dl)			
Baseline	2664	40.86	9.05
AV-1	2457	40.47	8.58
AV-3	2127	42.24	9.80
AV-1 – Baseline	2332	-0.51	5.55
AV-3 – Baseline	2011	1.42	6.98
Lp(a) (mg/dl)			
Baseline	2693	25.96	26.14
AV-1	2466	25.11	25.93
AV-3	2092	22.79	23.17
AV-1 – Baseline	2366	-0.66	10.22
AV-3 – Baseline	2002	-2.77	13.55

[1] Means and standard deviations are weighted by ethnicity using the ethnicity distribution of participants randomized to CT.

Table 3.9
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: August 31, 2002

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (μg/ml)			
Baseline	74	0.05	0.04
AV-1	58	0.06	0.05
AV-3	44	0.05	0.03
AV-1 – Baseline	57	0.01	0.04
AV-3 – Baseline	43	-0.01	0.03
Beta-Carotene (μg/ml)			
Baseline	74	0.25	0.24
AV-1	58	0.27	0.31
AV-3	44	0.21	0.14
AV-1 – Baseline	57	0.00	0.20
AV-3 – Baseline	43	-0.05	0.19
Alpha-tocopherol (μg/ml)			
Baseline	74	18.18	10.41
AV-1	58	18.10	9.60
AV-3	44	16.36	6.42
AV-1 – Baseline	57	1.00	5.58
AV-3 – Baseline	43	-1.70	9.23
Gamma-tocopherol (μg/ml)			
Baseline	74	2.20	1.27
AV-1	58	1.80	1.22
AV-3	44	1.88	1.14
AV-1 – Baseline	57	-0.41	0.84
AV-3 – Baseline	43	-0.33	1.04
Beta-Cryptoxanthine (μg/ml)			
Baseline	74	0.07	0.04
AV-1	58	0.07	0.04
AV-3	44	0.08	0.04
AV-1 – Baseline	57	0.01	0.04
AV-3 – Baseline	43	0.02	0.04
Lycopene (μg/ml)			
Baseline	74	0.36	0.17
AV-1	58	0.35	0.16
AV-3	44	0.32	0.18
AV-1 – Baseline	57	0.00	0.13
AV-3 – Baseline	43	-0.05	0.19
Lutein and Zeaxanthin (μg/ml)			
Baseline	74	0.20	0.13
AV-1	58	0.20	0.10
AV-3	44	0.17	0.08
AV-1 – Baseline	57	0.00	0.06
AV-3 – Baseline	43	-0.01	0.05
Retinol (μg/ml)			
Baseline	74	0.61	0.15
AV-1	58	0.60	0.16
AV-3	44	0.56	0.13
AV-1 – Baseline	57	-0.01	0.08
AV-3 – Baseline	43	-0.04	0.13

(continues)

Table 3.9 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: August 31, 2002

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	71	136.94	31.58
AV-1	56	138.29	30.70
AV-3	45	137.31	32.47
AV-1 – Baseline	54	0.72	18.41
AV-3 – Baseline	43	-1.21	26.72
Factor VII C (%)[1]			
Baseline	71	131.42	29.79
AV-1	56	127.55	26.77
AV-3	45	133.64	34.30
AV-1 – Baseline	54	-2.04	14.64
AV-3 – Baseline	43	2.51	23.28
Fibrinogen (mg/dl)			
Baseline	71	305.41	66.58
AV-1	56	312.86	75.90
AV-3	45	298.40	62.33
AV-1 – Baseline	54	4.89	54.99
AV-3 – Baseline	43	-10.95	41.25
Hormones/Other			
Glucose (mg/dl)			
Baseline	74	105.54	33.02
AV-1	58	102.17	21.11
AV-3	46	106.35	28.25
AV-1 – Baseline	57	-3.11	17.66
AV-3 – Baseline	45	0.02	37.99
Insulin (μIU/ml)			
Baseline	69	13.31	7.90
AV-1	56	12.09	6.16
AV-3	42	14.90	9.80
AV-1 – Baseline	52	-1.10	4.70
AV-3 – Baseline	39	2.48	8.12

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.9 (continued)
Blood Specimen Analysis: American Indian/Alaskan Native Women

Data as of: August 31, 2002

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	73	183.51	91.72
AV-1	57	170.98	88.64
AV-3	46	174.30	98.36
AV-1 – Baseline	55	-1.87	52.17
AV-3 – Baseline	44	-14.73	73.94
Total Cholesterol (mg/dl)			
Baseline	73	218.42	34.36
AV-1	57	210.86	36.96
AV-3	46	204.35	38.88
AV-1 – Baseline	55	-7.84	23.63
AV-3 – Baseline	44	-13.61	29.59
LDL-C (mg/dl)			
Baseline	71	127.08	33.42
AV-1	54	123.00	33.59
AV-3	44	117.11	38.03
AV-1 – Baseline	52	-5.42	20.42
AV-3 – Baseline	42	-10.79	27.20
HDL-C (mg/dl)			
Baseline	73	55.62	15.88
AV-1	57	56.05	15.58
AV-3	46	54.59	13.84
AV-1 – Baseline	55	-0.07	7.51
AV-3 – Baseline	44	0.68	6.65
HDL-2 (mg/dl)			
Baseline	70	16.94	8.07
AV-1	56	17.41	7.86
AV-3	45	15.51	5.32
AV-1 – Baseline	52	0.27	4.41
AV-3 – Baseline	41	-1.07	3.67
HDL-3 (mg/dl)			
Baseline	71	38.83	8.31
AV-1	56	38.21	8.59
AV-3	45	39.71	8.60
AV-1 – Baseline	53	-0.25	5.01
AV-3 – Baseline	42	1.90	5.49
Lp(a) (mg/dl)			
Baseline	71	21.48	20.85
AV-1	56	20.38	19.84
AV-3	44	17.41	16.56
AV-1 – Baseline	54	0.69	9.69
AV-3 – Baseline	41	-4.56	12.13

(continues)

Table 3.9 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: August 31, 2002

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (μg/ml)			
Baseline	194	0.10	0.10
AV-1	176	0.10	0.10
AV-3	159	0.09	0.09
AV-1 – Baseline	174	0.00	0.10
AV-3 – Baseline	157	-0.02	0.09
Beta-Carotene (μg/ml)			
Baseline	194	0.44	0.42
AV-1	176	0.48	0.53
AV-3	159	0.46	0.59
AV-1 – Baseline	174	0.05	0.40
AV-3 – Baseline	157	0.02	0.47
Alpha-tocopherol (μg/ml)			
Baseline	194	19.35	9.96
AV-1	176	19.48	11.01
AV-3	159	22.11	11.59
AV-1 – Baseline	174	0.34	6.81
AV-3 – Baseline	157	3.14	9.71
Gamma-tocopherol (μg/ml)			
Baseline	194	1.68	1.18
AV-1	176	1.30	0.98
AV-3	159	1.16	0.89
AV-1 – Baseline	174	-0.38	0.85
AV-3 – Baseline	157	-0.58	0.90
Beta-Cryptoxanthine (μg/ml)			
Baseline	194	0.18	0.17
AV-1	176	0.19	0.18
AV-3	159	0.21	0.22
AV-1 – Baseline	174	0.01	0.14
AV-3 – Baseline	157	0.03	0.18
Lycopene (μg/ml)			
Baseline	194	0.38	0.21
AV-1	176	0.37	0.19
AV-3	159	0.33	0.22
AV-1 – Baseline	174	-0.02	0.18
AV-3 – Baseline	157	-0.05	0.22
Lutein and Zeaxanthin (μg/ml)			
Baseline	194	0.27	0.12
AV-1	176	0.28	0.12
AV-3	159	0.25	0.12
AV-1 – Baseline	174	0.01	0.09
AV-3 – Baseline	157	-0.02	0.09
Retinol (μg/ml)			
Baseline	194	0.61	0.14
AV-1	176	0.62	0.15
AV-3	159	0.61	0.14
AV-1 – Baseline	174	0.01	0.09
AV-3 – Baseline	157	0.01	0.12

(continues)

Table 3.9 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: August 31, 2002

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	188	130.96	29.85
AV-1	167	130.84	29.26
AV-3	150	135.85	31.95
AV-1 – Baseline	161	-0.96	20.48
AV-3 – Baseline	145	3.99	27.42
Factor VII C (%)[1]			
Baseline	188	126.67	24.61
AV-1	167	126.11	26.33
AV-3	150	132.81	28.93
AV-1 – Baseline	161	-1.03	18.59
AV-3 – Baseline	145	5.53	24.09
Fibrinogen (mg/dl)			
Baseline	189	290.03	57.67
AV-1	167	284.84	57.04
AV-3	151	277.07	58.12
AV-1 – Baseline	162	-6.69	53.11
AV-3 – Baseline	147	-10.56	53.92
Hormones/Other			
Glucose (mg/dl)			
Baseline	194	99.77	18.15
AV-1	176	100.55	23.78
AV-3	161	101.75	21.77
AV-1 – Baseline	174	0.29	19.27
AV-3 – Baseline	159	1.81	14.56
Insulin (μIU/ml)			
Baseline	188	10.24	5.58
AV-1	168	10.02	5.92
AV-3	154	11.66	6.16
AV-1 – Baseline	164	-0.28	3.78
AV-3 – Baseline	148	1.21	5.49

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.9 (continued)
Blood Specimen Analysis: Asian/Pacific Islander Women

Data as of: August 31, 2002

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	193	171.96	92.30
AV-1	176	172.70	94.01
AV-3	161	191.74	214.54
AV-1 – Baseline	173	0.05	60.11
AV-3 – Baseline	158	18.96	200.05
Total Cholesterol (mg/dl)			
Baseline	193	219.75	35.95
AV-1	176	213.29	33.31
AV-3	161	209.53	35.43
AV-1 – Baseline	173	-7.59	24.36
AV-3 – Baseline	158	-7.81	28.78
LDL-C (mg/dl)			
Baseline	186	127.87	34.91
AV-1	170	120.72	30.18
AV-3	155	116.52	31.49
AV-1 – Baseline	164	-8.60	25.08
AV-3 – Baseline	149	-8.34	26.91
HDL-C (mg/dl)			
Baseline	193	58.23	13.48
AV-1	176	59.91	14.05
AV-3	161	58.24	14.10
AV-1 – Baseline	173	1.27	8.38
AV-3 – Baseline	158	-0.65	9.74
HDL-2 (mg/dl)			
Baseline	189	18.05	7.21
AV-1	174	19.51	7.32
AV-3	159	16.14	5.48
AV-1 – Baseline	168	1.10	4.53
AV-3 – Baseline	152	-2.36	5.18
HDL-3 (mg/dl)			
Baseline	189	40.39	8.00
AV-1	174	40.50	8.34
AV-3	159	42.06	9.35
AV-1 – Baseline	168	0.17	5.36
AV-3 – Baseline	152	1.50	7.40
Lp(a) (mg/dl)			
Baseline	190	18.31	16.20
AV-1	175	16.41	14.04
AV-3	157	13.97	12.26
AV-1 – Baseline	170	-2.14	12.79
AV-3 – Baseline	151	-3.95	9.96

(continues)

Table 3.9 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: August 31, 2002

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	778	0.06	0.08
AV-1	696	0.07	0.07
AV-3	557	0.05	0.06
AV-1 – Baseline	674	0.00	0.06
AV-3 – Baseline	537	-0.01	0.05
Beta-Carotene (µg/ml)			
Baseline	778	0.31	0.34
AV-1	696	0.32	0.30
AV-3	557	0.31	0.34
AV-1 – Baseline	674	0.00	0.22
AV-3 – Baseline	537	0.01	0.25
Alpha-tocopherol (µg/ml)			
Baseline	778	13.95	6.04
AV-1	696	14.55	6.12
AV-3	557	15.18	6.62
AV-1 – Baseline	674	0.49	4.71
AV-3 – Baseline	537	1.31	5.78
Gamma-tocopherol (µg/ml)			
Baseline	778	2.54	1.35
AV-1	696	2.27	1.31
AV-3	557	2.11	1.30
AV-1 – Baseline	674	-0.20	0.91
AV-3 – Baseline	537	-0.42	1.05
Beta-Cryptoxanthine (µg/ml)			
Baseline	778	0.09	0.06
AV-1	696	0.09	0.06
AV-3	557	0.09	0.07
AV-1 – Baseline	674	0.00	0.06
AV-3 – Baseline	537	0.01	0.06
Lycopene (µg/ml)			
Baseline	778	0.40	0.21
AV-1	696	0.38	0.20
AV-3	557	0.36	0.21
AV-1 – Baseline	674	-0.01	0.19
AV-3 – Baseline	537	-0.03	0.22
Lutein and Zeaxanthin (µg/ml)			
Baseline	778	0.23	0.11
AV-1	696	0.24	0.11
AV-3	557	0.22	0.10
AV-1 – Baseline	674	0.01	0.08
AV-3 – Baseline	537	-0.01	0.09
Retinol (µg/ml)			
Baseline	778	0.55	0.15
AV-1	696	0.55	0.14
AV-3	557	0.56	0.16
AV-1 – Baseline	674	0.01	0.09
AV-3 – Baseline	537	0.01	0.12

(continues)

Table 3.9 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: August 31, 2002

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	750	114.89	27.06
AV-1	677	115.59	27.52
AV-3	534	119.17	29.25
AV-1 – Baseline	635	0.95	20.65
AV-3 – Baseline	498	3.93	25.52
Factor VII C (%)[1]			
Baseline	730	118.33	30.11
AV-1	665	116.40	26.76
AV-3	532	119.80	30.26
AV-1 – Baseline	609	-1.90	21.05
AV-3 – Baseline	479	0.68	27.63
Fibrinogen (mg/dl)			
Baseline	748	321.11	66.58
AV-1	677	319.59	66.77
AV-3	533	310.26	66.67
AV-1 – Baseline	635	-3.57	49.22
AV-3 – Baseline	496	-15.24	58.52
Hormones/Other			
Glucose (mg/dl)			
Baseline	778	106.88	37.04
AV-1	693	106.99	38.21
AV-3	568	105.63	34.86
AV-1 – Baseline	671	0.67	26.78
AV-3 – Baseline	547	-0.97	28.29
Insulin (μIU/ml)			
Baseline	766	14.32	17.77
AV-1	686	13.94	10.91
AV-3	549	15.72	18.62
AV-1 – Baseline	658	-0.23	6.17
AV-3 – Baseline	523	0.64	14.44

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.9 (continued)
Blood Specimen Analysis: Black/African American Women

Data as of: August 31, 2002

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	778	119.73	53.08
AV-1	696	118.90	48.12
AV-3	568	119.93	51.54
AV-1 – Baseline	674	0.63	36.49
AV-3 – Baseline	547	0.93	42.12
Total Cholesterol (mg/dl)			
Baseline	778	220.25	41.98
AV-1	696	216.28	41.42
AV-3	568	210.66	39.57
AV-1 – Baseline	674	-3.45	25.91
AV-3 – Baseline	547	-9.46	30.43
LDL-C (mg/dl)			
Baseline	777	137.81	39.42
AV-1	695	132.76	39.29
AV-3	568	128.01	37.13
AV-1 – Baseline	672	-4.55	24.25
AV-3 – Baseline	546	-9.63	29.48
HDL-C (mg/dl)			
Baseline	777	58.50	15.06
AV-1	696	59.79	15.02
AV-3	568	58.67	14.37
AV-1 – Baseline	673	0.97	8.15
AV-3 – Baseline	546	0.00	9.15
HDL-2 (mg/dl)			
Baseline	766	18.30	7.83
AV-1	689	19.38	8.63
AV-3	562	16.30	5.78
AV-1 – Baseline	657	0.79	4.96
AV-3 – Baseline	536	-1.96	5.45
HDL-3 (mg/dl)			
Baseline	766	40.18	8.64
AV-1	689	40.35	8.02
AV-3	562	42.41	9.51
AV-1 – Baseline	657	0.11	5.17
AV-3 – Baseline	536	1.99	6.46
Lp(a) (mg/dl)			
Baseline	766	38.57	27.55
AV-1	691	37.91	28.00
AV-3	552	34.13	24.40
AV-1 – Baseline	660	-0.06	11.97
AV-3 – Baseline	526	-3.43	18.56

(continues)

Table 3.9 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: August 31, 2002

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (μg/ml)			
Baseline	304	0.09	0.10
AV-1	268	0.09	0.07
AV-3	218	0.07	0.08
AV-1 – Baseline	261	0.00	0.10
AV-3 – Baseline	212	-0.02	0.11
Beta-Carotene (μg/ml)			
Baseline	304	0.30	0.41
AV-1	268	0.28	0.27
AV-3	218	0.25	0.26
AV-1 – Baseline	261	-0.01	0.35
AV-3 – Baseline	212	-0.07	0.38
Alpha-tocopherol (μg/ml)			
Baseline	304	15.99	7.06
AV-1	268	17.01	7.71
AV-3	218	17.21	7.45
AV-1 – Baseline	261	1.26	5.94
AV-3 – Baseline	212	0.95	6.62
Gamma-tocopherol (μg/ml)			
Baseline	304	2.12	1.35
AV-1	268	1.89	1.40
AV-3	218	1.86	1.38
AV-1 – Baseline	261	-0.25	0.94
AV-3 – Baseline	212	-0.35	1.06
Beta-Cryptoxanthine (μg/ml)			
Baseline	304	0.11	0.10
AV-1	268	0.11	0.09
AV-3	218	0.11	0.09
AV-1 – Baseline	261	-0.01	0.09
AV-3 – Baseline	212	0.00	0.09
Lycopene (μg/ml)			
Baseline	304	0.43	0.21
AV-1	268	0.41	0.19
AV-3	218	0.39	0.20
AV-1 – Baseline	261	-0.02	0.16
AV-3 – Baseline	212	-0.05	0.20
Lutein and Zeaxanthin (μg/ml)			
Baseline	304	0.20	0.10
AV-1	268	0.20	0.10
AV-3	218	0.19	0.08
AV-1 – Baseline	261	0.00	0.08
AV-3 – Baseline	212	-0.01	0.07
Retinol (μg/ml)			
Baseline	304	0.55	0.13
AV-1	268	0.57	0.13
AV-3	218	0.57	0.14
AV-1 – Baseline	261	0.02	0.09
AV-3 – Baseline	212	0.00	0.10

(continues)

Table 3.9 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: August 31, 2002

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	292	123.52	27.45
AV-1	254	124.28	28.84
AV-3	214	128.82	32.44
AV-1 – Baseline	241	2.02	21.59
AV-3 – Baseline	204	4.72	26.97
Factor VII C (%)[1]			
Baseline	285	123.49	28.28
AV-1	244	121.88	27.43
AV-3	212	127.29	31.84
AV-1 – Baseline	229	0.34	21.10
AV-3 – Baseline	197	3.26	27.76
Fibrinogen (mg/dl)			
Baseline	291	305.49	65.72
AV-1	253	309.02	70.72
AV-3	214	293.64	61.06
AV-1 – Baseline	240	-0.18	55.83
AV-3 – Baseline	203	-12.57	51.93
Hormones/Other			
Glucose (mg/dl)			
Baseline	303	101.84	32.88
AV-1	267	105.04	35.37
AV-3	222	107.11	37.99
AV-1 – Baseline	259	1.56	20.97
AV-3 – Baseline	215	2.50	19.05
Insulin (μIU/ml)			
Baseline	295	13.48	8.60
AV-1	264	13.29	11.77
AV-3	212	14.06	8.24
AV-1 – Baseline	252	-0.41	8.83
AV-3 – Baseline	201	0.79	6.66

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.9 (continued)
Blood Specimen Analysis: Hispanic/Latino Women

Data as of: August 31, 2002

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	304	162.20	74.64
AV-1	268	165.55	76.95
AV-3	222	177.91	104.86
AV-1 – Baseline	261	2.52	54.45
AV-3 – Baseline	216	11.35	79.87
Total Cholesterol (mg/dl)			
Baseline	304	217.42	34.74
AV-1	268	211.75	35.63
AV-3	222	212.96	35.07
AV-1 – Baseline	261	-4.50	25.14
AV-3 – Baseline	216	-4.80	29.44
LDL-C (mg/dl)			
Baseline	299	130.02	32.07
AV-1	263	124.25	33.22
AV-3	214	123.62	32.10
AV-1 – Baseline	254	-5.89	22.66
AV-3 – Baseline	205	-6.30	26.80
HDL-C (mg/dl)			
Baseline	304	55.16	13.69
AV-1	268	55.39	12.67
AV-3	222	55.46	14.16
AV-1 – Baseline	261	1.38	7.92
AV-3 – Baseline	216	0.53	8.87
HDL-2 (mg/dl)			
Baseline	299	16.27	6.53
AV-1	265	16.84	6.84
AV-3	220	15.25	5.64
AV-1 – Baseline	256	0.79	4.83
AV-3 – Baseline	210	-1.02	5.30
HDL-3 (mg/dl)			
Baseline	299	38.53	8.03
AV-1	265	38.54	7.60
AV-3	220	40.10	9.05
AV-1 – Baseline	256	0.67	5.16
AV-3 – Baseline	210	1.50	6.25
Lp(a) (mg/dl)			
Baseline	303	20.75	22.48
AV-1	264	19.30	19.99
AV-3	216	17.76	19.56
AV-1 – Baseline	257	-1.04	7.88
AV-3 – Baseline	210	-2.15	11.05

(continues)

Table 3.9 (continued)
Blood Specimen Analysis: White Women

Data as of: August 31, 2002

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (μg/ml)			
Baseline	1327	0.08	0.08
AV-1	1255	0.08	0.07
AV-3	1113	0.07	0.07
AV-1 – Baseline	1212	0.00	0.06
AV-3 – Baseline	1073	-0.01	0.07
Beta-Carotene (μg/ml)			
Baseline	1327	0.29	0.26
AV-1	1255	0.30	0.27
AV-3	1113	0.28	0.26
AV-1 – Baseline	1212	0.01	0.21
AV-3 – Baseline	1073	0.00	0.25
Alpha-tocopherol (μg/ml)			
Baseline	1327	16.46	7.23
AV-1	1255	17.16	7.43
AV-3	1113	18.48	7.61
AV-1 – Baseline	1212	0.79	5.50
AV-3 – Baseline	1073	2.09	6.68
Gamma-tocopherol (μg/ml)			
Baseline	1327	2.19	1.43
AV-1	1254	1.82	1.31
AV-3	1113	1.64	1.32
AV-1 – Baseline	1211	-0.39	0.93
AV-3 – Baseline	1073	-0.58	1.15
Beta-Cryptoxanthine (μg/ml)			
Baseline	1327	0.08	0.06
AV-1	1254	0.09	0.07
AV-3	1113	0.09	0.07
AV-1 – Baseline	1211	0.00	0.05
AV-3 – Baseline	1073	0.01	0.06
Lycopene (μg/ml)			
Baseline	1327	0.41	0.19
AV-1	1255	0.41	0.19
AV-3	1113	0.39	0.20
AV-1 – Baseline	1212	-0.01	0.16
AV-3 – Baseline	1073	-0.03	0.20
Lutein and Zeaxanthin (μg/ml)			
Baseline	1327	0.21	0.10
AV-1	1255	0.21	0.10
AV-3	1113	0.19	0.10
AV-1 – Baseline	1212	0.00	0.07
AV-3 – Baseline	1073	-0.02	0.08
Retinol (μg/ml)			
Baseline	1327	0.63	0.15
AV-1	1255	0.63	0.15
AV-3	1113	0.62	0.15
AV-1 – Baseline	1212	0.00	0.10
AV-3 – Baseline	1073	-0.01	0.13

(continues)

Table 3.9 (continued)
Blood Specimen Analysis: White Women

Data as of: August 31, 2002

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	1285	133.03	32.74
AV-1	1199	132.97	32.99
AV-3	1055	133.94	33.48
AV-1 – Baseline	1139	-0.47	22.67
AV-3 – Baseline	986	0.31	28.46
Factor VII C (%)[1]			
Baseline	1267	131.72	30.77
AV-1	1191	129.05	30.81
AV-3	1051	132.63	34.30
AV-1 – Baseline	1113	-3.18	22.90
AV-3 – Baseline	967	0.57	28.55
Fibrinogen (mg/dl)			
Baseline	1277	297.02	59.14
AV-1	1193	294.43	58.41
AV-3	1056	286.92	57.44
AV-1 – Baseline	1127	-2.46	49.42
AV-3 – Baseline	980	-9.98	52.33
Hormones/Other			
Glucose (mg/dl)			
Baseline	1326	99.21	24.82
AV-1	1251	97.36	23.57
AV-3	1120	97.99	24.79
AV-1 – Baseline	1209	-1.79	17.66
AV-3 – Baseline	1080	-1.35	19.99
Insulin (μIU/ml)			
Baseline	1289	11.31	6.90
AV-1	1209	10.90	10.28
AV-3	1072	12.37	8.61
AV-1 – Baseline	1146	-0.32	8.94
AV-3 – Baseline	1003	1.11	7.53

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.9 (continued)
Blood Specimen Analysis: White Women

Data as of: August 31, 2002

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	1329	161.16	88.95
AV-1	1255	163.56	89.10
AV-3	1120	163.10	84.58
AV-1 – Baseline	1214	2.93	56.73
AV-3 – Baseline	1081	1.35	69.94
Total Cholesterol (mg/dl)			
Baseline	1329	225.13	37.82
AV-1	1255	217.95	36.96
AV-3	1120	216.56	35.07
AV-1 – Baseline	1214	-7.11	26.89
AV-3 – Baseline	1081	-8.39	32.53
LDL-C (mg/dl)			
Baseline	1296	133.76	34.74
AV-1	1225	125.95	33.38
AV-3	1102	125.55	33.29
AV-1 – Baseline	1173	-7.27	23.73
AV-3 – Baseline	1044	-7.51	29.51
HDL-C (mg/dl)			
Baseline	1322	59.37	15.86
AV-1	1253	59.41	15.46
AV-3	1120	59.06	15.93
AV-1 – Baseline	1207	-0.33	8.91
AV-3 – Baseline	1076	-0.50	10.13
HDL-2 (mg/dl)			
Baseline	1285	18.40	8.27
AV-1	1225	18.86	8.40
AV-3	1103	16.54	6.82
AV-1 – Baseline	1149	0.20	4.97
AV-3 – Baseline	1033	-1.93	5.69
HDL-3 (mg/dl)			
Baseline	1286	41.11	9.18
AV-1	1226	40.60	8.70
AV-3	1103	42.36	9.88
AV-1 – Baseline	1151	-0.68	5.61
AV-3 – Baseline	1034	1.33	7.07
Lp(a) (mg/dl)			
Baseline	1309	24.94	25.94
AV-1	1234	24.15	25.81
AV-3	1086	21.97	23.08
AV-1 – Baseline	1179	-0.68	10.00
AV-3 – Baseline	1038	-2.66	12.82

(continues)

Table 3.9 (continued)
Blood Specimen Analysis: Unknown Women

Data as of: August 31, 2002

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (μg/ml)			
Baseline	54	0.08	0.08
AV-1	48	0.08	0.08
AV-3	38	0.08	0.09
AV-1 – Baseline	48	0.00	0.06
AV-3 – Baseline	37	0.00	0.06
Beta-Carotene (μg/ml)			
Baseline	54	0.27	0.22
AV-1	48	0.27	0.21
AV-3	38	0.29	0.26
AV-1 – Baseline	48	0.01	0.13
AV-3 – Baseline	37	0.04	0.24
Alpha-tocopherol (μg/ml)			
Baseline	54	17.31	9.14
AV-1	48	17.12	9.40
AV-3	38	17.84	8.97
AV-1 – Baseline	48	-0.32	6.54
AV-3 – Baseline	37	0.17	6.12
Gamma-tocopherol (μg/ml)			
Baseline	54	2.14	1.16
AV-1	48	2.01	1.05
AV-3	38	2.08	1.39
AV-1 – Baseline	48	-0.11	0.76
AV-3 – Baseline	37	0.03	0.91
Beta-Cryptoxanthine (μg/ml)			
Baseline	54	0.11	0.11
AV-1	48	0.10	0.06
AV-3	38	0.10	0.08
AV-1 – Baseline	48	-0.01	0.08
AV-3 – Baseline	37	0.00	0.07
Lycopene (μg/ml)			
Baseline	54	0.41	0.20
AV-1	48	0.40	0.20
AV-3	38	0.33	0.16
AV-1 – Baseline	48	-0.01	0.18
AV-3 – Baseline	37	-0.06	0.19
Lutein and Zeaxanthin (μg/ml)			
Baseline	54	0.22	0.12
AV-1	48	0.23	0.16
AV-3	38	0.22	0.11
AV-1 – Baseline	48	0.01	0.10
AV-3 – Baseline	37	-0.01	0.08
Retinol (μg/ml)			
Baseline	54	0.60	0.19
AV-1	48	0.59	0.15
AV-3	38	0.59	0.11
AV-1 – Baseline	48	0.00	0.11
AV-3 – Baseline	37	0.00	0.14

(continues)

Table 3.9 (continued)
Blood Specimen Analysis: Unknown Women

Data as of: August 31, 2002

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	54	122.80	29.36
AV-1	46	117.07	27.58
AV-3	35	127.14	29.11
AV-1 – Baseline	46	-2.28	24.54
AV-3 – Baseline	34	1.71	39.35
Factor VII C (%)[1]			
Baseline	54	124.19	29.15
AV-1	45	120.33	24.54
AV-3	35	126.20	30.24
AV-1 – Baseline	45	0.24	21.75
AV-3 – Baseline	34	1.47	36.76
Fibrinogen (mg/dl)			
Baseline	54	303.07	65.04
AV-1	46	299.48	64.12
AV-3	35	277.51	55.42
AV-1 – Baseline	46	-8.85	39.70
AV-3 – Baseline	34	-22.29	39.13
Hormones/Other			
Glucose (mg/dl)			
Baseline	54	98.13	24.54
AV-1	48	100.52	25.50
AV-3	38	105.21	35.68
AV-1 – Baseline	48	0.63	11.85
AV-3 – Baseline	37	7.62	29.80
Insulin (μIU/ml)			
Baseline	54	10.05	5.84
AV-1	48	10.77	5.60
AV-3	37	12.60	6.78
AV-1 – Baseline	48	0.44	3.29
AV-3 – Baseline	36	3.19	4.98

(continues)

[1] Factor VII C values greater than 300% are considered biologically implausible and are set to missing.

Table 3.9 (continued)
Blood Specimen Analysis: Unknown Women

Data as of: August 31, 2002

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	53	164.81	100.03
AV-1	47	156.70	77.06
AV-3	38	163.24	72.13
AV-1 – Baseline	47	-5.06	60.23
AV-3 – Baseline	37	-2.05	67.13
Total Cholesterol (mg/dl)			
Baseline	53	227.85	36.95
AV-1	47	228.19	34.97
AV-3	38	223.03	34.50
AV-1 – Baseline	47	-2.96	26.93
AV-3 – Baseline	37	-2.65	31.98
LDL-C (mg/dl)			
Baseline	51	135.41	35.38
AV-1	47	135.53	34.62
AV-3	38	129.97	33.15
AV-1 – Baseline	45	-1.62	24.69
AV-3 – Baseline	36	-2.83	31.09
HDL-C (mg/dl)			
Baseline	53	59.77	16.73
AV-1	47	61.23	15.74
AV-3	38	60.34	17.70
AV-1 – Baseline	47	0.81	9.88
AV-3 – Baseline	37	0.19	9.79
HDL-2 (mg/dl)			
Baseline	53	19.72	10.47
AV-1	47	20.62	10.35
AV-3	38	17.97	7.99
AV-1 – Baseline	47	0.38	6.46
AV-3 – Baseline	37	-2.16	7.02
HDL-3 (mg/dl)			
Baseline	53	40.06	7.72
AV-1	47	40.62	7.03
AV-3	38	42.37	10.51
AV-1 – Baseline	47	0.43	6.08
AV-3 – Baseline	37	2.35	6.72
Lp(a) (mg/dl)			
Baseline	54	23.89	29.23
AV-1	46	21.20	20.78
AV-3	37	21.03	20.21
AV-1 – Baseline	46	-0.57	9.08
AV-3 – Baseline	36	-3.78	29.11

Table 3.10
Bone Mineral Density[1] Analysis: DM Participants

Data as of: August 31, 2002

	N	Mean	S.D.
Whole Body Scan			
Baseline	3594	1.03	0.11
AV1	3261	1.03	0.11
AV3	3077	1.04	0.11
AV6	2286	1.05	0.12
AV1 % Change from baseline BMD[2]	3220	0.17	2.49
AV3 % Change from baseline BMD[3]	3038	1.27	3.58
AV6 % Change from baseline BMD[4]	2253	2.34	5.30
Spine Scan			
Baseline	3515	0.99	0.17
AV1	3182	1.00	0.17
AV3	3006	1.01	0.17
AV6	2233	1.02	0.18
AV1 % Change from baseline BMD[2]	3157	0.73	3.83
AV3 % Change from baseline BMD[3]	2982	2.12	5.20
AV6 % Change from baseline BMD[4]	2216	3.48	6.75
Hip Scan			
Baseline	3620	0.87	0.14
AV1	3275	0.87	0.14
AV3	3099	0.88	0.14
AV6	2329	0.88	0.14
AV1 % Change from baseline BMD[2]	3254	-0.04	2.76
AV3 % Change from baseline BMD[3]	3071	0.98	4.17
AV6 % Change from baseline BMD[4]	2303	0.74	5.21

[1] Measured in (g/cm^2).
[2] AV1 % Change from baseline BMD is defined as ((AV1-Baseline)/Baseline)x100.
[3] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[4] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 3.11
Bone Mineral Density[1] Analysis: DM Participants by Race/Ethnicicty

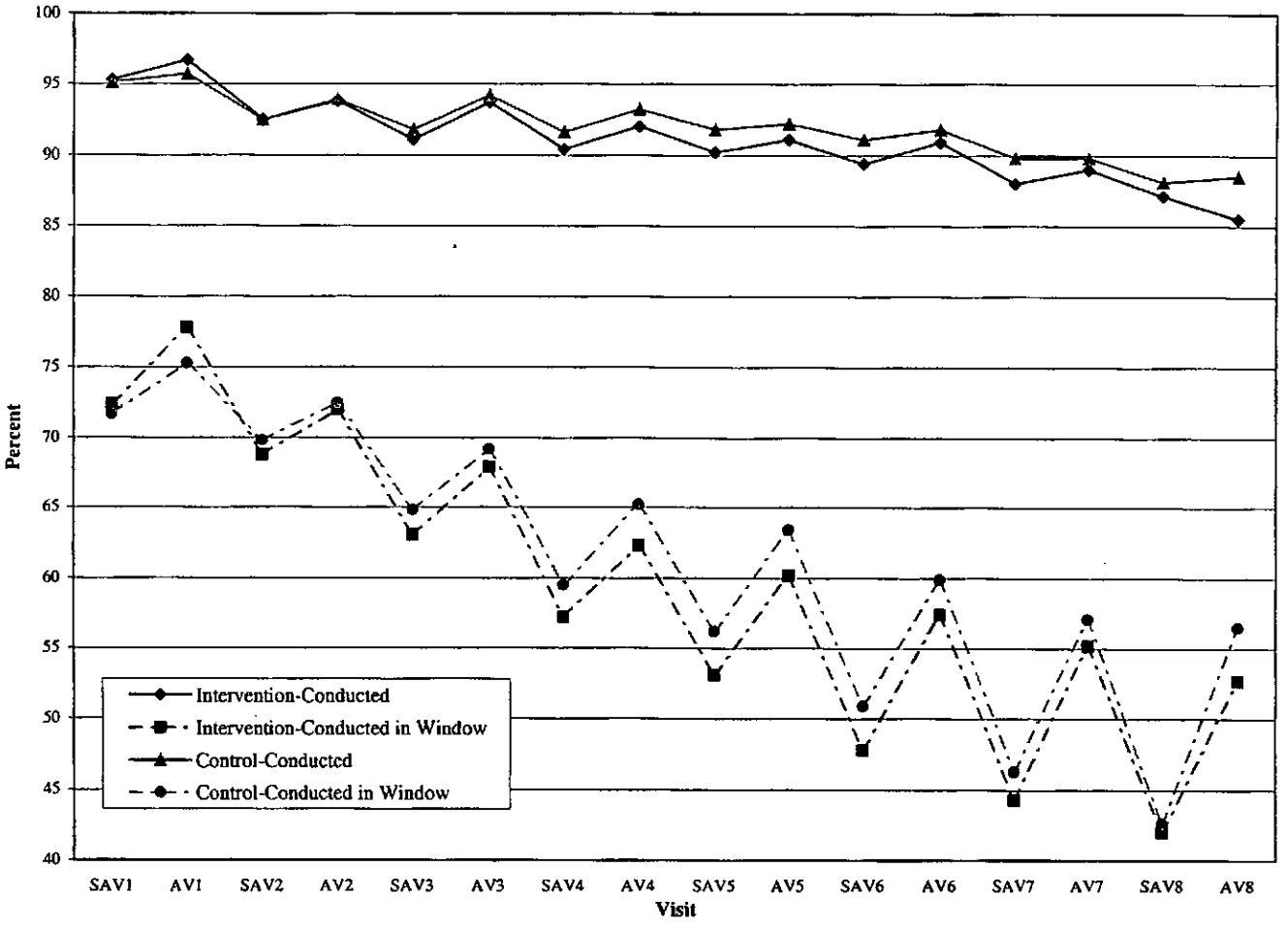
Data as of: August 31, 2002

	Black/African American			Hispanic/Latino			White		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan									
Baseline	581	1.07	0.11	195	1.05	0.11	2761	1.01	0.10
AV1	512	1.08	0.11	152	1.05	0.11	2554	1.01	0.10
AV3	495	1.10	0.12	152	1.05	0.12	2388	1.02	0.11
AV6	332	1.08	0.12	144	1.10	0.14	1769	1.05	0.12
AV1 % Change from baseline BMD[2]	506	0.98	2.96	151	-0.33	2.24	2521	0.04	2.36
AV3 % Change from baseline BMD[3]	490	1.97	2.89	151	0.65	4.45	2356	1.16	3.63
AV6 % Change from baseline BMD[4]	329	0.48	3.16	144	4.57	7.51	1740	2.49	5.31
Spine Scan									
Baseline	575	1.07	0.18	190	0.98	0.16	2693	0.97	0.16
AV1	506	1.08	0.18	148	0.98	0.16	2485	0.98	0.16
AV3	491	1.09	0.19	148	0.96	0.15	2325	0.99	0.17
AV6	314	1.09	0.19	141	0.98	0.15	1737	1.01	0.17
AV1 % Change from baseline BMD[2]	500	0.79	4.31	147	0.15	4.36	2468	0.74	3.67
AV3 % Change from baseline BMD[3]	486	2.09	5.14	147	0.09	5.90	2308	2.28	5.14
AV6 % Change from baseline BMD[4]	311	2.62	6.83	141	1.04	6.86	1724	3.83	6.68
Hip Scan									
Baseline	584	0.97	0.15	195	0.88	0.14	2784	0.85	0.13
AV1	514	0.98	0.15	152	0.88	0.14	2566	0.85	0.13
AV3	497	0.99	0.15	152	0.88	0.15	2408	0.86	0.13
AV6	340	0.96	0.15	145	0.89	0.14	1803	0.87	0.13
AV1 % Change from baseline BMD[2]	510	0.84	2.86	151	-0.62	2.94	2551	-0.18	2.66
AV3 % Change from baseline BMD[3]	493	1.40	3.82	150	0.80	5.76	2387	0.91	4.10
AV6 % Change from baseline BMD[4]	337	-1.05	4.87	143	2.09	6.02	1783	0.95	5.10

[1] Measured in (g/cm^2).
[2] AV1 % Change from baseline BMD is defined as ((AV1-Baseline)/Baseline)x100.
[3] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[4] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 3.12
Adherence to Follow-up Contacts

Data as of: August 31, 2002



Contact		Due N	Conducted N	Conducted %	Conducted in Window N	Conducted in Window %
Semi-Annual Contact 3	Intervention	19541	17801	91.1	12306	63.0
	Control	29294	26878	91.8	18989	64.8
Annual Visit 3	Intervention	19541	18314	93.7	13262	67.9
	Control	29294	27598	94.2	20262	69.2
Semi-Annual Contact 4	Intervention	19541	17673	90.4	11170	57.2
	Control	29294	26836	91.6	17430	59.5
Annual Visit 4	Intervention	19538	17972	92.0	12166	62.3
	Control	29289	27284	93.2	19108	65.2
Semi-Annual Contact 5	Intervention	18099	16321	90.2	9614	53.1
	Control	27154	24928	91.8	15266	56.2
Annual Visit 5	Intervention	15678	14285	91.1	9442	60.2
	Control	23494	21663	92.2	14898	63.4
Semi-Annual Visit 6	Intervention	12708	11361	89.4	6073	47.8
	Control	19045	17359	91.1	9689	50.9
Annual Visit 6	Intervention	9530	8662	90.9	5472	57.4
	Control	14314	13144	91.8	8579	59.9
Semi-Annual Visit 7	Intervention	6659	5857	88.0	2948	44.3
	Control	9951	8937	89.8	4611	46.3
Annual Visit 7	Intervention	4372	3891	89.0	2413	55.2
	Control	6531	5864	89.8	3730	57.1
Semi-Annual Visit 8	Intervention	2690	2342	87.1	1129	42.0
	Control	4017	3539	88.1	1710	42.6
Annual Visit 8	Intervention	1322	1130	85.5	697	52.7
	Control	1998	1768	88.5	1128	56.5

Table 3.13
Lost-to-Follow-up and Vital Status: DM Participants

Data as of: August 31, 2002

	DM Participants (N = 48,835)	
	N	%
Vital Status/Participation		
Deceased	1282	2.6
Alive: Current Participation[1]	44857	91.9
Alive: Recent Participation[2]	838	1.7
Alive: Past/Unknown Participation[3]	40	0.1
Stopped Follow-Up[4]	1076	2.2
Lost to Follow-Up[5]	742	1.5

[1] Participants who have filled in a Form 33 within the last 9 months.
[2] Participants who last filled in a Form 33 between 9 and 18 months ago.
[3] Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

Table 3.14
Locally Verified Outcomes (Annualized Percentages) by Age for Dietary Modification

Data as of: August 31, 2002

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48835	6961	11043	22713	8118
Mean follow-up (months)	67.8	74.1	70.1	65.7	65.0
Cancer					
Breast cancer[1]	1385 (0.50%)	153 (0.36%)	315 (0.49%)	669 (0.54%)	248 (0.56%)
Invasive breast cancer	1105 (0.40%)	108 (0.25%)	255 (0.40%)	542 (0.44%)	200 (0.45%)
Non-invasive breast cancer	286 (0.10%)	45 (0.10%)	61 (0.09%)	131 (0.11%)	49 (0.11%)
Ovarian cancer	129 (0.05%)	18 (0.04%)	24 (0.04%)	55 (0.04%)	32 (0.07%)
Endometrial cancer[2]	184 (0.12%)	22 (0.09%)	42 (0.11%)	83 (0.12%)	37 (0.15%)
Colorectal cancer	347 (0.13%)	21 (0.05%)	54 (0.08%)	180 (0.14%)	92 (0.21%)
Other cancer[3]	1279 (0.46%)	116 (0.27%)	202 (0.31%)	637 (0.51%)	324 (0.74%)
Total cancer	3234 (1.17%)	323 (0.75%)	615 (0.95%)	1583 (1.27%)	713 (1.62%)
Cardiovascular					
CHD[4]	821 (0.30%)	45 (0.10%)	97 (0.15%)	385 (0.31%)	294 (0.67%)
CHD death[5]	168 (0.06%)	7 (0.02%)	17 (0.03%)	74 (0.06%)	70 (0.16%)
Total MI[6]	713 (0.26%)	39 (0.09%)	85 (0.13%)	339 (0.27%)	250 (0.57%)
Clinical MI	679 (0.25%)	32 (0.07%)	81 (0.13%)	324 (0.26%)	242 (0.55%)
Evolving Q-wave MI[7]	36 (0.01%)	7 (0.02%)	4 (0.01%)	17 (0.01%)	8 (0.02%)
Possible evolving Q-wave MI[7]	136 (0.05%)	19 (0.04%)	21 (0.03%)	62 (0.05%)	34 (0.08%)
Angina	1094 (0.40%)	62 (0.14%)	144 (0.22%)	572 (0.46%)	316 (0.72%)
CABG/PTCA	1117 (0.40%)	45 (0.10%)	140 (0.22%)	583 (0.47%)	349 (0.79%)
Carotid artery disease	168 (0.06%)	4 (0.01%)	20 (0.03%)	84 (0.07%)	60 (0.14%)
Congestive heart failure	633 (0.23%)	28 (0.07%)	68 (0.11%)	287 (0.23%)	250 (0.57%)
Stroke	630 (0.23%)	30 (0.07%)	55 (0.09%)	293 (0.24%)	252 (0.57%)
PVD	153 (0.06%)	6 (0.01%)	18 (0.03%)	73 (0.06%)	56 (0.13%)
CHD[4]/Possible evolving Q-wave MI	953 (0.35%)	64 (0.15%)	118 (0.18%)	443 (0.36%)	328 (0.75%)
Coronary disease[8]	2434 (0.88%)	140 (0.33%)	306 (0.47%)	1212 (0.97%)	776 (1.76%)
Total cardiovascular disease	3198 (1.16%)	174 (0.40%)	378 (0.59%)	1594 (1.28%)	1052 (2.39%)
Fractures					
Hip fracture	251 (0.09%)	8 (0.02%)	19 (0.03%)	105 (0.08%)	119 (0.27%)
Vertebral fracture	298 (0.11%)	12 (0.03%)	33 (0.05%)	127 (0.10%)	126 (0.29%)
Other fracture[3]	3574 (1.30%)	454 (1.06%)	717 (1.11%)	1664 (1.34%)	739 (1.68%)
Total fracture	3991 (1.45%)	470 (1.09%)	761 (1.18%)	1841 (1.48%)	919 (2.09%)
Deaths					
Cardiovascular deaths	352 (0.13%)	14 (0.03%)	27 (0.04%)	154 (0.12%)	157 (0.36%)
Cancer deaths	579 (0.21%)	36 (0.08%)	68 (0.11%)	287 (0.23%)	188 (0.43%)
Other known cause	192 (0.07%)	13 (0.03%)	21 (0.03%)	82 (0.07%)	76 (0.17%)
Unknown cause	53 (0.02%)	3 (0.01%)	8 (0.01%)	29 (0.02%)	13 (0.03%)
Not yet adjudicated	106 (0.04%)	5 (0.01%)	14 (0.02%)	51 (0.04%)	36 (0.08%)
Total death	1282 (0.46%)	71 (0.17%)	138 (0.21%)	603 (0.48%)	470 (1.07%)

[1] Excludes five cases with borderline malignancy.
[2] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[3] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[4] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[5] "CHD death" includes definite and possible CHD death.
[6] "Total MI" includes clinical MI and evolving Q-wave MI.
[7] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[8] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 3.14 (continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Dietary Modification

Data as of: August 31, 2002

Outcome	Race/Ethnicity					
	American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	202	1105	5262	1845	39762	659
Mean follow-up (months)	66.3	64.2	66.0	63.6	68.4	63.7
Cancer						
Breast cancer[1]	2 (0.18%)	31 (0.52%)	89 (0.31%)	35 (0.36%)	1211 (0.53%)	17 (0.49%)
Invasive breast cancer	2 (0.18%)	23 (0.39%)	67 (0.23%)	29 (0.30%)	971 (0.43%)	13 (0.37%)
Non-invasive breast cancer	0 (0.00%)	8 (0.14%)	23 (0.08%)	6 (0.06%)	245 (0.11%)	4 (0.11%)
Ovarian cancer	1 (0.09%)	2 (0.03%)	12 (0.04%)	2 (0.02%)	109 (0.05%)	3 (0.09%)
Endometrial cancer[2]	0 (0.00%)	1 (0.03%)	11 (0.08%)	7 (0.13%)	162 (0.12%)	3 (0.15%)
Colorectal cancer	4 (0.36%)	5 (0.08%)	40 (0.14%)	14 (0.14%)	278 (0.12%)	6 (0.17%)
Other cancer[3]	4 (0.36%)	18 (0.30%)	96 (0.33%)	27 (0.28%)	1118 (0.49%)	16 (0.46%)
Total cancer	11 (0.99%)	57 (0.96%)	241 (0.83%)	81 (0.83%)	2803 (1.24%)	41 (1.17%)
Cardiovascular						
CHD[4]	1 (0.09%)	8 (0.14%)	78 (0.27%)	14 (0.14%)	713 (0.31%)	7 (0.20%)
CHD death[5]	0 (0.00%)	1 (0.02%)	20 (0.07%)	1 (0.01%)	144 (0.06%)	2 (0.06%)
Total MI[6]	1 (0.09%)	8 (0.14%)	68 (0.23%)	14 (0.14%)	615 (0.27%)	7 (0.20%)
Clinical MI	1 (0.09%)	7 (0.12%)	64 (0.22%)	14 (0.14%)	587 (0.26%)	6 (0.17%)
Evolving Q-wave MI[7]	0 (0.00%)	1 (0.02%)	4 (0.01%)	0 (0.00%)	30 (0.01%)	1 (0.03%)
Possible evolving Q-wave MI[7]	2 (0.18%)	3 (0.05%)	20 (0.07%)	3 (0.03%)	107 (0.05%)	1 (0.03%)
Angina	2 (0.18%)	13 (0.22%)	150 (0.52%)	30 (0.31%)	882 (0.39%)	17 (0.49%)
CABG/PTCA	1 (0.09%)	9 (0.15%)	108 (0.37%)	22 (0.22%)	967 (0.43%)	10 (0.29%)
Carotid artery disease	2 (0.18%)	1 (0.02%)	15 (0.05%)	1 (0.01%)	147 (0.06%)	2 (0.06%)
Congestive heart failure	0 (0.00%)	3 (0.05%)	118 (0.41%)	14 (0.14%)	488 (0.22%)	10 (0.29%)
Stroke	3 (0.27%)	14 (0.24%)	75 (0.26%)	14 (0.14%)	514 (0.23%)	10 (0.29%)
PVD	1 (0.09%)	1 (0.02%)	29 (0.10%)	1 (0.01%)	118 (0.05%)	3 (0.09%)
CHD[4]/Possible evolving Q-wave MI	3 (0.27%)	11 (0.19%)	98 (0.34%)	17 (0.17%)	816 (0.36%)	8 (0.23%)
Coronary disease[8]	5 (0.45%)	25 (0.42%)	330 (1.14%)	59 (0.60%)	1983 (0.88%)	32 (0.92%)
Total cardiovascular disease	11 (0.99%)	40 (0.68%)	418 (1.44%)	73 (0.75%)	2612 (1.15%)	44 (1.26%)
Fractures						
Hip fracture	0 (0.00%)	1 (0.02%)	7 (0.02%)	4 (0.04%)	236 (0.10%)	3 (0.09%)
Vertebral fracture	0 (0.00%)	7 (0.12%)	3 (0.01%)	6 (0.06%)	279 (0.12%)	3 (0.09%)
Other fracture[3]	14 (1.25%)	53 (0.90%)	201 (0.69%)	86 (0.88%)	3181 (1.40%)	39 (1.12%)
Total fracture	14 (1.25%)	60 (1.01%)	209 (0.72%)	94 (0.96%)	3569 (1.58%)	45 (1.29%)
Deaths						
Cardiovascular deaths	1 (0.09%)	4 (0.07%)	48 (0.17%)	5 (0.05%)	290 (0.13%)	4 (0.11%)
Cancer deaths	1 (0.09%)	8 (0.14%)	52 (0.18%)	13 (0.13%)	496 (0.22%)	9 (0.26%)
Other known cause	5 (0.45%)	0 (0.00%)	28 (0.10%)	4 (0.04%)	153 (0.07%)	2 (0.06%)
Unknown cause	0 (0.00%)	0 (0.00%)	7 (0.02%)	1 (0.01%)	45 (0.02%)	0 (0.00%)
Not yet adjudicated	1 (0.09%)	3 (0.05%)	12 (0.04%)	5 (0.05%)	85 (0.04%)	0 (0.00%)
Total death	8 (0.72%)	15 (0.25%)	147 (0.51%)	28 (0.29%)	1069 (0.47%)	15 (0.43%)

[1] Excludes five cases with borderline malignancy.
[2] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[3] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[4] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[5] "CHD death" includes definite and possible CHD death.
[6] "Total MI" includes clinical MI and evolving Q-wave MI.
[7] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[8] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 3.15
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for DM Participants who did not report a prevalent condition at baseline

Data as of: August 31, 2002

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48835	6961	11043	22713	8118
Mean follow-up (months)	67.8	74.1	70.1	65.7	65.0
Hospitalizations					
Ever	18750 (6.80%)	2001 (4.66%)	3507 (5.44%)	9106 (7.32%)	4136 (9.41%)
Two or more	8717 (3.16%)	784 (1.82%)	1465 (2.27%)	4228 (3.40%)	2240 (5.09%)
Other					
DVT[1]	365 (0.14%)	22 (0.05%)	58 (0.09%)	168 (0.14%)	117 (0.28%)
Pulmonary embolism	226 (0.08%)	11 (0.03%)	40 (0.06%)	113 (0.09%)	62 (0.14%)
Diabetes (treated)	2438 (0.92%)	335 (0.80%)	555 (0.89%)	1129 (0.95%)	419 (1.01%)
Gallbladder disease[2]	2777 (1.20%)	425 (1.11%)	659 (1.20%)	1297 (1.27%)	396 (1.12%)
Hysterectomy	1122 (0.72%)	166 (0.68%)	256 (0.65%)	530 (0.76%)	170 (0.71%)
Glaucoma	3567 (1.34%)	355 (0.84%)	712 (1.13%)	1745 (1.46%)	755 (1.86%)
Osteoporosis	7341 (2.82%)	735 (1.75%)	1336 (2.14%)	3670 (3.15%)	1600 (4.07%)
Osteoarthritis[3]	6975 (4.14%)	998 (3.17%)	1594 (3.67%)	3236 (4.51%)	1147 (5.26%)
Rheumatoid arthritis	2023 (0.76%)	283 (0.68%)	460 (0.74%)	934 (0.78%)	346 (0.83%)
Intestinal polyps	5150 (2.01%)	620 (1.49%)	1132 (1.85%)	2570 (2.24%)	828 (2.11%)
Lupus	336 (0.12%)	55 (0.13%)	81 (0.13%)	159 (0.13%)	41 (0.09%)
Kidney stones[3]	812 (0.37%)	108 (0.34%)	183 (0.37%)	389 (0.39%)	132 (0.38%)
Cataracts[3]	10656 (5.41%)	634 (1.95%)	1730 (3.49%)	5942 (6.59%)	2350 (9.47%)
Pills for hypertension	8767 (4.55%)	1163 (3.36%)	1932 (3.97%)	4102 (4.92%)	1570 (6.02%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	202	1105	5262	1845	39762	659
Mean follow-up (months)	66.3	64.2	66.0	63.6	68.4	63.7
Hospitalizations						
Ever	72 (6.45%)	268 (4.53%)	2012 (6.95%)	589 (6.02%)	15580 (6.88%)	229 (6.55%)
Two or more	41 (3.67%)	90 (1.52%)	955 (3.30%)	239 (2.44%)	7283 (3.21%)	109 (3.12%)
Other						
DVT[1]	0 (0.00%)	0 (0.00%)	32 (0.11%)	5 (0.05%)	322 (0.15%)	6 (0.18%)
Pulmonary embolism	2 (0.18%)	1 (0.02%)	19 (0.07%)	2 (0.02%)	198 (0.09%)	4 (0.12%)
Diabetes (treated)	15 (1.44%)	70 (1.25%)	463 (1.81%)	137 (1.49%)	1717 (0.78%)	36 (1.09%)
Gallbladder disease[2]	10 (1.26%)	41 (0.77%)	218 (0.84%)	113 (1.53%)	2358 (1.25%)	37 (1.24%)
Hysterectomy	4 (0.75%)	23 (0.61%)	68 (0.53%)	34 (0.65%)	984 (0.74%)	9 (0.45%)
Glaucoma	17 (1.59%)	66 (1.16%)	510 (1.89%)	135 (1.42%)	2799 (1.28%)	40 (1.21%)
Osteoporosis	33 (3.11%)	182 (3.26%)	419 (1.50%)	271 (2.98%)	6339 (2.97%)	97 (3.00%)
Osteoarthritis[3]	35 (5.48%)	154 (3.63%)	712 (4.14%)	293 (4.45%)	5679 (4.12%)	102 (4.80%)
Rheumatoid arthritis	17 (1.70%)	36 (0.63%)	372 (1.38%)	163 (1.75%)	1400 (0.64%)	35 (1.06%)
Intestinal polyps	28 (2.71%)	109 (2.01%)	566 (2.09%)	165 (1.77%)	4204 (2.00%)	78 (2.43%)
Lupus	3 (0.27%)	3 (0.05%)	51 (0.18%)	10 (0.10%)	265 (0.12%)	4 (0.12%)
Kidney stones[3]	6 (0.71%)	14 (0.30%)	81 (0.36%)	39 (0.50%)	659 (0.37%)	13 (0.47%)
Cataracts[3]	45 (5.84%)	211 (4.89%)	1032 (4.96%)	359 (4.81%)	8856 (5.49%)	153 (6.07%)
Pills for hypertension	33 (4.56%)	187 (4.73%)	947 (6.53%)	367 (5.04%)	7122 (4.34%)	111 (4.71%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

4. CaD Component

4.1 Recruitment

Table 4.1 presents the final sample size for number of women randomized in the Calcium and Vitamin D component of the WHI Clinical Trial. A total of 36,282 women have been randomized which is 80.6% of the overall goal of 45,000. The age distribution of the CaD trial participants is somewhat younger than anticipated in the design assumptions for the trial. Seventeen percent of women randomized are aged 70-79 years compared with the design assumption of 25%.

4.2 Adherence

Table 4.2 presents rates of follow-up, stopping intervention and pill collection, and adherence to pill taking by visit schedule for all CaD participants. The adherence summary for all CaD participants, defined as those women known to be consuming 80% or more of the prescribed dose, has remained steady since the last report (see *Figure 4.1*) at 56%-64%. At AV-4, which is nearly complete, 96% of visits due have been conducted, 2% of women have stopped taking the CaD study medication, and 83% completed the pill collection procedure. AV-5 and AV-6 adherence have improved slightly over the most recent time interval (*Figure 4.1*). The adherence summary remains low primarily because about 20-37% of women on study medication take less than 80% of their CaD pills.

Table 4.3 summarizes interval and cumulative drop-out rates in comparison to the original design assumptions. The original power calculations for CaD assumed a 6% drop-out rate in year 1 and a 3% per year drop-out rate thereafter. An independent lost-to-follow-up rate of 3% per year was also incorporated, resulting in approximately 8.8% stopping intervention in year 1 and 5.9% in subsequent years. Drop-out rates in this report now account for re-starting CaD, which results in lower rates than seen in earlier reports. At every annual visit, the observed drop-out rates are lower than design assumptions. Interval drop-out rates at AV-3 and beyond range from 2.8-5.0%, which compares favorably to the 5.9% design assumption. At AV-4, the cumulative drop-out rate was 12.7% (design assumption was 19.2%). By AV-6 and AV-7, observed rates are below the design assumption by >10%.

Table 4.4 summarizes the frequency of reported reasons for stopping CaD. The majority of women stopping study supplements do so of their own accord. Only 7.9% have indicated that they were advised by their physician to discontinue these supplements. 809 women (9.1%) reported health problems or diseases, 2,260 women (25.4%) reported symptoms not known to be related to the intervention, and 501 women (5.6%) reported that the study conflicts with other health issues. "Other pill issues" was the most frequently reported intervention-related reason (11.1%) followed by not liking the randomized nature of the intervention (4.1%). Miscellaneous reasons grouped together as "other reasons not listed above" were reported by 22.1% of women. Four common reasons for stopping CaD are shown first by age, and then by race/ethnicity, in *Table 4.5*. No strong associations by race/ethnicity are present, though "being advised by one's health care provider not to participate" and "study conflicts with other health issues" were slightly more common among white women. These reasons were reported with similar frequency by women in the various age groups.

We also monitor the number of women who have begun alternative anti-osteoporosis therapies within the CaD trial. As of August 31, 2002, 2,030 (5.6%) women were taking alendronate, 265 (0.7%) were taking calcitonin, and 649 (1.8%) were taking raloxifene.

4.3 Bone Mineral Density

Table 4.6 presents the mean bone mineral density levels at AV-1, AV-3, and AV-6 and percent change in BMD during these intervals among women randomized at the three BMD measurement sites (Pittsburgh, Arizona, Birmingham). At the three skeletal sites examined (hip, spine, and whole body), BMD has increased between AV-1 and AV-3 from 1.3-1.6%, with the greatest change occurring at the spine. The percent changes between AV-6 and AV-1 were approximately 2 times as large as those observed at AV-3 for the spine and whole body but only slightly larger at the hip. *Table 4.7* presents the mean bone mineral density levels and percent change according to race/ethnicity. At AV-3 the rates of change relative to AV-1 were generally in the range of 1-2% gains for all skeletal sites.

4.4 Vital Status

Table 4.8 presents data on the vital status and the participation status of participants in the CaD trial. A detailed description of CCC and clinic activities to actively locate participants who do not complete their periodic visits is given in *Section 6 – Outcomes Processing*. For operational purposes, we define CT participants to have an "unknown" participation status if there is no outcomes information from the participant for 18 months and no other contacts for 6 months. Currently, 1.9% of the participants are lost-to-follow-up or have stopped follow-up, and 2.2% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. The design assumed that 3% per year would be lost-to-follow-up or death. Currently, the average follow-up for CaD participants is about 4.6 years, suggesting that approximately 13.1% could be expected to be dead or lost-to-follow ~~lost-to-follow~~ up. Our overall rates compare favorably to design assumptions.

4.5 Outcomes

Table 4.9 contains counts of the number of locally verified major WHI outcomes for CaD participants. In this table only outcomes that took place after randomization in the CaD trial are included. Approximately 4% of the self-reported outcomes have not yet been verified, so the numbers in this table should thus be seen as a lower bound to the actual number of outcomes that have taken place. Currently, with 165 cases of hip fracture locally verified, we have observed only about 35% of the number of hip fractures that were projected by the assumptions underlying the power calculations. The number of observed colorectal cancer cases (208 cases) is approximately 75%, the number of invasive breast cancer cases (661 cases) is approximately 110%, and the number of CHD cases is about 70% of what was expected (535 cases).

Table 4.10 contains counts of the number of self-reports for some outcomes that are not locally verified in WHI. As most of the self-reported outcomes are somewhat over reported (see *Section 6.3 – Outcomes Data Quality*), the number in this table should be taken as an upper bound to the number of events that have occurred in CaD participants.

4.6 Issues

During this period of follow-up, our focus remains primarily on maximizing adherence (if applicable) and retention in all components of the WHI Clinical Trial. Work continues on identifying and implementing strategies to improve adherence to CaD study medication. The CaD committee has overseen the development of a handbook, which is currently being printed for distribution at annual visits in the clinic. In addition, the CaD committee is organizing the development of brief articles on special CaD-relevant topics for publication in the WHI Matters newsletter.

A key issue during this last period was communicating with CaD participants about the E+P findings. When the E+P findings were published on July 9, 2002, CaD participants received the HRT update and a special letter informing them about the E+P findings and emphasizing that all other components of the WHI program are continuing as planned. Following publication of the E+P findings on July 9, 2002, a one-page update entitled "Your Important Role" was developed for mailing to CaD participants to encourage their continued participation.

Table 4.1
Calcium and Vitamin D Component Age – and Race/Ethnicity – Specific Recruitment

Data as of: August 31, 2002

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**36,282**			
50-54	5157	118%	14%	10
55-59	8265	94%	23%	20
60-69	16520	84%	46%	45
70-79	6340	58%	17%	25
Race/Ethnicity	**36,282**			
American Indian	149		<1%	
Asian	721		2%	
Black	3315		9%	
Hispanic	1502		4%	
White	30155		83%	
Unknown	440		1%	

Table 4.2
CaD Adherence Summary
All CaD Participants

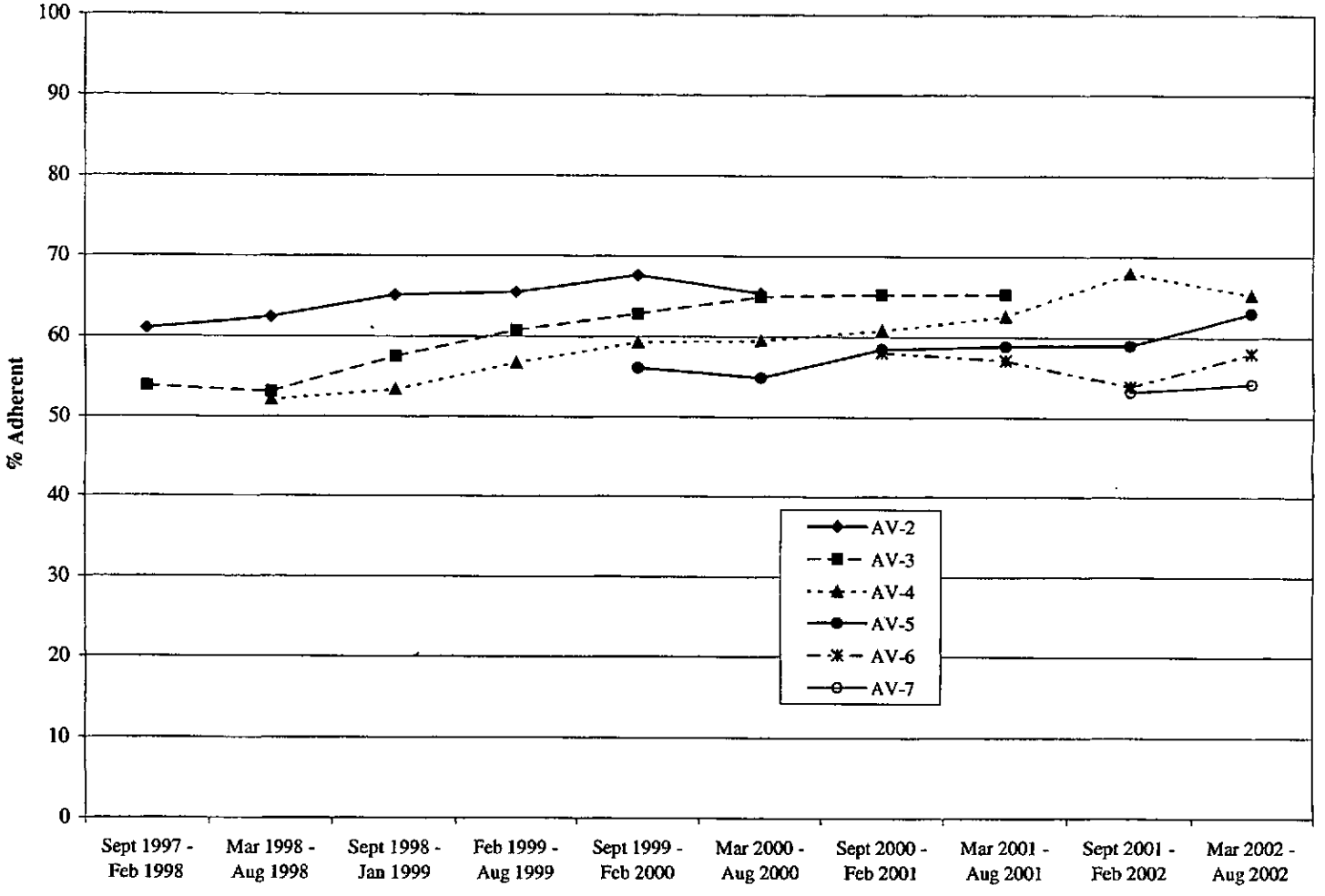
Data as of: August 31, 2002

	Due	Conducted		Conducted in Window		Stopped CaD		Missed Pill Collection		Total with Collections		Medication Rate[1] <50%		Medication Rate[1] 50%-80%		Medication Rate[1] 80% +		Adherence Summary[2]
	N	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	%
Semi-Annual Contact - 2	33047	32217	97	26177	79	1252	4	202	1	32824	99	5742	17	6712	20	20370	62	62
Annual Visit - 2	33047	32262	98	25858	78	1146	3	517	2	33069	98	5691	17	6235	19	21143	64	64
Annual Visit - 3	36243	35233	97	26515	73	873	2	543	2	32071	98	4684	15	5133	16	22254	69	62
Annual Visit - 4	36216	34690	96	24577	68	682	2	684	2	30046	98	3542	12	4382	15	22122	74	62
Annual Visit - 5	28784	27206	95	18736	65	523	2	739	3	22416	97	2423	11	2991	13	17002	76	60
Annual Visit - 6	16558	15553	94	10252	62	206	1	478	4	12181	96	1231	10	1594	13	9356	77	58
Annual Visit - 7	7297	6762	93	4362	60	97	1	257	5	5118	95	504	10	620	12	3994	78	56
Annual Visit - 8	1966	1793	91	1170	60	32	2	104	7	1322	93	114	9	146	11	1062	80	56

[1] Medication rate calculated as the number of pills taken divided by the number of days since bottle(s) were dispensed.
[2] Adherence summary calculated as the number of women consuming ≥80% of pills divided by the number due for a visit.
Note: Deceased women are excluded from all medication adherence calculations, but are included in the number "Due."

Figure 4.1
CaD Adherence Summary
% Participants Due for a Visit Who Took at Least 80% of Study Pills[1]

Data as of: August 31, 2002



[1] Adherence calculations changed as of the September 2001 – February 2002 interval.

Table 4.3
CaD Drop-Out Rates by Follow-Up Time

Data as of: August 31, 2002

	Design		Observed			
	Int	Cum	Stopped[1]	Dead/ Lost[2]	Int[3]	Cum[4]
Drop-Outs[5]						
AV-2	8.8	8.8	7.2	0.3	7.4	7.4
AV-3	5.9	14.2	2.4	0.6	3.0	10.2
AV-4	5.9	19.2	1.9	0.9	2.8	12.7
AV-5	5.9	24.0	1.8	1.3	3.1	15.4
AV-6	5.9	28.5	1.3	1.7	3.0	17.9
AV-7	5.9	32.7	1.4	2.2	3.6	20.8
AV-8	5.9	36.7	1.7	3.3	5.0	24.8

[1] Estimated rate of stopping CaD in the interval.
[2] Death or lost to follow-up rate in the interval.
[3] Combined rate of stopping and death or lost to follow-up in the interval.
[4] Estimated cumulative rate of stopping and death or lost to follow-up.
[5] Drop-out rates derived from Form 7 by date. Cumulative rates calculated as life-table estimates.

Table 4.4
Reasons for Stopping CaD[1]

Data as of: August 31, 2002

Reasons[2]	(N = 8896)	
Personal/family		
Demands of work	194	2.2%
Family illness, emergency or other family demands[3]	337	3.8%
Financial problems	14	0.2%
Lack of cooperation/support from family/friends[4]	63	0.7%
Living in nursing home	30	0.3%
Issues of interest in study[5]	292	3.3%
Travel		
Too far to CC	222	2.5%
Moved out of area or refuses to be followed at another CC	85	1.0%
Other travel issues[6]	90	1.0%
Visits & Procedures		
Doesn't like visits, calls	81	0.9%
Doesn't like required forms or safety procedures[7]	78	0.9%
Problems with other procedures[8]	34	0.4%
Worried about health effects of medical tests/procedures	30	0.3%
Wants results of blood analyses	4	<0.1%
Wants results of bone mineral density	2	<0.1%
Problems with CC[9]	54	0.6%

(continues)

[1] Does not include reasons reported by women who stopped and later restarted CaD.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Family illness, emergency or other family demands", "Death in the family or of a close friend", and "Caregiver responsibilities demanding time, effort, lifestyle changes".
[4] Combines "Lack of cooperation/support from family and/or friends" and "Family/friends request that she withdraw".
[5] Combines "Conflicting priorities other than work or family", "Feels discouraged regarding participation overall", "Loss of interest, boredom", "Feels it is not an important study", and "In another study in conflict with WHI intervention".
[6] Combines "Transportation problems (other than distance)", "Traffic", "Parking at CC", and "CC neighborhood/safety".
[7] Combines "Doesn't like filling out forms (other than those required for safety)", and "Doesn't like required safety forms and/or procedures".
[8] Combines "Doesn't like mammograms", "Cost of mammograms", "Doesn't like having blood drawn", "Doesn't like ECG", "Doesn't like gynecologic procedures" and "Doesn't like other procedures (other than those required for safety)".
[9] Combines "Problem with the CC", "Problem with CC staff person (other than DM Group Nutritionist)", and "Staff change/turnover".

Table 4.4 (continued)
Reasons for Stopping CaD[1]

Data as of: August 31, 2002

Reasons[2]	(N = 8896)	
Symptoms		
Bloating/gas	168	1.9%
Constipation	195	2.2%
Other gastrointestinal problems	230	2.6%
HRT Related Symptoms[3]	42	0.5%
Other[4]	2260	25.4%
Health Conditions		
Hypercalcemia	154	1.7%
Renal calculi	152	1.7%
Osteoporosis	66	0.7%
Other Diseases/Health Conditions[5]	809	9.1%
Communication difficulties[6]	78	0.9%
Intervention		
Doesn't like randomized nature of intervention	367	4.1%
Expected some benefit from intervention	56	0.6%
Feels guilty, unhappy, or like a failure for not meeting study goals of intervention	20	0.2%
Takes too many pills	265	3.0%
Other pill issues[7]	985	11.1%
HRT Issues[8]	129	1.5%
DM Issues[9]	17	0.2%
Wants to take her own calcium	316	3.6%
Feels diet is already sufficient in calcium/Vit D	32	0.4%
Taking more than the max allowable IU of Vit D	34	0.4%
Taking Calcitrol	19	0.2%
Other Health Issues		
Worried about cost if adverse effects occur	8	0.1%
Expected more health care	23	0.3%
Advised not to participate by health care provider[10]	706	7.9%
Study conflicts with other health issues[11]	501	5.6%
Other		
Other reasons not listed above	1964	22.1%
Refuses to give a reason	143	1.6%

[1] Does not include reasons reported by women who stopped and later restarted CaD.
[2] Multiple reasons may be reported for a woman.
[3] Combines "Vaginal bleeding", "Breast tenderness", "Other breast changes", "Vaginal changes (e.g., dryness)", and "Hot flashes/night sweats".
[4] Combines "Experiencing health problems or symptoms not due to intervention", "Reports other health problems or symptoms from the WHI intervention", "Reports health problems or symptoms from the WHI intervention", "Hair/skin changes", "Headaches", "Weight loss/gain", "Low energy/too tired", "Possible allergic reaction", and "Other symptoms not listed above".
[5] Combines "Removed from intervention due to WHI symptom management", "Removed from intervention due to adverse health event", "Breast cancer", "Complex or atypical hyperplasia", "Endometrial cancer", "Deep vein thrombosis", "Pulmonary embolism", "Gallbladder disease", "Kidney failure/dialysis", "High triglycerides (> 1000 mg/dl)", "Malignant melanoma", "Meningioma", "Heart attack", "Stroke", "Arthritis", "Diabetes", "Depression", "Cholesterol (high or concern about levels)", and "Other health conditions not listed above".
[6] Combines "Communication problem", "Loss of vision and/or hearing", and "Cognitive/memory changes".
[7] Combines "Doesn't like taking pills", "Doesn't like taste of pills", and "Unable to swallow pills".
[8] Combines "Has made a personal decision to go on active HRT", "Has made a personal decision that she does not want to be on HRT", "Advised to go on active HRT by health care provider", "Advised to not be on active HRT by health care provider", "Has made a personal decision to go on SERM (e.g., Evista/raloxifene, tamoxifen)", "Advised to go on SERM (e.g., Evista/raloxifene, tamoxifen) by health care provider", and "Taking testosterone medications".
[9] Combines "Doesn't like DM requirements", "Problem with DM Group Nutritionist or group members", "Doesn't like DM eating pattern", "Doesn't like attending DM intervention classes", "Doesn't like self-monitoring", "Doesn't like budgeting fat grams", "Has concerns regarding long-term risks/benefits of low fat diet", "Unhappy that not losing weight", "Not in control of meal preparation", "Too difficult to meet or maintain dietary goals", "Doesn't like eating low fat diet", "Doesn't like eating 5 vegetables/fruits per day", "Doesn't like eating 6 grains per day", "Feels fat gram goal is unrealistic", and "Eating pattern conflicts with personal health beliefs".
[10] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason".
[11] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues".

Table 4.5
Reasons for Stopping CaD by Age at Screening and Race/Ethnicity[1]

Data as of August 31, 2002

	All (N = 36,282)		Age at Screening: 50 – 54 (N = 5,157)		55 – 59 (N = 8,265)		60 – 69 (N = 16,520)		70 – 79 (N = 6,340)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping CaD	8896	24.5%	1407	27.3%	1980	24.0%	3777	22.9%	1732	27.3%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Doesn't like randomized nature of intervention	367	4.1%	59	4.2%	83	4.2%	164	4.3%	61	3.5%
Other pill issues[5]	985	11.1%	155	11.0%	229	11.6%	420	11.1%	181	10.5%
Advised not to participate by health care provider[6]	706	7.9%	74	5.3%	150	7.6%	331	8.8%	151	8.7%
Study conflicts with other health issues[7]	501	5.6%	63	4.5%	96	4.8%	222	5.9%	120	6.9%

	Race/Ethnicity: American Indian/ Alaskan Native (N = 149)		Asian/Pacific Islander (N = 721)		Black/African American (N = 3,315)		Hispanic/Latino (N = 1,502)		White (N = 30,155)		Unknown (N = 440)	
	N	%[8]	N	%[8]	N	%[8]	N	%[8]	N	%[8]	N	%[8]
Women Stopping CaD	42	28.2%	174	24.1%	939	28.3%	434	28.9%	7184	23.8%	123	28.0%
REASONS FOR STOPPING[3]	N	%[9]	N	%[9]	N	%[9]	N	%[9]	N	%[9]	N	%[9]
Doesn't like randomized nature of intervention	0	0.0%	3	1.7%	33	3.5%	9	2.1%	317	4.4%	5	4.1%
Other pill issues[5]	6	14.3%	20	11.5%	96	10.2%	53	12.2%	800	11.1%	10	8.1%
Advised not to participate by health care provider[6]	2	4.8%	6	3.4%	60	6.4%	31	7.1%	598	8.3%	9	7.3%
Study conflicts with other health issues[7]	1	2.4%	6	3.4%	41	4.4%	18	4.1%	428	6.0%	7	5.7%

[1] Does not include reasons reported by women who stopped and later restarted CaD.
[2] Percentages are of CaD participants in the same age category.
[3] Multiple reasons may be reported for a woman.
[4] Percentages are of CaD participants in the same age category who stopped CaD.
[5] Combines "Doesn't like taking pills", "Doesn't like taste of pills", and "Unable to swallow pills".
[6] Combines "Advised not to participate by health care provider" and "Advised not to participate by health care provider for other reason".
[7] Combines "Study conflicts with health care needs" and "Study conflicts with other health issues".
[8] Percentages are of CaD participants in the same race/ethnicity category.
[9] Percentages are of CaD participants in the same race/ethnicity category who stopped CaD.

Table 4.6
Bone Mineral Density[1] Analysis: CaD Participants

Data as of: August 31, 2002

	N	Mean	S.D.
Whole Body Scan			
AV1	2426	1.02	0.10
AV3	2263	1.03	0.11
AV6	1475	1.05	0.12
AV3 % Change from AV1 BMD[2]	2190	1.42	3.36
AV6 % Change from AV1 BMD[3]	1422	2.62	5.18
Spine Scan			
AV1	2350	0.99	0.16
AV3	2211	1.01	0.17
AV6	1447	1.02	0.17
AV3 % Change from AV1 BMD[2]	2141	1.58	4.21
AV6 % Change from AV1 BMD[3]	1396	3.07	5.88
Hip Scan			
AV1	2431	0.86	0.14
AV3	2285	0.88	0.14
AV6	1506	0.88	0.14
AV3 % Change from AV1 BMD[2]	2211	1.28	3.55
AV6 % Change from AV1 BMD[3]	1447	1.13	4.84

[1] Measured in (g/cm^2).
[2] Percent Change from BMD is defined as ((AV3-AV1)/AV1)x100.
[3] Percent Change from BMD is defined as ((AV6-AV1)/AV1)x100.

Table 4.7
Bone Mineral Density[1] Analysis: CaD Participants by Race/Ethnicity

Data as of: August 31, 2002

	Black/African American			Hispanic/Latino			White		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan									
AV1	279	1.08	0.11	123	1.04	0.12	1986	1.01	0.10
AV3	265	1.10	0.12	116	1.05	0.12	1846	1.02	0.11
AV6	157	1.08	0.12	89	1.11	0.16	1202	1.04	0.12
AV3 % Change from AV1 BMD[2]	261	1.21	3.02	104	2.20	4.36	1791	1.41	3.34
AV6 % Change from AV1 BMD[3]	154	0.27	3.61	73	5.76	8.42	1171	2.74	4.96
Spine Scan									
AV1	274	1.07	0.18	120	0.98	0.17	1918	0.98	0.16
AV3	261	1.08	0.19	114	0.97	0.15	1800	1.00	0.17
AV6	146	1.09	0.18	88	1.00	0.16	1186	1.02	0.17
AV3 % Change from AV1 BMD[2]	257	1.16	4.40	101	0.39	3.99	1749	1.75	4.17
AV6 % Change from AV1 BMD[3]	143	1.98	6.13	72	1.84	5.89	1157	3.28	5.84
Hip Scan									
AV1	279	0.98	0.14	123	0.87	0.14	1991	0.85	0.13
AV3	265	0.99	0.15	116	0.88	0.13	1868	0.86	0.13
AV6	161	0.97	0.14	90	0.90	0.14	1228	0.86	0.13
AV3 % Change from AV1 BMD[2]	261	0.82	3.18	103	1.68	4.67	1813	1.32	3.52
AV6 % Change from AV1 BMD[3]	157	-1.10	4.29	73	3.38	5.27	1193	1.31	4.77

[1] Measured in (g/cm^2).
[2] Percent Change from BMD is defined as ((AV3-AV1)/AV1)x100.
[3] Percent Change from BMD is defined as ((AV6-AV1)/AV1)x100.

Table 4.8
Lost-to-Follow-up and Vital Status: CaD Participants

Data as of: August 31, 2002

	CaD Participants (N=36,282)	
	N	%
Vital Status/Participation		
Deceased	803	2.2
Alive: Current Participation[1]	34278	94.5
Alive: Recent Participation[2]	486	1.3
Alive: Past/Unknown Participation[3]	16	0.0
Stopped Follow-Up[4]	394	1.1
Lost to Follow-Up[5]	305	0.8

[1] Participants who have filled in a Form 33 within the last 9 months.
[2] Participants who last filled in a Form 33 between 9 and 18 months ago.
[3] Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

Table 4.9
Locally Verified Outcomes (Annualized Percentages) by Age for Calcium and Vitamin D

Data as of: August 31, 2002

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number of participants	36282	5157	8265	16520	6340
Mean follow-up (months)	55.1	60.7	57.3	53.4	52.4
Fractures					
Hip fracture	165 (0.10%)	4 (0.02%)	12 (0.03%)	66 (0.09%)	83 (0.30%)
Vertebral fracture	188 (0.11%)	5 (0.02%)	20 (0.05%)	80 (0.11%)	83 (0.30%)
Other fracture[1]	2295 (1.38%)	300 (1.15%)	455 (1.15%)	1042 (1.42%)	498 (1.80%)
Total fracture	2567 (1.54%)	306 (1.17%)	483 (1.22%)	1152 (1.57%)	626 (2.26%)
Cancer					
Colorectal cancer	208 (0.12%)	13 (0.05%)	32 (0.08%)	99 (0.13%)	64 (0.23%)
Breast cancer[2]	834 (0.50%)	94 (0.36%)	198 (0.50%)	398 (0.54%)	144 (0.52%)
Invasive breast cancer	661 (0.40%)	71 (0.27%)	158 (0.40%)	316 (0.43%)	116 (0.42%)
Non-invasive breast cancer	175 (0.10%)	23 (0.09%)	40 (0.10%)	84 (0.11%)	28 (0.10%)
Ovarian cancer	79 (0.05%)	10 (0.04%)	19 (0.05%)	32 (0.04%)	18 (0.07%)
Endometrial cancer[3]	112 (0.11%)	14 (0.09%)	26 (0.11%)	51 (0.12%)	21 (0.13%)
Other cancer[1]	797 (0.48%)	74 (0.28%)	133 (0.34%)	382 (0.52%)	208 (0.75%)
Total cancer	1987 (1.19%)	203 (0.78%)	398 (1.01%)	943 (1.28%)	443 (1.60%)
Cardiovascular					
CHD[4]	535 (0.32%)	32 (0.12%)	52 (0.13%)	251 (0.34%)	200 (0.72%)
CHD death[5]	115 (0.07%)	7 (0.03%)	12 (0.03%)	46 (0.06%)	50 (0.18%)
Total MI[6]	457 (0.27%)	27 (0.10%)	42 (0.11%)	223 (0.30%)	165 (0.60%)
Clinical MI	423 (0.25%)	23 (0.09%)	39 (0.10%)	209 (0.28%)	152 (0.55%)
Evolving Q-wave MI[7]	36 (0.02%)	4 (0.02%)	3 (0.01%)	16 (0.02%)	13 (0.05%)
Possible evolving Q-wave MI[7]	111 (0.07%)	15 (0.06%)	20 (0.05%)	44 (0.06%)	32 (0.12%)
Angina	697 (0.42%)	31 (0.12%)	96 (0.24%)	348 (0.47%)	222 (0.80%)
CABG/PTCA	733 (0.44%)	32 (0.12%)	87 (0.22%)	370 (0.50%)	244 (0.88%)
Carotid artery disease	108 (0.06%)	3 (0.01%)	11 (0.03%)	58 (0.08%)	36 (0.13%)
Congestive heart failure	408 (0.24%)	15 (0.06%)	43 (0.11%)	193 (0.26%)	157 (0.57%)
Stroke	399 (0.24%)	15 (0.06%)	39 (0.10%)	180 (0.24%)	165 (0.60%)
PVD	103 (0.06%)	5 (0.02%)	13 (0.03%)	48 (0.07%)	37 (0.13%)
CHD[4]/Possible evolving Q-wave MI	641 (0.38%)	47 (0.18%)	72 (0.18%)	292 (0.40%)	230 (0.83%)
Coronary disease[8]	1600 (0.96%)	87 (0.33%)	202 (0.51%)	764 (1.04%)	547 (1.98%)
Total cardiovascular disease	2092 (1.25%)	106 (0.41%)	254 (0.64%)	1010 (1.37%)	722 (2.61%)
Deaths					
Cardiovascular deaths	216 (0.13%)	11 (0.04%)	19 (0.05%)	86 (0.12%)	100 (0.36%)
Cancer deaths	364 (0.22%)	29 (0.11%)	44 (0.11%)	171 (0.23%)	120 (0.43%)
Other known cause	107 (0.06%)	6 (0.02%)	14 (0.04%)	48 (0.07%)	39 (0.14%)
Unknown cause	37 (0.02%)	3 (0.01%)	5 (0.01%)	19 (0.03%)	10 (0.04%)
Not yet adjudicated	79 (0.05%)	3 (0.01%)	8 (0.02%)	40 (0.05%)	28 (0.10%)
Total death	803 (0.48%)	52 (0.20%)	90 (0.23%)	364 (0.50%)	297 (1.07%)

[1] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[2] Excludes five cases with borderline malignancy.
[3] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[4] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[5] "CHD death" includes definite and possible CHD death.
[6] "Total MI" includes clinical MI and evolving Q-wave MI.
[7] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[8] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 4.9 (continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Calcium and Vitamin D

Data as of: August 31, 2002

Outcome	Race/Ethnicity: American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number of participants	149	721	3315	1502	30155	440
Mean follow-up (months)	54.9	51.4	53.7	53.5	55.5	51.5
Fractures						
Hip fracture	0 (0.00%)	3 (0.10%)	4 (0.03%)	2 (0.03%)	156 (0.11%)	0 (0.00%)
Vertebral fracture	0 (0.00%)	3 (0.10%)	2 (0.01%)	5 (0.07%)	174 (0.12%)	4 (0.21%)
Other fracture[1]	11 (1.61%)	28 (0.91%)	113 (0.76%)	56 (0.84%)	2067 (1.48%)	20 (1.06%)
Total fracture	11 (1.61%)	32 (1.04%)	118 (0.80%)	63 (0.94%)	2320 (1.66%)	23 (1.22%)
Cancer						
Colorectal cancer	2 (0.29%)	4 (0.13%)	21 (0.14%)	7 (0.10%)	172 (0.12%)	2 (0.11%)
Breast cancer[2]	1 (0.15%)	18 (0.58%)	47 (0.32%)	26 (0.39%)	735 (0.53%)	7 (0.37%)
Invasive breast cancer	1 (0.15%)	12 (0.39%)	33 (0.22%)	23 (0.34%)	585 (0.42%)	7 (0.37%)
Non-invasive breast cancer	0 (0.00%)	6 (0.19%)	14 (0.09%)	3 (0.04%)	152 (0.11%)	0 (0.00%)
Ovarian cancer	0 (0.00%)	2 (0.06%)	7 (0.05%)	0 (0.00%)	69 (0.05%)	1 (0.05%)
Endometrial cancer[3]	1 (0.35%)	0 (0.00%)	2 (0.03%)	2 (0.05%)	106 (0.13%)	1 (0.09%)
Other cancer[1]	3 (0.44%)	15 (0.49%)	48 (0.32%)	16 (0.24%)	708 (0.51%)	7 (0.37%)
Total cancer	7 (1.03%)	39 (1.26%)	124 (0.84%)	48 (0.72%)	1751 (1.25%)	18 (0.95%)
Cardiovascular						
CHD[4]	1 (0.15%)	2 (0.06%)	45 (0.30%)	11 (0.16%)	468 (0.34%)	8 (0.42%)
CHD death[5]	1 (0.15%)	1 (0.03%)	17 (0.11%)	2 (0.03%)	92 (0.07%)	2 (0.11%)
Total MI[6]	1 (0.15%)	2 (0.06%)	32 (0.22%)	10 (0.15%)	405 (0.29%)	7 (0.37%)
Clinical MI	1 (0.15%)	2 (0.06%)	29 (0.20%)	10 (0.15%)	375 (0.27%)	6 (0.32%)
Evolving Q-wave MI[7]	0 (0.00%)	0 (0.00%)	3 (0.02%)	0 (0.00%)	32 (0.02%)	1 (0.05%)
Possible evolving Q-wave MI[7]	0 (0.00%)	3 (0.10%)	17 (0.11%)	3 (0.04%)	88 (0.06%)	0 (0.00%)
Angina	1 (0.15%)	8 (0.26%)	72 (0.49%)	26 (0.39%)	582 (0.42%)	8 (0.42%)
CABG/PTCA	1 (0.15%)	5 (0.16%)	62 (0.42%)	23 (0.34%)	632 (0.45%)	10 (0.53%)
Carotid artery disease	1 (0.15%)	1 (0.03%)	5 (0.03%)	0 (0.00%)	101 (0.07%)	0 (0.00%)
Congestive heart failure	1 (0.15%)	3 (0.10%)	62 (0.42%)	11 (0.16%)	326 (0.23%)	5 (0.26%)
Stroke	3 (0.44%)	10 (0.32%)	42 (0.28%)	10 (0.15%)	328 (0.24%)	6 (0.32%)
PVD	1 (0.15%)	1 (0.03%)	16 (0.11%)	0 (0.00%)	84 (0.06%)	1 (0.05%)
CHD[4]/Possible evolving Q-wave MI	1 (0.15%)	5 (0.16%)	61 (0.41%)	14 (0.21%)	552 (0.40%)	8 (0.42%)
Coronary disease[8]	2 (0.29%)	15 (0.49%)	178 (1.20%)	46 (0.69%)	1339 (0.96%)	20 (1.06%)
Total cardiovascular disease	6 (0.88%)	27 (0.87%)	230 (1.55%)	56 (0.84%)	1746 (1.25%)	27 (1.43%)
Deaths						
Cardiovascular deaths	1 (0.15%)	4 (0.13%)	34 (0.23%)	4 (0.06%)	171 (0.12%)	2 (0.11%)
Cancer deaths	0 (0.00%)	11 (0.36%)	32 (0.22%)	6 (0.09%)	312 (0.22%)	3 (0.16%)
Other known cause	2 (0.29%)	0 (0.00%)	13 (0.09%)	0 (0.00%)	91 (0.07%)	1 (0.05%)
Unknown cause	1 (0.15%)	0 (0.00%)	5 (0.03%)	0 (0.00%)	31 (0.02%)	0 (0.00%)
Not yet adjudicated	0 (0.00%)	1 (0.03%)	3 (0.02%)	2 (0.03%)	72 (0.05%)	1 (0.05%)
Total death	4 (0.59%)	16 (0.52%)	87 (0.59%)	12 (0.18%)	677 (0.49%)	7 (0.37%)

[1] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[2] Excludes five cases with borderline malignancy.
[3] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[4] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[5] "CHD death" includes definite and possible CHD death.
[6] "Total MI" includes clinical MI and evolving Q-wave MI.
[7] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[8] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 4.10
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for CaD Participants who did not report a prevalent condition at baseline

Data as of: August 31, 2002

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	36282	5157	8265	16520	6340
Mean follow-up (months)	55.1	60.7	57.3	53.4	52.4
Hospitalizations					
Ever	12115 (7.27%)	1257 (4.82%)	2279 (5.77%)	5773 (7.86%)	2806 (10.14%)
Two or more	5089 (3.05%)	450 (1.72%)	862 (2.18%)	2398 (3.26%)	1379 (4.98%)
Other					
DVT[1]	253 (0.16%)	14 (0.05%)	45 (0.12%)	108 (0.15%)	86 (0.32%)
Pulmonary embolism	144 (0.09%)	8 (0.03%)	29 (0.07%)	71 (0.10%)	36 (0.13%)
Diabetes (treated)	1717 (1.07%)	252 (0.99%)	401 (1.06%)	768 (1.09%)	296 (1.13%)
Gallbladder disease[2]	1669 (1.19%)	256 (1.11%)	426 (1.25%)	758 (1.24%)	229 (1.01%)
Hysterectomy	653 (0.67%)	92 (0.61%)	154 (0.63%)	310 (0.72%)	97 (0.62%)
Glaucoma	2331 (1.45%)	240 (0.93%)	462 (1.20%)	1117 (1.58%)	512 (1.98%)
Osteoporosis	4745 (2.99%)	444 (1.73%)	867 (2.26%)	2313 (3.32%)	1121 (4.45%)
Osteoarthritis[3]	4578 (4.42%)	661 (3.44%)	1067 (3.97%)	2077 (4.79%)	773 (5.48%)
Rheumatoid arthritis	1212 (0.76%)	187 (0.74%)	298 (0.78%)	514 (0.73%)	213 (0.81%)
Intestinal polyps	3195 (2.05%)	384 (1.52%)	700 (1.86%)	1564 (2.30%)	547 (2.21%)
Lupus	211 (0.13%)	38 (0.15%)	51 (0.13%)	85 (0.12%)	37 (0.13%)
Kidney stones[3]	433 (0.32%)	59 (0.29%)	105 (0.33%)	194 (0.32%)	75 (0.33%)
Cataracts[3]	7499 (6.26%)	462 (2.33%)	1251 (4.10%)	4061 (7.59%)	1725 (10.93%)
Pills for hypertension	6442 (5.40%)	838 (3.93%)	1424 (4.68%)	2951 (5.84%)	1229 (7.21%)

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	149	721	3315	1502	30155	440
Mean follow-up (months)	54.9	51.4	53.7	53.5	55.5	51.5
Hospitalizations						
Ever	49 (7.19%)	158 (5.12%)	1133 (7.64%)	414 (6.19%)	10215 (7.32%)	146 (7.74%)
Two or more	28 (4.11%)	53 (1.72%)	485 (3.27%)	151 (2.26%)	4312 (3.09%)	60 (3.18%)
Other						
DVT[1]	2 (0.30%)	0 (0.00%)	18 (0.12%)	4 (0.06%)	227 (0.17%)	2 (0.11%)
Pulmonary embolism	3 (0.44%)	0 (0.00%)	10 (0.07%)	2 (0.03%)	126 (0.09%)	3 (0.16%)
Diabetes (treated)	9 (1.43%)	46 (1.59%)	279 (2.11%)	120 (1.91%)	1239 (0.92%)	24 (1.36%)
Gallbladder disease[2]	8 (1.55%)	27 (0.96%)	107 (0.80%)	78 (1.51%)	1427 (1.22%)	22 (1.39%)
Hysterectomy	2 (0.69%)	10 (0.50%)	29 (0.45%)	20 (0.54%)	587 (0.69%)	5 (0.47%)
Glaucoma	12 (1.84%)	36 (1.21%)	303 (2.18%)	114 (1.76%)	1846 (1.37%)	20 (1.12%)
Osteoporosis	17 (2.62%)	96 (3.22%)	246 (1.72%)	191 (3.04%)	4138 (3.11%)	57 (3.24%)
Osteoarthritis[3]	27 (6.27%)	85 (3.81%)	407 (4.52%)	229 (5.03%)	3766 (4.37%)	64 (5.23%)
Rheumatoid arthritis	11 (1.82%)	20 (0.68%)	207 (1.51%)	107 (1.67%)	848 (0.63%)	19 (1.07%)
Intestinal polyps	18 (2.86%)	56 (1.97%)	308 (2.22%)	107 (1.66%)	2672 (2.05%)	34 (1.96%)
Lupus	3 (0.45%)	1 (0.03%)	26 (0.18%)	5 (0.08%)	174 (0.13%)	2 (0.11%)
Kidney stones[3]	3 (0.55%)	9 (0.35%)	31 (0.26%)	22 (0.41%)	362 (0.32%)	6 (0.39%)
Cataracts[3]	38 (7.63%)	120 (5.34%)	615 (5.75%)	304 (5.97%)	6340 (6.35%)	82 (5.89%)
Pills for hypertension	26 (6.03%)	120 (5.66%)	634 (8.21%)	296 (5.73%)	5294 (5.15%)	72 (5.99%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

5. Observational Study

5.1 Recruitment

Recruitment into the OS component, completed in December of 1998, reached 93,717, approximately 94% of the expected sample size. After removing duplicate enrollments and a few enrollments with insufficient data, the final analytic cohort was established with 93,676 participants. *Table 5.1* documents the age distribution and the racial/ethnic composition of this cohort.

5.2 Overview of Follow-up

OS follow-up is conducted by annual mailed self-administered questionnaires except for year 3, when participants attend a clinic follow-up visit. Participants at the 3 bone density sites also attend a clinic visit at year 6 for a bone density scan. For all other years, the CCC mails the *Medical History Update* and the *OS Exposure Update* questionnaires approximately 2 months prior to the anniversary of the participants' enrollment. Participants mail their completed questionnaires to their local CC for data entry and outcomes processing. Non-respondents receive up to two additional mailings from the CCC. For odd numbered follow-up years, CCs attempt to complete follow-up of non-responders by local contacts, usually telephone reminders or interviews.

The year 3 clinic visit was incorporated to assess change in physical measures, blood analytes, diet, and use of medications and supplements. These visits began in the first VCCs in Fall 1997.

5.3 Completeness of Annual Mail Follow-up

Table 5.2 shows completeness of OS mail follow-up by follow-up year, type of contact, and clinic group. These rates include participants for whom the full sequence of mailings are complete and there has been at least two months for CC follow-up of non-responders.

The overall response of 95.7% for year 1 data collection, which includes mailings plus CC follow-up of non-responders, slightly exceeds the 95% goal for completion of *Form 48 – OS Exposure Update*, but falls short of the optimal goal (98%) for completion of *Form 33 – Medical History Update*. For years 2, 4, 5, and 6 the rates of 94.2% (Y2), 93.6% (Y4), 94.8% (Y5), and 94.5% (Y6) exceed the 94% (Y2), 92% (Y4), 91% (Y5), and 90% (Y6) goals for the *Exposure Update*. These rates fall slightly short of the optimal goals (98% at Y1 with a ½% annual decline to 95.5% by Y6) for the *Medical History Update*.

5.4 Completeness of Year 3 Clinic Visit

Table 5.3 shows completeness of activities conducted at the year 3 clinic visit for all participants and at the year 6 visit for bone density participants. Of those participants due for the year 3 visit through 8/31/02, 96.0% overall completed *Form 33 - Medical History Updates* and 82.6% provided *Form 100 – Blood Samples*. Of those participants due for the year 6 visit, 87.1% completed *Form 33 – Medical History Updates* and 78.5% completed *Form 87 – Bone Densitometry*.

5.5 Bone Mineral Density

Bone scans are given to all enrolled WHI participants in three Clinical Centers: Birmingham, Pittsburgh, and Tucson. The choice of three centers was based on reducing the variability

associated with multiple sites and operators while achieving adequate sample size. The selection of these three clinical centers was based both on their previous experience in bone densitometry and the expected enrollment of minorities which will allow us to address hypotheses regarding racial/ethnic differences. Bone scans are given at baseline and years 1, 3, 6, and 9 in these centers.

Table 5.4 (overall) and *Table 5.5* (by race and ethnicity) show the OS component-specific BMD means and standard deviations for baseline AV-3 along with % change from baseline for the three types of scans available: whole body, spine, and hip. Baseline and % change is also given using only those women who have an AV-3 bone scan, as nearly 3,000 of the women with a baseline do not have an AV-3 measure. The current data suggest overall a small increase in bone density over three years in this group of women. In general, we would have expected a small decrease in BMD over time. As with the corresponding DM results, this increase could be related to some selection of health conscious women who may be taking hormone replacement therapy or calcium supplements of their own, or could be due to measurement issues.

5.6 Vital Status

Table 5.6 presents data on the vital status and the participation status of participants in the OS. A detailed description of CC and CCC activities to actively locate participants who do not complete their periodic visits is given in *Section 6 – Outcomes Processing*. For operational purposes, we define OS participants to be lost-to-follow-up if there is no outcomes information from the participant for 24 months. Currently 2.2% of the participants are lost-to-follow-up, and an additional 1.5% of the participants have stopped follow-up. 3.2% of the OS participants are deceased. Compared to six months ago, the percentage of participants who were lost-to-follow-up or stopped follow-up increased by 0.5%. Over the same period, participation levels have remained stable, as 90.0% of the participants are considered current, 0.3% more than six months ago.

5.7 Outcomes

Table 5.7 contains counts of the number of locally verified major WHI outcomes for OS participants by age and race/ethnicity. As approximately 5% of the self-reported outcomes have not yet been verified, the numbers in this table can be seen as a lower bound to the actual number of outcomes that took place. Compared to the incidence rates used in the CT design, we have about 125% of the expected number of breast cancers, 65% of the expected number of colorectal cancers, about 50% of the expected number of CHD events, and about 30% of the expected number hip fractures.

Table 5.8 contains counts of the number of self-reports for some outcomes that are not locally verified in WHI. As most of the locally verified outcomes are somewhat over-reported (see *Section 6.3 – Outcomes Data Quality*), the number in this table should be taken as an upper bound to the number of events that have occurred among OS participants.

Tables 5.9 and *5.10,* contain counts of outcomes relative to AV-3. These tables count the *first* event of a particular type, thus a participant who reports, say, an Angina at AV-1 and another one at AV-4 gets only counted in the "Before AV-3" category. These tables may be useful for investigators who want to propose ancillary studies or papers.

Table 5.1
Observational Study Age and Race/Ethnicity Specific Recruitment

Data as of: August 31, 2002

	Total Enrolled	Distribution
Age	**93,676**	
50-54	12386	13%
55-59	17321	18%
60-69	41196	44%
70-79	22773	24%
Race/Ethnicity	**93,676**	
American Indian	421	<1%
Asian	2671	3%
Black	7635	8%
Hispanic	3609	4%
White	78016	83%
Unknown	1324	1%

Table 5.2
Response Rates to OS Follow-up Procedures

Data as of: August 31, 2002

	# Due[1]	Mailings Initiated[2] N	Mailings Initiated[2] %	Response to Mailings N	Response to Mailings %[3]	Response to CC follow-up N	Response to CC follow-up %[4]	Total Responses N	Total Responses %[5]
Year 1	93,466	93,280	99.8%	86,656	92.9%	2,829	42.8%	89,485	95.7%
VCC	41,637	41,603	99.9%	38,421	92.4%	1,689	53.1%	40,110	96.3%
NCC	51,829	51,677	99.7%	48,235	93.4%	1,140	33.2%	49,375	95.3%
Year 2	93,032	91,394	98.2%	86,317	94.4%	N/A		87,615	94.2%
VCC	41,453	40,707	98.2%	38,479	94.5%	N/A		39,100	94.3%
NCC	51,579	50,687	98.3%	47,838	94.4%	N/A		48,515	94.1%
Year 4	64,796	63,549	98.1%	59,360	93.4%	N/A		60,663	93.6%
VCC	30,333	29,698	97.9%	27,620	93.0%	N/A		28,171	92.9%
NCC	34,463	33,851	98.2%	31,740	93.8%	N/A		32,492	94.3%
Year 5	41,705	40,958	98.2%	38,615	94.3%	936	39.9%	39,551	94.8%
VCC	20,151	19,851	98.5%	18,553	93.5%	460	35.4%	19,013	94.4%
NCC	21,554	21,107	97.9%	20,062	95.0%	476	45.6%	20,538	95.3%
Year 6[6]	11,038	10,799	97.8%	10,242	94.8%	N/A		10,434	94.5%
VCC	5,959	5,835	97.9%	5,480	93.9%	N/A		5,573	93.5%
NCC	5,079	4,964	97.7%	4,762	95.9%	N/A		4,861	95.7%

[1] Excludes women who are deceased.
[2] Mailings are not sent to women who have requested no follow-up, who are deceased, who have a non-deliverable address at the time of mailing, or who have a Form 33 completed within the previous 3 months.
[3] Percent response of those initiated.
[4] Percent response from OS participants not responding to mailings. CC follow-up not required in even numbered follow-up years.
[5] Percent response of those due.
[6] Does not include bone density sites.

Table 5.3
OS Annual Visit 3 Task Completeness

Data as of: August 31, 2002

	Task	# Due[1]	# Done[2]	% Done
Year 3	Form 33 - Medical History Update	92,136	88,419	96.0%
	Form 38 - Daily Life	92,136	81,938	88.9%
	Form 44 - Current Medications	92,136	78,839	85.6%
	Form 45 - Current Supplements	92,136	78,738	85.5%
	Form 60 - Food Frequency Quest	92,136	82,096	89.1%
	Form 80 - Physical Measures	92,136	77,006	83.6%
	Form 100 - Blood Collection	92,136	76,117	82.6%
	Form 143 - Follow-up	92,136	81,590	88.6%
Year 6[3]	Form 33 - Medical History Update	2,663	2,320	87.1%
	Form 80 - Physical Measures	2,663	2,097	78.7%
	Form 87 - Bone Densitometry	2,663	2,090	78.5%
	Form 146 - Follow-up	2,663	2,240	84.1%

[1] Includes all Year 3/6 contacts due through 5/31/02. Excludes women who are deceased.
[2] Tasks completed within the -6/+15 month window for Year 3 and -2/+10 month window for Year 6.
[3] Includes bone density sites only.

Table 5.4
Bone Mineral Density[1] Analysis: OS Participants

Data as of: August 31, 2002

	N	Mean	S.D.
Whole Body Scan			
Baseline	6390	1.01	0.11
Baseline (for ppts. with an AV3 scan)	5075	1.01	0.11
Baseline (for ppts. with an AV6 scan)	3248	1.01	0.11
AV3	5134	1.02	0.11
AV6	3273	1.03	0.12
AV3 % Change from baseline BMD[2]	5068	0.92	3.63
AV6 % Change from baseline BMD[3]	3240	1.88	5.45
Spine Scan			
Baseline	6265	0.98	0.17
Baseline (for ppts. with an AV3 scan)	4995	0.97	0.17
Baseline (for ppts. with an AV6 scan)	3155	0.98	0.17
AV3	5033	0.99	0.17
AV6	3167	1.01	0.18
AV3 % Change from baseline BMD[2]	4987	1.67	5.14
AV6 % Change from baseline BMD[3]	3147	3.73	6.87
Hip Scan			
Baseline	6418	0.84	0.14
Baseline (for ppts. with an AV3 scan)	5145	0.84	0.14
Baseline (for ppts. with an AV6 scan)	3296	0.84	0.14
AV3	5185	0.85	0.14
AV6	3308	0.84	0.14
AV3 % Change from baseline BMD[2]	5113	0.49	4.35
AV6 % Change from baseline BMD[3]	3262	0.22	5.30

[1] Measured in (g/cm^2).
[2] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[3] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 5.5
Bone Mineral Density[1] Analysis: OS Participants by Race/Ethnicity

Data as of: August 31, 2002

	American Indian/ Alaskan Native			Asian/Pacific Islander			Black/African American			Hispanic/Latino			White			Unknown		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan																		
Baseline	108	1.01	0.12	25	1.02	0.09	824	1.04	0.11	462	1.01	0.11	4925	1.00	0.10	46	1.01	0.12
Baseline (for ppts. with an AV3 scan)	77	1.02	0.12	22	1.03	0.09	568	1.05	0.11	323	1.01	0.10	4049	1.01	0.10	36	1.00	0.11
Baseline (for ppts. with an AV6 scan)	24	1.07	0.13	11	1.02	0.08	343	1.04	0.11	144	1.04	0.10	2709	1.01	0.10	17	1.00	0.14
AV3	81	1.03	0.13	22	1.03	0.11	576	1.06	0.12	338	1.03	0.11	4080	1.01	0.11	37	1.01	0.10
AV6	24	1.08	0.14	11	1.03	0.12	346	1.05	0.12	144	1.08	0.14	2731	1.03	0.12	17	0.99	0.14
AV3 % Change from baseline BMD[2]	77	0.70	4.45	22	-0.03	5.44	568	1.52	3.35	322	1.51	4.43	4043	0.80	3.56	36	0.42	2.92
AV6 % Change from baseline BMD[3]	24	0.87	4.91	11	1.22	5.12	343	0.29	3.70	143	3.75	6.72	2702	2.01	5.52	17	-0.89	5.45
Spine Scan																		
Baseline	109	0.99	0.17	25	0.95	0.12	815	1.04	0.18	454	0.95	0.16	4817	0.97	0.17	45	0.99	0.19
Baseline (for ppts. with an AV3 scan)	77	0.99	0.15	22	0.96	0.12	571	1.04	0.17	315	0.95	0.16	3976	0.97	0.17	34	0.95	0.18
Baseline (for ppts. with an AV6 scan)	24	1.06	0.18	10	0.94	0.10	326	1.04	0.18	142	0.98	0.17	2636	0.97	0.16	17	0.97	0.26
AV3	81	1.00	0.16	22	0.96	0.12	574	1.05	0.19	328	0.95	0.16	3993	0.98	0.17	35	0.95	0.17
AV6	24	1.09	0.15	10	0.95	0.10	326	1.07	0.19	142	0.99	0.18	2648	1.01	0.18	17	1.01	0.27
AV3 % Change from baseline BMD[2]	77	0.19	5.80	22	0.22	4.62	571	1.16	5.53	314	0.30	5.42	3969	1.90	5.02	34	0.84	5.17
AV6 % Change from baseline BMD[3]	24	3.62	7.06	10	1.61	4.39	326	2.40	6.00	141	0.79	6.85	2629	4.06	6.92	17	4.43	7.75
Hip Scan																		
Baseline	109	0.87	0.15	25	0.82	0.10	827	0.93	0.15	463	0.83	0.13	4948	0.83	0.13	46	0.85	0.14
Baseline (for ppts. with an AV3 scan)	78	0.88	0.15	22	0.82	0.10	581	0.93	0.15	324	0.83	0.12	4104	0.83	0.13	36	0.83	0.12
Baseline (for ppts. with an AV6 scan)	24	0.95	0.17	11	0.79	0.09	347	0.93	0.15	144	0.85	0.12	2752	0.83	0.13	18	0.82	0.17
AV3	82	0.88	0.15	22	0.82	0.09	587	0.94	0.15	338	0.85	0.13	4119	0.83	0.13	37	0.82	0.13
AV6	24	0.94	0.15	11	0.81	0.09	349	0.91	0.15	144	0.87	0.12	2762	0.83	0.13	18	0.82	0.17
AV3 % Change from baseline BMD[2]	77	-0.34	4.95	22	0.81	4.42	581	0.37	4.01	322	1.70	5.07	4075	0.43	4.30	36	-0.81	4.76
AV6 % Change from baseline BMD[3]	24	-0.38	6.41	11	3.06	6.01	345	-1.61	4.76	143	1.91	5.89	2721	0.36	5.26	18	-0.49	6.87

[1] Measured in (g/cm^2).
[2] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.
[3] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 5.6
Lost-to-Follow-up and Vital Status: OS Participants

Data as of: August 31, 2002

	OS Participants (N=93,676)	
	N	%
Vital Status/Participation		
Deceased	2981	3.2
Alive: Current Participation[1]	84308	90.0
Alive: Recent Participation[2]	2691	2.9
Alive: Past/Unknown Participation[3]	260	0.3
Stopped Follow-Up[4]	1393	1.5
Lost to Follow-Up[5]	2043	2.2

[1] Participants who have filled in a Form 33 within the last 15 months.
[2] Participants who last filled in a Form 33 between 15 and 24 months ago.
[3] Participants without a Form 33 within the last 24 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

Table 5.7
Locally Verified Outcomes (Annualized Percentages) by Age for OS Participants

Data as of: August 31, 2002

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number enrolled	93676	12386	17321	41196	22773
Mean follow-up (months)	60.8	64.5	63.2	59.8	58.6
Cardiovascular					
CHD[1]	1297 (0.27%)	40 (0.06%)	110 (0.12%)	532 (0.26%)	615 (0.55%)
CHD death[2]	329 (0.07%)	5 (0.01%)	19 (0.02%)	111 (0.05%)	194 (0.17%)
Clinical MI	1069 (0.23%)	36 (0.05%)	97 (0.11%)	452 (0.22%)	484 (0.44%)
Angina	1982 (0.42%)	88 (0.13%)	199 (0.22%)	911 (0.44%)	784 (0.71%)
CABG/PTCA	1872 (0.39%)	64 (0.10%)	186 (0.20%)	870 (0.42%)	752 (0.68%)
Carotid artery disease	409 (0.09%)	23 (0.03%)	29 (0.03%)	157 (0.08%)	200 (0.18%)
Congestive heart failure	1263 (0.27%)	41 (0.06%)	101 (0.11%)	497 (0.24%)	624 (0.56%)
Stroke	1061 (0.22%)	29 (0.04%)	84 (0.09%)	408 (0.20%)	540 (0.49%)
PVD	297 (0.06%)	11 (0.02%)	29 (0.03%)	114 (0.06%)	143 (0.13%)
Coronary disease[3]	4058 (0.86%)	161 (0.24%)	385 (0.42%)	1750 (0.85%)	1762 (1.58%)
Total cardiovascular disease	5498 (1.16%)	216 (0.32%)	498 (0.55%)	2293 (1.12%)	2491 (2.24%)
Cancer					
Breast cancer[4]	2570 (0.54%)	258 (0.39%)	460 (0.50%)	1183 (0.58%)	669 (0.60%)
Invasive breast cancer	2138 (0.45%)	217 (0.33%)	379 (0.42%)	972 (0.47%)	570 (0.51%)
Non-invasive breast cancer	454 (0.10%)	45 (0.07%)	87 (0.10%)	220 (0.11%)	102 (0.09%)
Ovarian cancer	226 (0.05%)	20 (0.03%)	38 (0.04%)	101 (0.05%)	67 (0.06%)
Endometrial cancer[5]	329 (0.12%)	28 (0.07%)	44 (0.08%)	157 (0.13%)	100 (0.16%)
Colorectal cancer	554 (0.12%)	31 (0.05%)	64 (0.07%)	251 (0.12%)	208 (0.19%)
Other cancer[6]	2374 (0.50%)	164 (0.25%)	290 (0.32%)	1084 (0.53%)	836 (0.75%)
Total cancer	5878 (1.24%)	490 (0.74%)	872 (0.96%)	2696 (1.31%)	1820 (1.64%)
Fractures					
Hip fracture	540 (0.11%)	12 (0.02%)	46 (0.05%)	173 (0.08%)	309 (0.28%)
Vertebral fracture[7]	66 (0.18%)	4 (0.07%)	5 (0.07%)	24 (0.15%)	33 (0.38%)
Other fracture[6,7]	487 (1.33%)	63 (1.17%)	81 (1.18%)	192 (1.23%)	151 (1.72%)
Total fracture[8]	1061 N/A	78 N/A	129 N/A	378 N/A	476 N/A
Deaths					
Cardiovascular deaths	747 (0.16%)	18 (0.03%)	45 (0.05%)	252 (0.12%)	432 (0.39%)
Cancer deaths	1254 (0.26%)	71 (0.11%)	137 (0.15%)	543 (0.26%)	503 (0.45%)
Other known cause	476 (0.10%)	23 (0.03%)	55 (0.06%)	179 (0.09%)	219 (0.20%)
Unknown cause	200 (0.04%)	8 (0.01%)	16 (0.02%)	75 (0.04%)	101 (0.09%)
Not yet adjudicated	304 (0.06%)	10 (0.02%)	25 (0.03%)	129 (0.06%)	140 (0.13%)
Total death	2981 (0.63%)	130 (0.20%)	278 (0.30%)	1178 (0.57%)	1395 (1.25%)

[1] "CHD" includes clinical MI and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[4] Excludes seven cases with borderline malignancy.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[6] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[7] For the OS, only women from three bone density clinics are used to compute the annual rates for vertebral and other fractures.
[8] Hip fractures are adjudicated at all clinics, while other fractures for OS participants are adjudicated only at a few clinics. A combined annualized percentage cannot be computed.

Table 5.7 (continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for OS Participants

Data as of: August 31, 2002

Outcomes	Ethnicity: American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number enrolled	421	2671	7635	3609	78016	1324
Mean follow-up (months)	56.7	58.7	56.5	53.2	61.7	58.0
Cardiovascular						
CHD[1]	7 (0.35%)	27 (0.21%)	111 (0.31%)	23 (0.14%)	1107 (0.28%)	22 (0.34%)
CHD death[2]	2 (0.10%)	8 (0.06%)	42 (0.12%)	2 (0.01%)	269 (0.07%)	6 (0.09%)
Clinical MI	6 (0.30%)	22 (0.17%)	81 (0.23%)	22 (0.14%)	921 (0.23%)	17 (0.27%)
Angina	12 (0.60%)	39 (0.30%)	170 (0.47%)	49 (0.31%)	1693 (0.42%)	19 (0.30%)
CABG/PTCA	9 (0.45%)	37 (0.28%)	117 (0.33%)	47 (0.29%)	1636 (0.41%)	26 (0.41%)
Carotid artery disease	3 (0.15%)	6 (0.05%)	24 (0.07%)	10 (0.06%)	359 (0.09%)	7 (0.11%)
Congestive heart failure	9 (0.45%)	19 (0.15%)	139 (0.39%)	26 (0.16%)	1054 (0.26%)	16 (0.25%)
Stroke	7 (0.35%)	33 (0.25%)	107 (0.30%)	19 (0.12%)	880 (0.22%)	15 (0.23%)
PVD	2 (0.10%)	4 (0.03%)	32 (0.09%)	4 (0.02%)	250 (0.06%)	5 (0.08%)
Coronary disease[3]	22 (1.11%)	72 (0.55%)	366 (1.02%)	92 (0.57%)	3459 (0.86%)	47 (0.73%)
Total cardiovascular disease	29 (1.46%)	109 (0.83%)	509 (1.42%)	120 (0.75%)	4662 (1.16%)	69 (1.08%)
Cancer						
Breast cancer[4]	6 (0.30%)	46 (0.35%)	157 (0.44%)	65 (0.41%)	2274 (0.57%)	22 (0.34%)
Invasive breast cancer	4 (0.20%)	35 (0.27%)	127 (0.35%)	51 (0.32%)	1902 (0.47%)	19 (0.30%)
Non-invasive breast cancer	2 (0.10%)	11 (0.08%)	31 (0.09%)	14 (0.09%)	392 (0.10%)	4 (0.06%)
Ovarian cancer	0 (0.00%)	4 (0.03%)	11 (0.03%)	7 (0.04%)	203 (0.05%)	1 (0.02%)
Endometrial cancer[5]	0 (0.00%)	6 (0.07%)	8 (0.05%)	6 (0.07%)	303 (0.13%)	6 (0.16%)
Colorectal cancer	1 (0.05%)	8 (0.06%)	64 (0.18%)	12 (0.07%)	464 (0.12%)	5 (0.08%)
Other cancer[6]	10 (0.50%)	39 (0.30%)	158 (0.44%)	44 (0.27%)	2086 (0.52%)	37 (0.58%)
Total cancer	17 (0.85%)	99 (0.76%)	384 (1.07%)	133 (0.83%)	5176 (1.29%)	69 (1.08%)
Fractures						
Hip fracture	3 (0.15%)	7 (0.05%)	13 (0.04%)	6 (0.04%)	504 (0.13%)	7 (0.11%)
Vertebral fracture[7]	1 (0.21%)	0 (0.00%)	1 (0.02%)	2 (0.08%)	62 (0.22%)	0 (0.00%)
Other fracture[6,7]	7 (1.45%)	2 (1.34%)	27 (0.58%)	21 (0.87%)	425 (1.48%)	5 (2.18%)
Total fracture[8]	10 N/A	9 N/A	40 N/A	28 N/A	962 N/A	12 N/A
Deaths						
Cardiovascular deaths	6 (0.30%)	20 (0.15%)	87 (0.24%)	10 (0.06%)	613 (0.15%)	11 (0.17%)
Cancer deaths	5 (0.25%)	22 (0.17%)	104 (0.29%)	26 (0.16%)	1079 (0.27%)	18 (0.28%)
Other known cause	8 (0.40%)	9 (0.07%)	41 (0.11%)	26 (0.16%)	385 (0.10%)	7 (0.11%)
Unknown cause	2 (0.10%)	4 (0.03%)	34 (0.09%)	7 (0.04%)	151 (0.04%)	2 (0.03%)
Not yet adjudicated	3 (0.15%)	7 (0.05%)	39 (0.11%)	12 (0.07%)	240 (0.06%)	3 (0.05%)
Total death	24 (1.21%)	62 (0.47%)	305 (0.85%)	81 (0.51%)	2468 (0.62%)	41 (0.64%)

[1] "CHD" includes clinical MI and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[4] Excludes seven cases with borderline malignancy.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[6] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[7] For the OS, only women from three bone density clinics are used to compute the annual rates for vertebral and other fractures.
[8] Hip fractures are adjudicated at all clinics, while other fractures for OS participants are adjudicated only at a few clinics. A combined annualized percentage cannot be computed.

Table 5.8
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for OS Participants who did not report a prevalent condition at baseline

Data as of: August 31, 2002

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	93676	12386	17321	41196	22773
Mean follow-up (months)	60.8	64.5	63.2	59.8	58.6
Hospitalizations					
Ever	32187 (6.79%)	2983 (4.48%)	4618 (5.06%)	14386 (7.01%)	10200 (9.17%)
Two or more	13681 (2.88%)	1065 (1.60%)	1652 (1.81%)	6059 (2.95%)	4905 (4.41%)
Other					
DVT[1]	469 (0.10%)	40 (0.06%)	52 (0.06%)	210 (0.11%)	167 (0.16%)
Pulmonary embolism	295 (0.06%)	29 (0.04%)	38 (0.04%)	126 (0.06%)	102 (0.09%)
Diabetes (treated)	3174 (0.70%)	387 (0.60%)	574 (0.65%)	1444 (0.73%)	769 (0.72%)
Gallbladder disease[2]	3903 (0.98%)	607 (1.03%)	778 (0.99%)	1735 (1.01%)	783 (0.86%)
Hysterectomy	2133 (0.77%)	303 (0.76%)	416 (0.73%)	990 (0.83%)	424 (0.68%)
Glaucoma	5182 (1.15%)	509 (0.78%)	758 (0.85%)	2403 (1.23%)	1512 (1.48%)
Osteoporosis	15091 (3.48%)	1438 (2.24%)	2305 (2.65%)	6982 (3.73%)	4366 (4.54%)
Osteoarthritis[3]	10903 (3.95%)	1335 (2.78%)	1913 (3.19%)	4921 (4.29%)	2734 (5.09%)
Rheumatoid arthritis	3126 (0.70%)	437 (0.68%)	601 (0.69%)	1267 (0.65%)	821 (0.79%)
Intestinal polyps	8434 (1.96%)	961 (1.52%)	1551 (1.81%)	3929 (2.13%)	1993 (2.08%)
Lupus	702 (0.15%)	109 (0.16%)	140 (0.15%)	307 (0.15%)	146 (0.13%)
Kidney stones[3]	1436 (0.38%)	190 (0.38%)	261 (0.37%)	611 (0.37%)	374 (0.42%)
Cataracts[3]	18043 (5.67%)	930 (1.84%)	2324 (3.36%)	9445 (6.66%)	5344 (9.43%)
Pills for hypertension	14526 (4.29%)	1626 (2.94%)	2518 (3.53%)	6309 (4.42%)	4073 (5.84%)

Outcomes	Race/Ethnicity: American Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	421	2671	7635	3609	78016	1324
Mean follow-up (months)	56.7	58.7	56.5	53.2	61.7	58.0
Hospitalizations						
Ever	166 (8.35%)	570 (4.37%)	2522 (7.02%)	906 (5.66%)	27616 (6.89%)	407 (6.36%)
Two or more	79 (3.97%)	206 (1.58%)	1068 (2.97%)	313 (1.96%)	11834 (2.95%)	181 (2.83%)
Other						
DVT[1]	3 (0.16%)	4 (0.03%)	38 (0.11%)	8 (0.05%)	413 (0.11%)	3 (0.05%)
Pulmonary embolism	1 (0.05%)	3 (0.02%)	23 (0.06%)	2 (0.01%)	264 (0.07%)	2 (0.03%)
Diabetes (treated)	35 (2.06%)	116 (0.94%)	513 (1.62%)	209 (1.40%)	2261 (0.58%)	40 (0.65%)
Gallbladder disease[2]	25 (1.59%)	55 (0.46%)	256 (0.80%)	156 (1.24%)	3359 (1.00%)	52 (0.97%)
Hysterectomy	4 (0.41%)	35 (0.41%)	93 (0.57%)	78 (0.90%)	1885 (0.79%)	38 (1.02%)
Glaucoma	32 (1.76%)	164 (1.32%)	623 (1.89%)	178 (1.17%)	4110 (1.07%)	75 (1.22%)
Osteoporosis	67 (3.69%)	452 (3.79%)	667 (1.95%)	495 (3.37%)	13179 (3.60%)	231 (3.94%)
Osteoarthritis[3]	44 (3.97%)	321 (3.49%)	904 (4.34%)	498 (4.73%)	8967 (3.89%)	169 (4.33%)
Rheumatoid arthritis	24 (1.32%)	67 (0.54%)	466 (1.43%)	266 (1.79%)	2243 (0.59%)	60 (1.00%)
Intestinal polyps	30 (1.64%)	205 (1.75%)	662 (2.01%)	249 (1.66%)	7175 (1.98%)	113 (1.96%)
Lupus	7 (0.36%)	12 (0.09%)	69 (0.19%)	37 (0.23%)	566 (0.14%)	11 (0.17%)
Kidney stones[3]	12 (0.77%)	24 (0.23%)	167 (0.58%)	85 (0.65%)	1124 (0.36%)	24 (0.47%)
Cataracts[3]	62 (4.66%)	470 (5.43%)	1301 (5.22%)	571 (4.78%)	15371 (5.75%)	268 (6.21%)
Pills for hypertension	67 (5.29%)	398 (4.33%)	1201 (6.83%)	611 (5.09%)	12030 (4.09%)	219 (4.89%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 5.9
First Reported Locally Verified Outcomes Before and After AV-3[1] for OS Participants

Data as of: August 31, 2002

Outcome	Number of Events	
	Before AV-3	After AV-3
Cardiovascular		
CHD[2]	747	550
CHD death[3]	166	163
Clinical MI	630	439
Angina	1340	642
CABG/PTCA	1151	720
Carotid artery disease	250	159
Congestive heart failure	707	556
Stroke	565	496
PVD	196	101
Coronary disease[4]	2556	1502
Total cardiovascular disease	3407	2091
Cancer		
Breast cancer[5]	1581	989
Invasive breast cancer	1287	851
Non-invasive breast cancer	309	145
Ovarian cancer	150	76
Endometrial cancer	202	127
Colorectal cancer	339	215
Other cancer[6]	1409	965
Total cancer	3615	2263
Fractures		
Hip fracture[7]	289	251
Vertebral fracture[7]	34	32
Other fracture[6, 7]	275	212
Total fracture[7]	588	473
Deaths		
Cardiovascular deaths	357	390
Cancer deaths	588	666
Deaths: other known cause	215	261
Deaths: unknown cause	62	138
Deaths: not yet adjudicated	38	266
Total death	1260	1721

[1] AV-3 date is the blood draw date for participants with an AV-3 blood draw and the OS enrollment date plus 3 years for participants without an AV-3 blood draw. All participants have completed at least 3 years of follow-up.
[2] "CHD" includes clinical MI and CHD death.
[3] "CHD death" includes definite and possible CHD death.
[4] "Coronary disease" includes clinical MI, Evolving Q-wave MI, Possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[5] Excludes seven cases with borderline malignancy.
[6] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.
[7] Hip fractures are adjudicated at all clinics, while other fractures are adjudicated only at a few clinics.

Table 5.10
Counts of Participants with Self-Reported Outcomes Before and After AV-3[1]
for OS Participants who did not report a prevalent condition at baseline

Data as of: August 31, 2002

Outcome	Number of Events	
	Before AV-3	After AV-3
Ever hospitalized	19141	13046
DVT[2]	226	243
Pulmonary embolism	130	165
Diabetes (treated)	1739	1435
Gallbladder disease[3]	2133	1770
Hysterectomy	1245	888
Glaucoma	2750	2432
Osteoporosis	8693	6398
Osteoarthritis[4]	6330	4573
Rheumatoid arthritis	1722	1404
Intestinal polyps	4393	4041
Lupus	347	355
Kidney stones[4]	644	792
Cataracts[4]	9138	8905
Pills for hypertension	8137	6389

[1] AV-3 date is the blood draw date for participants with an AV-3 blood draw and the OS enrollment date plus 3 years for participants without an AV-3 blood draw. All participants have completed at least 3 years of follow-up.
[2] Inpatient DVT only.
[3] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[4] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

6. Outcomes Processing

6.1 Overview

Most outcomes are initially ascertained by self-report on *Form 33 – Medical History Update.* CT participants complete this form every six months; OS participants complete this form every year. Those participants who report an outcome requiring documentation and adjudication are asked to complete a more detailed form (*Form 33D*) that collects the information needed to request the associated medical records.

After these forms are completed and entered into the database, the CCs identify adjudication cases based on the *Form 33D* information. CCs then request hospital and related records. Once the cases are documented, clinic staff sends the charts having potential cardiovascular, cancer, and fracture outcomes to the local physician adjudicator for evaluation and classification. Key cardiovascular outcomes are further adjudicated by a central committee process. The investigators at UCSF (Steve Cummings, PI) subcontract to the CCC to adjudicate all hip fractures. Staff at the CCC code and adjudicate all cancers of major interest in the study (breast, colon, rectum, ovary, and endometrium) using standardized SEER guidelines. Outcomes for selected other diseases, such as diabetes, gallbladder disease, and hysterectomy, are collected as self-reports only.

The monitoring analysis is conducted on outcomes as classified by the local adjudicator. Currently, about 94% of the self-reports have been adjudicated. We do *not* report on the self-reports for which the adjudication process is not yet finished. We feel that we have now reached the stage in the study where the fraction of the self-reports that are not yet adjudicated is sufficiently small that omitting unadjudicated self-reports does not distort the larger picture.

6.2 Terminology

When a particular outcome, say MI, is investigated, all participants can be divided into five groups:

1. Those who have no self-report of an MI and have no locally confirmed MI.

2. Those who have a self-report of an MI and a locally confirmed MI. We refer to these participants' cases as *confirmed (with self-report).*

3. Those who have no self-report of an MI but do have a locally confirmed MI usually as a result of an investigation of a self-report of another outcome. We refer to these participants' cases as *confirmed (without self-report).*

4. Those who have a self-report of an MI but do not have a locally confirmed MI, and for whom all relevant adjudication cases are closed. We refer to these participants' self-reports as *denied.*

5. Those who have a self-report of an MI, but do not have a locally confirmed MI, while some of the relevant adjudication cases are still open. We refer to these participants' self-reports as *open.*

The *confirmed cases* are the cases of participants in categories 2 and 3; the *self-reports* are the cases of participants in categories 2, 4, and 5; the *closed self-reports* are the cases of participants in categories 2 and 4. For some analyses we divide the *denied* self-reports into three groups:

4a. The reports of the participants for which the self-reported outcome was denied, but for whom a related outcome (e.g., an angina based on an MI self-report) was found. We refer to those participants' self-reports as *denied - related outcome found*. For the outcome tables, we consider all cardiovascular outcomes to be related, all cancer outcomes to be related, and all fracture outcomes to be related.

4b. The reports of the participants for which the self-reported outcome was denied after review of the relevant documentation. We refer to those participants' self-reports as *denied - no (related) outcome found*.

4c. The reports of the participants for which the self-report was *denied* for *administrative reasons*. Self-reports can only be denied if they satisfy one of several narrowly defined rules. Usually this means that no documentation was obtained after several attempts over a one-year period.

6.3 Outcomes Data Quality

Tables 6.1-6.2 – Timeliness and Completeness of Local Adjudications display the distribution of time required to locally adjudicate a self-reported outcome by month on *Form 33* for the CT and the OS, respectively. This table is based on the day on which the form was received by the clinic, which may not be the same as the day on which the form was entered in the database. Overall 96% of self-reported outcomes in the CT and 95% of the self-reported outcomes in the OS requiring adjudication have been closed. In particular, 56% of the outcomes in the CT and 58% of the outcomes in the OS have been closed within 90 days of self-report and 75% (CT) and 78% (OS) within 180 days. (Note: the fact that the percentages for the OS appear better is because most of the outcomes in 1996 and earlier, when outcomes processing was considerably slower, are CT outcomes.)

Since 1997, the percentage of forms that were adjudicated within 90 days has increased from about 40% to about 75%, and the percentage of forms that were adjudicated within 180 days has increased from about 60% to over 90%. At the same time, the percentage of forms that are more than a year old that have not yet been adjudicated has been reduced to 0.3%. Currently, 33 of the 40 clinics have twelve or fewer outstanding *Forms 33D* that are more than a year old.

Figures 6.1-6.2 – Timeliness per Period of Self-Report display Kaplan-Meier curves for the time period from reporting an outcome on *Form 33D* until the adjudication case is closed per year of self-report separately for the CT and OS. Both figures clearly show that improvements in the processing of outcomes have happened throughout the study. The CCC continues to work closely with the Outcomes-PMC to develop reports and other tools that will facilitate timely outcomes processing by the CCs.

Tables 6.3-6.4 – Agreement of Local Adjudications with Self-Reports show condition types that the participant can indicate on *Form 33* or *Form 33D* and the fraction of time that the local adjudicator agrees with that self-report. Because of the complications of the adjudication

process, it is not straightforward to define an appropriate estimate of the accuracy of individual self-reports. For example, for most outcome types, second occurrences do not need to be adjudicated, but if the participant reports a second occurrence before the first is confirmed, an adjudication case will be opened. This case will be closed without a locally confirmed outcome when the first self-report is confirmed. To circumvent this and similar problems, the unit in *Tables 6.3* and *6.4* is defined to be a *participant* rather than an outcome event. For some participants whose self-report is denied, related outcomes may be found. We also note that on *Form 33* and *Form 33D* participants report a "stroke or transient ischemic attack (TIA)," while for monitoring purposes only the outcome "stroke" is used. Thus, the number of confirmed cases in *Tables 6.3* and *6.4,* which include TIA, is substantially larger than that in some of the outcomes tables in other sections of this report.

A self-reported outcome may be denied for the following reasons: (i) the outcome did take place, but could not be verified because insufficient evidence was available to the WHI adjudicator; (ii) the outcome did not take place, but a related outcome (which may or may not be of interest to WHI) occurred; (iii) the outcome took place before enrollment in WHI; and (iv) the current self-report was a duplicate report of a previous self-report.

The accuracy of self-reports varies considerably by outcome. For many outcomes the agreement rates for the CT are a few percentage points higher than for the OS. The accuracy of cancer and fracture self-reports may be higher than that for cardiovascular disease because more cardiovascular self-reports result in a related outcome. If those related outcomes are included with the confirmed self-reports, cardiovascular outcomes have a 76% agreement rate between self-reports and locally confirmed outcomes (83% if we exclude angina, which is probably the softest cardiovascular outcome), cancer outcomes have an agreement rate of 87% (93% for the primary cancers), and fracture outcomes have an agreement rate of 80% for the CT and OS combined.

Note that the accuracy of self-reports for *other fractures* (*other cancers*) reflects the percentage of people who reported an *other fracture* (*other cancer*) for whom any of the fractures (cancers) in the other category was found, even if the participant indicated the wrong skeletal site (cancer site).

The current rules regarding which cases are centrally adjudicated are:

- Clinical MI, angina, CHF, CABG/PTCA, self reports of MI that are denied locally: all cases that occurred before January 1, 2001, all cases for HRT participants, and 10% of the cases that occurred after January 1, 2001 for other participants are centrally adjudicated. Note that many of the self-reports of MI that are denied locally are already centrally adjudicated because another outcome, such as CHF or angina, was found.

- Stroke, PE, DVT, self reports of stroke that are denied locally: all cases for HRT participants are centrally adjudicated.

- Primary cancer, hip fracture, self reports of primary cancer and hip fracture that are denied locally: all cases are centrally adjudicated.

- Death: all cases for CT participants, all cases for OS participants that occurred before January 1, 2001, 10% of all cases for OS participants that occurred after January 1, 2001 are centrally adjudicated.

Tables 6.5-6.6 – Agreement of Central Adjudications with Local Adjudications have been modified to reflect these changes. In particular, we added a column for which cases are called forward for central adjudication. These tables show that there is good agreement between local and central adjudications for all outcomes. Often angina and congestive heart failure occur in conjunction with an MI. Disagreement on angina or CHF, when there is agreement about the MI is not considered very serious. Some self-reports are locally adjudicated as one type of outcome, while they are centrally adjudicated as another outcome. Data regarding such cross-classification is not shown.

We note that, thanks to the effort of the central adjudicators and the CCC cancer coders the fraction of outcomes that were called forward for central adjudication that have been centrally adjudicated has increased considerably. Except for stroke, now about 85% of the cardiovascular outcomes has been adjudicated (was 80%) and over 90% of the cancer outcomes has been centrally adjudicated (was also 80%).

Tables 6.5 and *6.6* show how many outcomes were identified by local adjudicators, but denied central. *Tables 6.7* and *6.8 – Source of Central Confirmed Outcomes* shows outcomes that were identified by the central adjudicators, but not by the local adjudicators. Approximately 16%(CT)-18%(OS) of the MIs that were identified by central adjudicators were not found by local adjudicators. All of these MIs were identified on cases that were called forward for "related" events, such as angina, CHF, and CABG/PTCA. Currently, few cases have been reviewed for self-reports that were denied locally and did not have a related outcome. Most of the cases of endometrial cancer that were identified based on a locally confirmed other outcome, were identified because of a locally confirmed case of cancer of the uterus; most of the cases of hip fracture that were identified based on a locally confirmed other outcome, were identified because of a locally confirmed case of fractures of the upper leg. Cancer of the uterus and upper leg fractures are reviewed centrally specifically for this reason.

Tables 6.9-6.10 – Agreement of Locally and Centrally Adjudicated Cause of Death. We note that in general there is good agreement between the local and central assessment of the cause of death. For most causes the agreement is about 80-90%. Notable exceptions are the "other" and "unknown" categories of all types: central adjudication seems to be able to determine the cause of death more frequently than local adjudication. In this table artherosclerotic death includes both definite and possible CHD death, as early on in the study these two categories were a combined cause of death.

6.4 Outcomes Data Summary

Table 6.11 – Locally Verified Outcomes (Annualized Percentages) by Age and Ethnicity for CT contains the number of locally verified outcomes for the major WHI outcomes categories. Since about 5% of the self-reports still need to be adjudicated, the numbers in these tables give a lower bound on the number of outcomes that currently have occurred.

Currently, for the CT we observe approximately 100% of the invasive breast cancer, 75% of the colorectal cancer and 35% of the hip fracture, and 65% of the CHD cases of what was assumed

for the power calculations. Note that DVT and PE, which are only adjudicated for HRT participants, are not included in this table.

Table 6.12 – Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Ethnicity for CT Participants contains counts of the number of self-reports for some of the WHI outcomes that are not adjudicated. As for many of the confirmed outcomes, the participants over report (see *Tables 6.3-6.4).* The numbers in these tables should be seen as upper bounds to the number of outcomes that have currently occurred. Not surprisingly, for many of the outcomes the rates differ considerably by minority status and by age at baseline.

Similar tables for the HRT, DM, CaD, and the OS components are in the chapters about these components. Currently, the rate of fractures in the OS and CT is very similar. The rate of cardiovascular events is slightly higher and the rate of cancers is slightly lower in the CT than in the OS.

Table 6.13 – Locally Confirmed Other Cancers and *Table 6.14 – Locally Confirmed Other Fractures* split out the other cancers and other fractures for the locally verified outcomes by event type and by study. Since for OS participants other fractures are only locally verified at the three bone mineral density clinics, we provide the number of self-reported fractures for these participants. In the CT, approximately 80% of self-reported fractures are confirmed, though the location of the fracture is misreported in approximately 25-30% of cases.

6.5 ECG Data

Electrocardiograms (ECGs) are given to all CT participants at baseline and in years 3, 6, and 9. The ECGs are sent to EPICARE (Pentti Rauthaharju, PI), which subcontracts to the CCC. EPICARE provides the CCC with a comprehensive analysis of each individual ECG, as well as with a serial analysis of the follow-up ECGs of a participant relative to that participant's baseline ECG. This serial analysis is intended to identify silent MIs: MIs that are detected by this ECG analysis, but were not reported by the participant (and locally confirmed, if closed). As of August 31, 2002, the CCC had received serial analysis on 57,978 CT participants whose year 3 ECGs and/or their year 6 ECGs had been analyzed by EPICARE.

Table 6.15 – Cross-tabulation of ECG Codes Suggesting an MI and Locally Confirmed and Self-Reported MI for All CT Participants shows the relation between MIs that have been identified prior to the follow-up ECG and incident MIs as identified by the ECG analysis. A total of 45 evolving Q-wave MIs have been identified. We note that 18 of these MIs were also identified by the regular outcomes reporting process. The remaining 27 evolving Q-wave MIs are thus the "definite silent MIs." *Table 6.15* also gives the number of possible silent MIs.

6.6 Vital Status

Table 6.16 – Cause of Death: CT and OS Participants (Annualized Percentages) presents the cause of death for CT and OS participants. To reduce the time that it takes before cause of death information is available on WHI participants who have passed away, clinics are encouraged to report a "temporary" cause of death for those participants for whom some, but not all, documentation related to the death has been collected. The goal is that a temporary cause is entered in the database as soon as possible, preferably within eight weeks. The cause based on the complete documentation should be entered as soon as all documents are collected.

Cases for which reported unsuccessful requests for documentation have been made over a one-year period can be closed out with incomplete documentation.

During the summer of 2001, we have completed the first NDI search. Results of this investigation are detailed in *Table 6.17*. The NDI search identified 26 women as dead, whose death had not otherwise been ascertained by WHI. The death of an additional 10 participants was also identified by WHI, but their death was not yet adjudicated. For these participants we used the cause of death based on the NDI provided ICD code, in *Table 6.16*.

As of the August 31, 2002 database, there were 1,929 deaths in the CT and 2,981 in the OS. Of the 1,929 CT deaths, there were 1,617 (84%) for which a final adjudication (or NDI report) was available, and an additional 1,146 (8%) for which a temporary adjudication was available. For the OS there is cause of death information on 90% of all deaths.

Table 6.18 – Lost-to-follow-up and Vital Status by Clinic: CT Participants displays information about the follow-up and vital status by clinic. Since 1999, clinics are regularly provided with a list of participants for whom there is no *Form 33* within the last 18 months and who are not known to be deceased. Clinics are asked to make every effort to try to locate these participants and to encourage further study participation. Some participants had information in the database that indicated that she never wanted to be contacted again by WHI. If this were the case, clinics were to verify whether this participation status was correct. If indeed a participant has expressed this opinion, she is not to be contacted again. For these participants, we will still be able to obtain limited vital status information from National Death Index (NDI) searches.

About 2.8% of the CT participants are deceased, we do not know the vital status of about 1.5% of the CT participants, and 2.2% of the participants request no further follow-up. In addition, we lack recent outcomes information on an additional 0.1% of the participants. The study design assumed that 3% per year of the participants would be lost-to-follow-up or death. As the average follow-up of participants is now 5.7 years, we note that the follow-up is much better than what was assumed in the design.

There is considerable clinic-to-clinic variation in the vital status data. The percentage of participants who are lost-to-follow-up ranges from 0 to 10.6% per clinic. The percentage of participants who stopped follow-up ranges from less than 0.1 to 6.8%.

Table 6.19 – Lost-to-Follow-up and Vital Status by Clinic: OS Participants contains the same information as *Table 6.18* but about the OS. For OS, the participants are considered lost-to-follow-up if we have not received a *Form 33* within the last 24 months. Approximately 3.7% of the OS participants are either lost-to-follow-up or have stopped follow-up.

Table 6.1
Timeliness and Completeness of Local Adjudications – CT Participants[1]

Data as of: August 31, 2002

Forms with conditions[2]		Number and % of forms with conditions locally adjudicated by days from Form 33 encounter date to completion of local adjudication							
Date of Form 33 encounter		≤ 90		≤ 180		Closed		Open	
	N	N	%	N	%	N	%	N	%
<= June 30 1996	3947	269	7%	778	20%	3937	100%	10	<1%
1996 July-December	1382	307	22%	716	52%	1382	100%	0	0%
1997 January-June	2179	764	35%	1328	61%	2173	100%	6	<1%
1997 July-December	2548	980	38%	1517	60%	2547	100%	1	<1%
1998 January-June	3576	1664	47%	2782	78%	3575	100%	1	<1%
1998 July-December	4160	2361	57%	3336	80%	4158	100%	2	<1%
1999 January-June	4604	2831	61%	3806	83%	4601	100%	3	<1%
1999 July-December	4472	2870	64%	3695	83%	4470	100%	2	<1%
2000 January-June	4714	3103	66%	3963	84%	4702	100%	12	<1%
2000 July-December	4409	2986	68%	3814	87%	4398	100%	11	<1%
2001 January- June	5207	3661	70%	4563	88%	5174	99%	33	1%
2001 July	838	571	68%	748	89%	825	98%	13	2%
2001 August	835	566	68%	744	89%	814	97%	21	3%
2001 September	713	513	72%	654	92%	702	98%	11	2%
2001 October	943	614	65%	862	91%	919	97%	24	3%
2001 November	794	515	65%	727	92%	765	96%	29	4%
2001 December	640	470	73%	583	91%	619	97%	21	3%
2002 January	941	714	76%	874	93%	901	96%	40	4%
2002 February	836	656	78%	762	91%	768	92%	68	8%
2002 March	890	687	77%	823	92%	823	92%	67	8%
2002 April	936	719	77%	809	86%	809	86%	127	14%
2002 May	900	714	79%	742	82%	742	82%	158	18%
2002 June	763	523	69%	523	69%	523	69%	240	31%
2002 July	1051	472	45%	472	45%	472	45%	579	55%
2002 August	760	87	11%	87	11%	87	11%	673	89%
Total	53038	29617	56%	39708	75%	50886	96%	2152	4%

[1] This table is based on the day *Form 33* was received by the clinic, not on the day the form was entered in the database.
[2] Conditions are self-reported events that require additional documentation.

Table 6.2
Timeliness and Completeness of Local Adjudications – OS Participants[1]

Data as of: August 31, 2002

Forms with conditions[2]		Number and % of forms with conditions locally adjudicated by days from Form 33 encounter date to completion of local adjudication							
Date of Form 33 encounter		≤ 90		≤ 180		Closed		Open	
	N	N	%	N	%	N	%	N	%
<= June 30 1996	238	84	35%	127	53%	238	100%	0	0%
1996 July-December	1311	307	23%	701	53%	1308	100%	3	<1%
1997 January-June	2154	844	39%	1402	65%	2154	100%	0	0%
1997 July-December	2296	709	31%	1357	59%	2296	100%	0	0%
1998 January-June	2834	1268	45%	2037	72%	2833	100%	1	<1%
1998 July-December	3806	2005	53%	2901	76%	3805	100%	1	<1%
1999 January-June	4753	2845	60%	3926	83%	4751	100%	2	<1%
1999 July-December	4222	2529	60%	3417	81%	4221	100%	1	<1%
2000 January-June	5929	3781	64%	4891	82%	5917	100%	12	<1%
2000 July-December	4316	2837	66%	3639	84%	4294	99%	22	1%
2001 January- June	5378	3587	67%	4612	86%	5303	99%	75	1%
2001 July	911	650	71%	799	88%	891	98%	20	2%
2001 August	1017	662	65%	869	85%	995	98%	22	2%
2001 September	696	502	72%	629	90%	679	98%	17	2%
2001 October	780	468	60%	695	89%	760	97%	20	3%
2001 November	658	412	63%	595	90%	626	95%	32	5%
2001 December	641	455	71%	583	91%	621	97%	20	3%
2002 January	886	652	74%	814	92%	840	95%	46	5%
2002 February	817	621	76%	752	92%	763	93%	54	7%
2002 March	823	597	73%	730	89%	730	89%	93	11%
2002 April	1121	795	71%	956	85%	956	85%	165	15%
2002 May	1129	860	76%	931	82%	931	82%	198	18%
2002 June	982	656	67%	656	67%	656	67%	326	33%
2002 July	952	443	47%	443	47%	443	47%	509	53%
2002 August	778	74	10%	74	10%	74	10%	704	90%
Total	49428	28643	58%	38536	78%	47085	95%	2343	5%

[1] This table is based on the day *Form 33* was received by the clinic, not on the day the form was entered in the database.
[2] Conditions are self-reported events that require additional documentation.

Figure 6.1 Clinical Trial Timeliness per Period of Self-Report

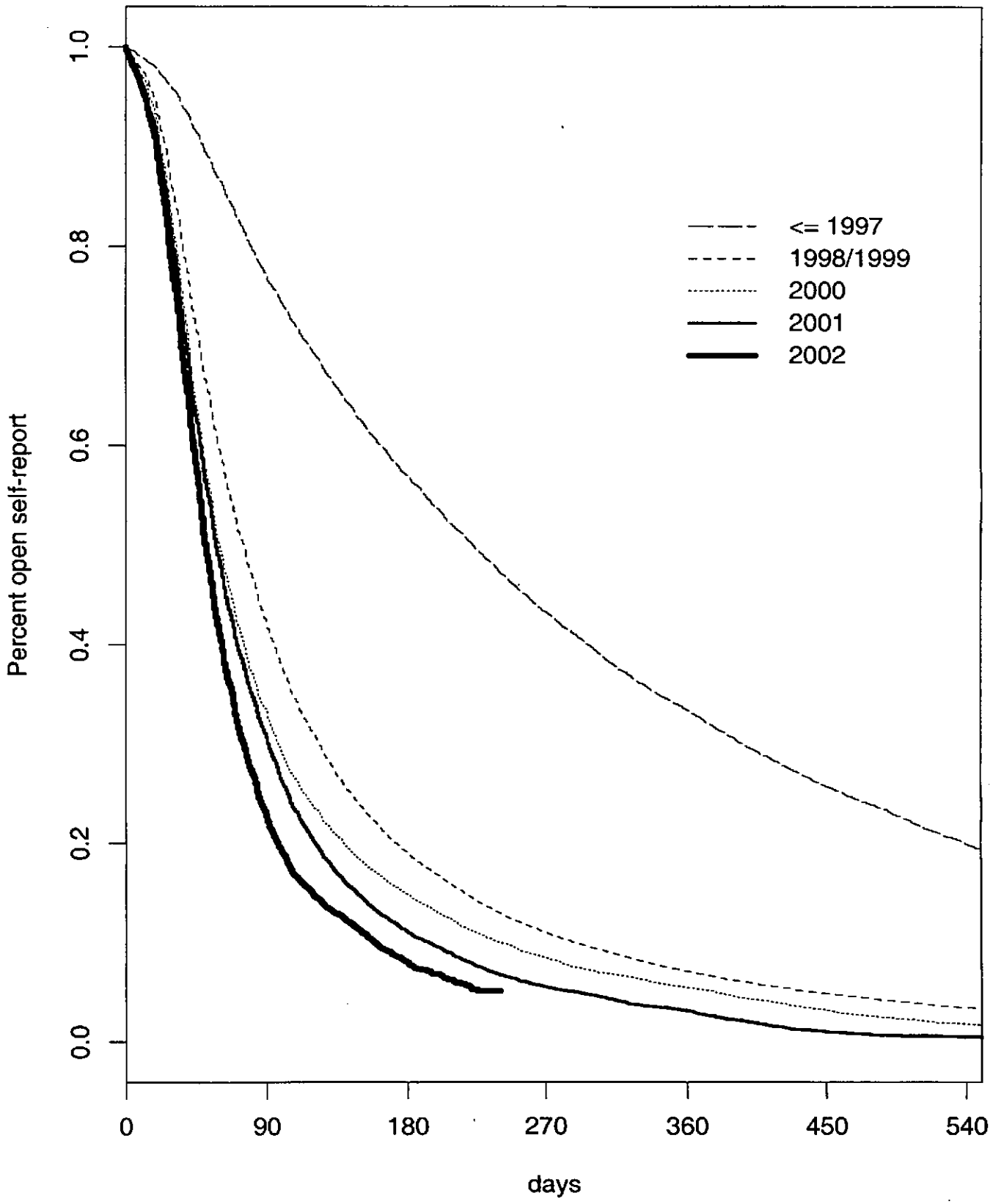


Figure 6.2 Observational Study Timeliness per Period of Self-Report

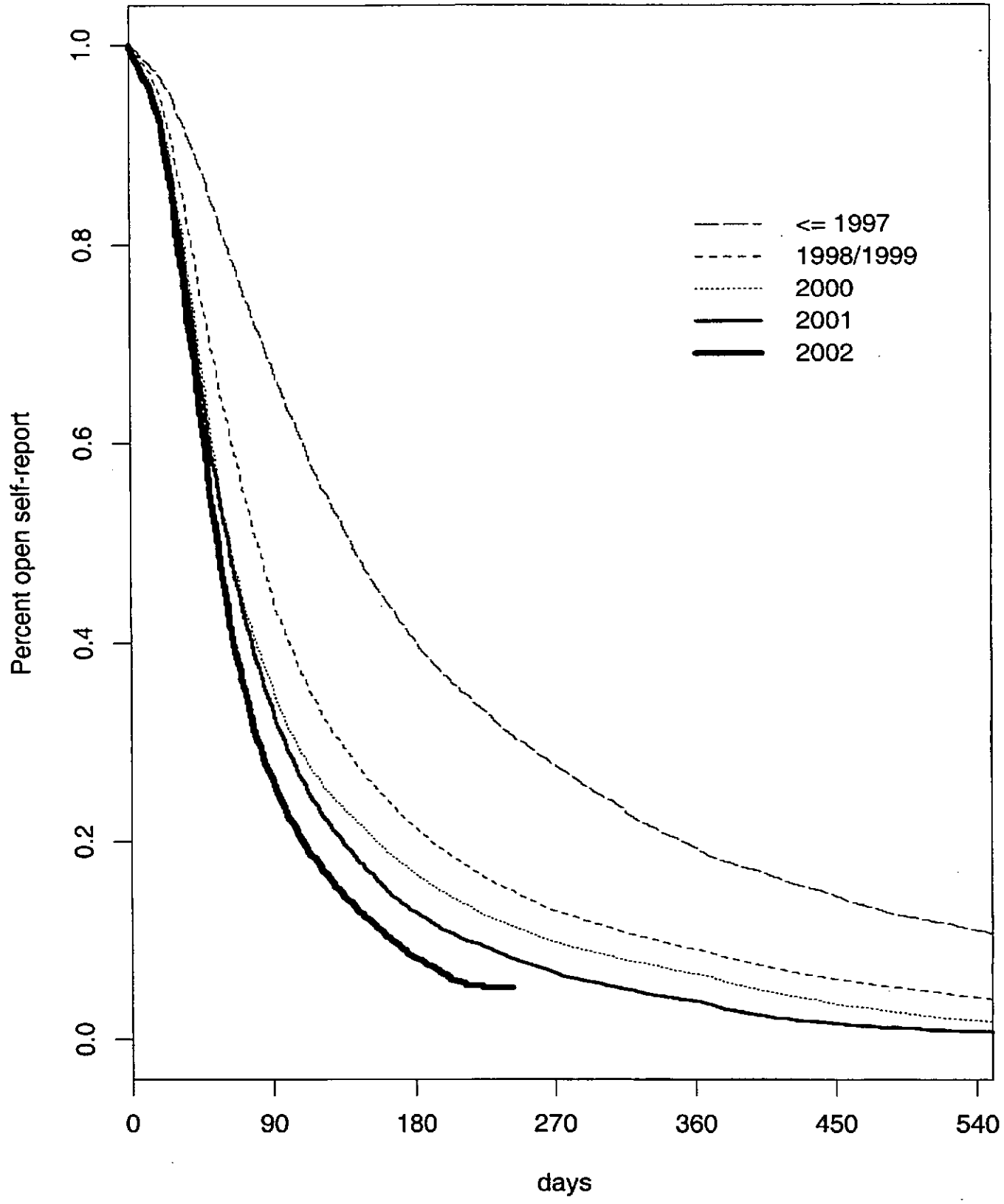


Table 6.3
Agreement of the Local Adjudications with Self-Reports — CT Participants

Data as of: August 31, 2002

	Participants with a self-report	Closed		Confirmed		Denied – related outcome found		Denied – no outcome found		Administrative denials	
		N	%	N	%[1]	N	%[1]	N	%[1]	N	%[1]
Cardiovascular											
Clinical MI	954	896	94%	638	(71%)	139	(16%)	108	(12%)	11	(1%)
Angina[2]	1886	1774	94%	845	(48%)	79	(4%)	815	(46%)	35	(2%)
Congestive heart failure	620	589	95%	428	(73%)	36	(6%)	116	(20%)	9	(2%)
CABG/PTCA	2074	1961	95%	1566	(80%)	159	(8%)	212	(11%)	24	(1%)
Carotid artery disease[3]	280	264	94%	218	(83%)	26	(10%)	16	(6%)	4	(2%)
Stroke/TIA[4]	1560	1451	93%	1113	(77%)	66	(5%)	246	(17%)	26	(2%)
PVD	200	186	93%	110	(59%)	26	(14%)	46	(25%)	4	(2%)
DVT[5]	315	289	92%	204	(71%)	38	(13%)	40	(14%)	7	(2%)
Pulmonary embolism[5]	151	140	93%	119	(85%)	7	(5%)	14	(10%)	0	(0%)
Cancers											
Breast cancer	1946	1826	94%	1759	(96%)	1	(<1%)	57	(3%)	9	(<1%)
Ovarian cancer	187	175	94%	128	(73%)	36	(21%)	8	(5%)	3	(2%)
Endometrial cancer	233	220	94%	171	(78%)	25	(11%)	22	(10%)	2	(1%)
Colorectal cancer	523	501	96%	438	(87%)	30	(6%)	32	(6%)	1	(<1%)
Other cancer[6]	2170	2029	94%	1537	(76%)	113	(6%)	341	(17%)	38	(2%)
Fractures											
Hip fracture	424	389	92%	317	(81%)	29	(7%)	38	(10%)	5	(1%)
Vertebral fracture	728	679	93%	364	(54%)	25	(4%)	269	(40%)	21	(3%)
Other fracture	6348	6099	96%	4968	(81%)	56	(1%)	907	(15%)	168	(3%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI is not adjudicated. In particular, 212 such self-reports of angina are excluded from this table.
[3] Carotid artery disease that is self-reported after a confirmed stroke is not adjudicated. In particular, 4 such self- reports of carotid artery disease are excluded from this table.
[4] Stroke and TIA have a combined self-report. Only stroke is monitored. There were 341 participants who reported stroke/TIA for whom only TIA was confirmed.
[5] HRT participants only.
[6] Excludes non-melanoma skin cancer.

Table 6.4
Agreement of the Local Adjudications with Self-Reports — OS Participants

Data as of: August 31, 2002

	Participants with a self-report	Closed		Confirmed		Denied – related outcome found		Denied – no outcome found		Administrative denials	
		N	%	N	%[1]	N	%[1]	N	%[1]	N	%[1]
Cardiovascular											
Clinical MI	910	843	93%	560	(66%)	149	(18%)	116	(14%)	18	(2%)
Angina[2]	2168	2055	95%	924	(45%)	125	(6%)	963	(47%)	43	(2%)
Congestive heart failure	763	704	92%	521	(74%)	47	(7%)	122	(17%)	14	(2%)
CABG/PTCA	2343	2209	94%	1687	(76%)	212	(10%)	270	(12%)	40	(2%)
Carotid artery disease[3]	342	327	96%	263	(80%)	33	(10%)	26	(8%)	5	(2%)
Stroke/TIA[4]	1841	1712	93%	1253	(73%)	75	(4%)	341	(20%)	43	(3%)
PVD	284	264	93%	155	(59%)	33	(13%)	70	(27%)	6	(2%)
Cancers											
Breast cancer	2820	2623	93%	2392	(91%)	18	(1%)	174	(7%)	39	(1%)
Ovarian cancer	248	231	93%	158	(68%)	37	(16%)	34	(15%)	2	(1%)
Endometrial cancer	312	289	93%	224	(78%)	40	(14%)	20	(7%)	5	(2%)
Colorectal	596	562	94%	472	(84%)	34	(6%)	45	(8%)	11	(2%)
Other cancer[5]	2925	2691	92%	1876	(70%)	180	(7%)	558	(21%)	77	(3%)
Fractures											
Hip fracture	606	563	93%	439	(78%)	3	(1%)	107	(19%)	14	(2%)
Vertebral fracture	95	86	91%	53	(62%)	6	(7%)	21	(24%)	6	(7%)
Other fracture	701	670	96%	491	(73%)	13	(2%)	137	(20%)	29	(4%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI, is not adjudicated. In particular, 191 such self-reports of angina are excluded from this table.
[3] Carotid artery disease that is self-reported after a confirmed stroke is not adjudicated. In particular, 5 such self-reports of carotid artery disease are excluded from this table.
[4] Stroke and TIA have a combined self-report. Only stroke is monitored. There were 422 participants who reported stroke/TIA for whom only TIA was confirmed.
[5] Excludes non-melanoma skin cancer.

Table 6.5
Agreement of Central Adjudications with Local Adjudications — CT Participants

Data as of: August 31, 2002

	Locally confirmed	Called forward for central adjudication		Centrally adjudicated		In agreement	
	N	N	%[1]	N	%[2]	N	%[3]
Cardiovascular							
Clinical MI	1016	809	80%	714	88%	606	85%
Angina[4]	1740	1438	83%	1301	90%	975	75%
Congestive heart failure	945	738	78%	621	84%	467	75%
CABG/PTCA	1688	1345	80%	1189	88%	1148	97%
DVT[5]	261	261	100%	224	86%	196	88%
Pulmonary embolism[5]	162	162	100%	126	78%	120	95%
Stroke	908	431	47%	83	19%	80	96%
Cancers							
Breast cancer	1781	1781	100%	1638	92%	1633	100%
Invasive	1412	1412	100%	1292	92%	1262	98%
Non-invasive	369	369	100%	346	94%	297	86%
Ovarian cancer	157	157	100%	138	88%	111	80%
Endometrial cancer	219	219	100%	201	92%	193	96%
Colorectal cancer	489	489	100%	434	89%	424	98%
Fractures							
Hip fracture	391	389	99%	353	91%	335	95%

[1] Percentage is relative to locally confirmed cases.
[2] Percentage is relative to cases called forward for central adjudication.
[3] Percentage is relative to centrally adjudicated cases.
[4] Participants with a confirmed MI no longer require adjudication of angina.
[5] HRT only.

Table 6.6
Agreement of Central Adjudications with Local Adjudications — OS Participants

Data as of: August 31, 2002

	Locally confirmed N	Called forward for central adjudication N	%[1]	Centrally adjudicated N	%[2]	In agreement N	%[3]
Cardiovascular							
Clinical MI	1069	697	65%	630	90%	514	82%
Angina[4]	1982	1411	71%	1300	92%	999	77%
Congestive heart failure	1263	774	61%	685	89%	543	79%
CABG/PTCA	1872	1246	67%	1149	92%	1098	96%
Cancers							
Breast cancer	2468	2468	100%	2322	94%	2274	98%
Invasive	2036	2036	100%	1912	94%	1822	95%
Non-Invasive	432	432	100%	410	95%	326	80%
Ovarian cancer	202	202	100%	178	88%	145	81%
Endometrial cancer	316	316	100%	262	83%	241	92%
Colorectal cancer	528	528	100%	451	85%	425	94%
Fractures							
Hip fracture	540	540	100%	445	82%	432	97%

[1] Percentage is relative to locally confirmed cases.
[2] Percentage is relative to cases called forward for central adjudication.
[3] Percentage is relative to centrally adjudicated cases.
[4] Participants with a confirmed MI no longer require adjudication of angina.

Table 6.7
Source of Outcomes Identified by Central Adjudications – CT Participants

Data as of: August 31, 2002

	Centrally confirmed N	Reason for central investigation						Denied self-reports reviewed by CCC N
		Locally confirmed same outcome N	%	Locally confirmed other outcome N	%	Self-report but no outcome found N	%	
Cardiovascular								
Clinical MI	702	590	84%	112	16%	0	0%	29
Angina	1178	940	80%	232	20%	6	1%	N/A
Congestive heart failure	540	454	84%	85	16%	1	<1%	N/A
CABG/PTCA	1183	1133	96%	49	4%	1	<1%	N/A
DVT	205	194	95%	7	3%	4	2%	38
Pulmonary embolism	126	120	95%	3	2%	3	2%	12
Stroke	80	78	98%	0	0%	2	3%	4
Cancers								
Breast cancer	1644	1638	100%	3	<1%	3	<1%	61
Ovarian cancer	120	111	93%	6	5%	3	3%	25
Endometrial cancer	208	192	92%	14	7%	2	1%	26
Colorectal cancer	429	423	99%	1	<1%	5	1%	45
Fractures								
Hip fracture	347	335	97%	7	2%	5	1%	32

Table 6.8
Source of Outcomes Identified by Central Adjudications – OS Participants

Data as of: August 31, 2002

	Centrally confirmed N	Reason for central investigation: Locally confirmed same outcome N	%	Locally confirmed other outcome N	%	Self-report but no outcome found N	%	Denied self-reports reviewed by CCC N
Cardiovascular								
Clinical MI	612	502	82%	110	18%	0	0%	13
Angina	1206	983	82%	218	18%	5	<1%	N/A
Congestive heart failure	609	536	88%	72	12%	1	<1%	N/A
CABG/PTCA	1125	1082	96%	43	4%	0	0%	N/A
Cancers								
Breast cancer	2286	2277	100%	1	<1%	8	<1%	118
Ovarian cancer	155	145	94%	8	5%	2	1%	40
Endometrial cancer	271	240	89%	29	11%	2	1%	22
Colorectal cancer	433	425	98%	4	1%	4	1%	69
Fractures								
Hip fracture	436	432	99%	1	0%	3	1%	43

Table 6.9
Agreement of Locally and Centrally Adjudicated Cause of Death for <u>All CT Participants</u>

Data as of: August 31, 2002

	Closed Local[1]	Closed Central N	Closed Central %	Confirmed Cause N	Confirmed Cause %[2]	Related Cause N	Related Cause %[2]	Unrelated Cause N	Unrelated Cause %[2]
Final adjudicated death	1617	1316	81%	1089	(83%)	108	(8%)	119	(9%)
Cardiovascular									
Atherosclerotic cardiac[3]	261	209	80%	177	(85%)	15	(7%)	17	(8%)
Cerebrovascular	117	88	75%	77	(88%)	3	(3%)	8	(9%)
Pulmonary embolism	10	6	60%	4	(67%)	1	(17%)	1	(17%)
Other cardiovascular	94	75	80%	37	(49%)	26	(35%)	12	(16%)
Unknown cardiovascular	26	22	85%	1	(5%)	13	(59%)	8	(36%)
Total cardiovascular deaths	508	400	79%	296	(74%)	58	(15%)	46	(12%)
Cancer									
Breast cancer	25	23	92%	22	(96%)	0	(0%)	1	(4%)
Ovarian cancer	63	51	81%	44	(86%)	6	(12%)	1	(2%)
Endometrial cancer	6	6	100%	5	(83%)	1	(17%)	0	(0%)
Colorectal cancer	79	63	80%	58	(92%)	2	(3%)	3	(5%)
Other cancer	576	500	87%	473	(95%)	14	(3%)	13	(3%)
Unknown cancer site	38	29	76%	17	(59%)	12	(41%)	0	(0%)
Total cancer deaths	787	672	85%	619	(92%)	35	(5%)	18	(3%)
Accident/injury									
Homicide	5	4	80%	3	(75%)	1	(25%)	0	(0%)
Accident	41	36	88%	31	(86%)	3	(8%)	2	(6%)
Suicide	7	6	86%	6	(100%)	0	(0%)	0	(0%)
Other injury	3	3	100%	0	(0%)	2	(67%)	1	(33%)
Total accidental deaths	56	49	88%	40	(82%)	6	(12%)	3	(6%)
Other									
Other known cause	209	149	71%	112	(75%)	4	(3%)	33	(22%)
Unknown cause	57	46	81%	22	(48%)	5	(11%)	19	(41%)
Total deaths - other causes	266	195	73%	134	(69%)	9	(5%)	52	(27%)

[1] Excludes temporary adjudications.
[2] Percentages are relative to closed central.
[3] "Atherosclerotic cardiac" combines definite and possible CHD death.

Table 6.10
Agreement of Locally and Centrally Adjudicated Cause of Death for <u>All OS Participants</u>

Data as of: August 31, 2002

	Closed Local[1]	Closed Central N	Closed Central %	Confirmed Cause N	Confirmed Cause %[2]	Related Cause N	Related Cause %[2]	Unrelated Cause N	Unrelated Cause %[2]
Final adjudicated death	2417	1605	66%	1304	(81%)	139	(9%)	162	(10%)
Cardiovascular									
Atherosclerotic cardiac[3]	317	221	70%	173	(78%)	19	(9%)	29	(13%)
Cerebrovascular	172	103	60%	92	(89%)	5	(5%)	6	(6%)
Pulmonary embolism	19	12	63%	8	(67%)	0	(0%)	4	(33%)
Other cardiovascular	155	109	70%	47	(43%)	46	(42%)	16	(15%)
Unknown cardiovascular	34	21	62%	1	(5%)	14	(67%)	6	(29%)
Total cardiovascular deaths	697	466	67%	321	(69%)	84	(18%)	61	(13%)
Cancer									
Breast cancer	155	97	63%	91	(94%)	3	(3%)	3	(3%)
Ovarian cancer	79	51	65%	48	(94%)	1	(2%)	2	(4%)
Endometrial cancer	22	11	50%	7	(64%)	4	(36%)	0	(0%)
Colorectal cancer	93	67	72%	63	(94%)	2	(3%)	2	(3%)
Other cancer	768	530	69%	491	(93%)	19	(4%)	20	(4%)
Unknown cancer site	66	44	67%	32	(73%)	11	(25%)	1	(2%)
Total cancer deaths	1183	800	68%	732	(92%)	40	(5%)	28	(4%)
Accident/injury									
Homicide	4	4	100%	4	(100%)	0	(0%)	0	(0%)
Accident	57	41	72%	36	(88%)	2	(5%)	3	(7%)
Suicide	17	15	88%	12	(80%)	1	(7%)	2	(13%)
Other injury	3	2	67%	2	(100%)	0	(0%)	0	(0%)
Total accidental deaths	81	62	77%	54	(87%)	3	(5%)	5	(8%)
Other									
Other known cause	361	223	62%	174	(78%)	4	(2%)	45	(20%)
Unknown cause	95	54	57%	23	(43%)	8	(15%)	23	(43%)
Total deaths - other causes	456	277	61%	197	(71%)	12	(4%)	68	(25%)

[1] Excludes temporary adjudications.
[2] Percentages are relative to closed central.
[3] "Atherosclerotic cardiac" combines definite and possible CHD death.

Table 6.11
Locally Verified Outcomes (Annualized Percentages) by Age for CT Participants

Data as of: August 31, 2002

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	68132		9190		14664		31391		12887	
Mean follow-up (months)	67.2		73.3		69.6		65.4		64.3	
Cardiovascular										
CHD[1]	1241	(0.33%)	72	(0.13%)	132	(0.16%)	558	(0.33%)	479	(0.69%)
CHD death[2]	271	(0.07%)	13	(0.02%)	26	(0.03%)	108	(0.06%)	124	(0.18%)
Total MI[3]	1062	(0.28%)	62	(0.11%)	112	(0.13%)	486	(0.28%)	402	(0.58%)
Clinical MI	1016	(0.27%)	55	(0.10%)	108	(0.13%)	465	(0.27%)	388	(0.56%)
Evolving Q-wave MI[4]	48	(0.01%)	7	(0.01%)	4	(<0.01%)	23	(0.01%)	14	(0.02%)
Possible evolving Q-wave MI[4]	210	(0.06%)	27	(0.05%)	30	(0.04%)	86	(0.05%)	67	(0.10%)
Angina	1659	(0.43%)	83	(0.15%)	213	(0.25%)	817	(0.48%)	546	(0.79%)
CABG/PTCA	1688	(0.44%)	69	(0.12%)	197	(0.23%)	845	(0.49%)	577	(0.84%)
Carotid artery disease	270	(0.07%)	6	(0.01%)	32	(0.04%)	136	(0.08%)	96	(0.14%)
Congestive heart failure	945	(0.25%)	45	(0.08%)	101	(0.12%)	405	(0.24%)	394	(0.57%)
Stroke	941	(0.25%)	34	(0.06%)	83	(0.10%)	430	(0.25%)	394	(0.57%)
PVD	243	(0.06%)	11	(0.02%)	27	(0.03%)	117	(0.07%)	88	(0.13%)
CHD[1]/Possible evolving Q-wave MI	1444	(0.38%)	99	(0.18%)	162	(0.19%)	640	(0.37%)	543	(0.79%)
Coronary disease[5]	3672	(0.96%)	209	(0.37%)	440	(0.52%)	1736	(1.01%)	1287	(1.86%)
Total cardiovascular disease	4831	(1.27%)	251	(0.45%)	547	(0.64%)	2307	(1.35%)	1726	(2.50%)
Cancer										
Breast cancer[6]	1784	(0.47%)	187	(0.33%)	376	(0.44%)	861	(0.50%)	360	(0.52%)
Invasive breast cancer	1416	(0.37%)	137	(0.24%)	303	(0.36%)	685	(0.40%)	291	(0.42%)
Non-invasive breast cancer	375	(0.10%)	50	(0.09%)	74	(0.09%)	181	(0.11%)	70	(0.10%)
Ovary cancer	173	(0.05%)	19	(0.03%)	33	(0.04%)	80	(0.05%)	41	(0.06%)
Endometrial cancer[7]	220	(0.10%)	23	(0.07%)	48	(0.09%)	101	(0.10%)	48	(0.12%)
Colorectal cancer	493	(0.13%)	26	(0.05%)	69	(0.08%)	253	(0.15%)	145	(0.21%)
Other cancer[8]	1810	(0.47%)	149	(0.27%)	280	(0.33%)	880	(0.51%)	501	(0.73%)
Total cancer	4359	(1.14%)	397	(0.71%)	781	(0.92%)	2116	(1.24%)	1065	(1.54%)
Fractures										
Hip fracture	391	(0.10%)	11	(0.02%)	21	(0.02%)	148	(0.09%)	211	(0.31%)
Vertebral fracture	440	(0.12%)	16	(0.03%)	48	(0.06%)	184	(0.11%)	192	(0.28%)
Other fracture[8]	5179	(1.36%)	623	(1.11%)	945	(1.11%)	2414	(1.41%)	1197	(1.73%)
Total fracture	5815	(1.52%)	643	(1.15%)	1002	(1.18%)	2665	(1.56%)	1505	(2.18%)
Deaths										
Cardiovascular deaths	543	(0.14%)	21	(0.04%)	44	(0.05%)	222	(0.13%)	256	(0.37%)
Cancer deaths	842	(0.22%)	49	(0.09%)	95	(0.11%)	414	(0.24%)	284	(0.41%)
Other known cause	282	(0.07%)	19	(0.03%)	30	(0.04%)	118	(0.07%)	115	(0.17%)
Unknown cause	96	(0.03%)	7	(0.01%)	13	(0.02%)	45	(0.03%)	31	(0.04%)
Not yet adjudicated	166	(0.04%)	6	(0.01%)	18	(0.02%)	80	(0.05%)	62	(0.09%)
Total death	1929	(0.51%)	102	(0.18%)	200	(0.24%)	879	(0.51%)	748	(1.08%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Excludes nine cases with borderline malignancy.
[7] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[8] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 6.11 (continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for CT Participants

Data as of: August 31, 2002

Outcome	Race/Ethnicity					
	American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	292	1519	6983	2875	55525	938
Mean follow-up (months)	65.0	63.8	65.7	63.4	67.7	63.2
Cardiovascular						
CHD[1]	3 (0.19%)	14 (0.17%)	115 (0.30%)	26 (0.17%)	1064 (0.34%)	19 (0.38%)
CHD death[2]	2 (0.13%)	4 (0.05%)	39 (0.10%)	4 (0.03%)	218 (0.07%)	4 (0.08%)
Total MI[3]	2 (0.13%)	13 (0.16%)	91 (0.24%)	23 (0.15%)	916 (0.29%)	17 (0.34%)
Clinical MI	2 (0.13%)	12 (0.15%)	87 (0.23%)	23 (0.15%)	877 (0.28%)	15 (0.30%)
Evolving Q-wave MI[4]	0 (0.00%)	1 (0.01%)	4 (0.01%)	0 (0.00%)	41 (0.01%)	2 (0.04%)
Possible evolving Q-wave MI[4]	2 (0.13%)	4 (0.05%)	28 (0.07%)	6 (0.04%)	168 (0.05%)	2 (0.04%)
Angina	5 (0.32%)	23 (0.28%)	200 (0.52%)	53 (0.35%)	1356 (0.43%)	22 (0.45%)
CABG/PTCA	5 (0.32%)	14 (0.17%)	158 (0.41%)	43 (0.28%)	1450 (0.46%)	18 (0.36%)
Carotid artery disease	3 (0.19%)	2 (0.02%)	19 (0.05%)	1 (0.01%)	243 (0.08%)	2 (0.04%)
Congestive heart failure	3 (0.19%)	8 (0.10%)	160 (0.42%)	21 (0.14%)	739 (0.24%)	14 (0.28%)
Stroke	5 (0.32%)	20 (0.25%)	110 (0.29%)	26 (0.17%)	768 (0.25%)	12 (0.24%)
PVD	3 (0.19%)	1 (0.01%)	36 (0.09%)	3 (0.02%)	197 (0.06%)	3 (0.06%)
CHD[1]/Possible evolving Q-wave MI	5 (0.32%)	18 (0.22%)	142 (0.37%)	32 (0.21%)	1226 (0.39%)	21 (0.42%)
Coronary disease[5]	12 (0.76%)	44 (0.54%)	452 (1.18%)	103 (0.68%)	3011 (0.96%)	50 (1.01%)
Total cardiovascular disease	20 (1.26%)	66 (0.82%)	582 (1.52%)	128 (0.84%)	3971 (1.27%)	64 (1.30%)
Cancer						
Breast cancer[6]	2 (0.13%)	43 (0.53%)	124 (0.32%)	46 (0.30%)	1551 (0.49%)	18 (0.36%)
Invasive breast cancer	2 (0.13%)	32 (0.40%)	94 (0.25%)	38 (0.25%)	1236 (0.39%)	14 (0.28%)
Non-invasive breast cancer	0 (0.00%)	11 (0.14%)	31 (0.08%)	8 (0.05%)	321 (0.10%)	4 (0.08%)
Ovary cancer	1 (0.06%)	2 (0.02%)	15 (0.04%)	2 (0.01%)	149 (0.05%)	4 (0.08%)
Endometrial cancer[7]	1 (0.14%)	1 (0.02%)	11 (0.07%)	7 (0.08%)	197 (0.10%)	3 (0.10%)
Colorectal cancer	4 (0.25%)	10 (0.12%)	54 (0.14%)	20 (0.13%)	398 (0.13%)	7 (0.14%)
Other cancer[8]	8 (0.51%)	29 (0.36%)	135 (0.35%)	45 (0.30%)	1572 (0.50%)	21 (0.42%)
Total cancer	16 (1.01%)	85 (1.05%)	329 (0.86%)	115 (0.76%)	3765 (1.20%)	49 (0.99%)
Fractures						
Hip fracture	0 (0.00%)	3 (0.04%)	13 (0.03%)	6 (0.04%)	365 (0.12%)	4 (0.08%)
Vertebral fracture	0 (0.00%)	9 (0.11%)	5 (0.01%)	6 (0.04%)	416 (0.13%)	4 (0.08%)
Other fracture[8]	21 (1.33%)	78 (0.97%)	269 (0.70%)	137 (0.90%)	4623 (1.48%)	51 (1.03%)
Total fracture	21 (1.33%)	88 (1.09%)	285 (0.75%)	146 (0.96%)	5218 (1.67%)	57 (1.15%)
Deaths						
Cardiovascular deaths	3 (0.19%)	8 (0.10%)	80 (0.21%)	8 (0.05%)	438 (0.14%)	6 (0.12%)
Cancer deaths	2 (0.13%)	18 (0.22%)	77 (0.20%)	20 (0.13%)	714 (0.23%)	11 (0.22%)
Other known cause	5 (0.32%)	1 (0.01%)	34 (0.09%)	4 (0.03%)	236 (0.08%)	2 (0.04%)
Unknown cause	1 (0.06%)	0 (0.00%)	13 (0.03%)	1 (0.01%)	80 (0.03%)	1 (0.02%)
Not yet adjudicated	1 (0.06%)	3 (0.04%)	17 (0.04%)	7 (0.05%)	137 (0.04%)	1 (0.02%)
Total death	12 (0.76%)	30 (0.37%)	221 (0.58%)	40 (0.26%)	1605 (0.51%)	21 (0.42%)

[1] "CHD" includes clinical MI, evolving Q-wave MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death.
[3] "Total MI" includes clinical MI and evolving Q-wave MI.
[4] Only women with a follow-up ECG are used to compute the annual rates for (possible) evolving Q-wave MIs.
[5] "Coronary disease" includes clinical MI, evolving Q-wave MI, possible evolving Q-wave MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[6] Excludes nine cases with borderline malignancy.
[7] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[8] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

Table 6.12
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for CT Participants who did not report a prevalent condition at baseline

Data as of: August 31, 2002

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68132	9190	14664	31391	12887
Mean follow-up (months)	67.2	73.3	69.6	65.4	64.3
Hospitalizations					
Ever	26388 (6.92%)	2620 (4.67%)	4652 (5.47%)	12558 (7.34%)	6558 (9.49%)
Two or more	12342 (3.24%)	1057 (1.88%)	1940 (2.28%)	5846 (3.42%)	3499 (5.06%)
Other					
DVT[1]	561 (0.15%)	33 (0.06%)	84 (0.10%)	250 (0.15%)	194 (0.29%)
Pulmonary embolism	323 (0.09%)	16 (0.03%)	52 (0.06%)	156 (0.09%)	99 (0.14%)
Diabetes (treated)	3415 (0.94%)	469 (0.86%)	722 (0.88%)	1568 (0.96%)	656 (1.00%)
Gallbladder disease[2]	3796 (1.19%)	552 (1.11%)	874 (1.20%)	1769 (1.25%)	601 (1.08%)
Hysterectomy	1492 (0.67%)	193 (0.60%)	322 (0.61%)	719 (0.73%)	258 (0.66%)
Glaucoma	5054 (1.38%)	467 (0.85%)	939 (1.13%)	2462 (1.50%)	1186 (1.86%)
Osteoporosis	10445 (2.90%)	939 (1.71%)	1771 (2.15%)	5130 (3.19%)	2605 (4.22%)
Osteoarthritis[3]	9385 (5.57%)	1269 (3.07%)	2049 (3.55%)	4319 (4.34%)	1748 (5.06%)
Rheumatoid arthritis	2816 (0.77%)	389 (0.71%)	640 (0.78%)	1251 (0.76%)	536 (0.82%)
Intestinal polyps	6962 (1.96%)	778 (1.43%)	1423 (1.76%)	3498 (2.21%)	1263 (2.06%)
Lupus	486 (0.13%)	77 (0.14%)	115 (0.14%)	225 (0.13%)	69 (0.10%)
Kidney stones[3]	1140 (0.53%)	147 (0.35%)	240 (0.36%)	535 (0.39%)	218 (0.39%)
Cataracts[3]	15013 (7.62%)	824 (1.93%)	2266 (3.45%)	8250 (6.65%)	3673 (9.45%)
Pills for hypertension	12534 (4.67%)	1532 (3.38%)	2592 (4.00%)	5799 (4.98%)	2611 (6.21%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Unknown
Number randomized	292	1519	6983	2875	55525	938
Mean follow-up (months)	65.0	63.8	65.7	63.4	67.7	63.2
Hospitalizations						
Ever	113 (7.14%)	382 (4.73%)	2735 (7.15%)	891 (5.86%)	21938 (7.00%)	329 (6.66%)
Two or more	62 (3.92%)	137 (1.70%)	1311 (3.43%)	361 (2.38%)	10324 (3.29%)	147 (2.97%)
Other						
DVT[1]	2 (0.13%)	1 (0.01%)	50 (0.13%)	9 (0.06%)	493 (0.16%)	6 (0.12%)
Pulmonary embolism	4 (0.25%)	2 (0.02%)	26 (0.07%)	3 (0.02%)	283 (0.09%)	5 (0.10%)
Diabetes (treated)	21 (1.47%)	94 (1.24%)	626 (1.85%)	228 (1.61%)	2396 (0.79%)	50 (1.08%)
Gallbladder disease[2]	16 (1.38%)	60 (0.82%)	299 (0.87%)	168 (1.45%)	3197 (1.23%)	56 (1.33%)
Hysterectomy	5 (0.70%)	25 (0.48%)	88 (0.53%)	49 (0.58%)	1313 (0.69%)	12 (0.42%)
Glaucoma	24 (1.60%)	97 (1.25%)	670 (1.88%)	227 (1.54%)	3972 (1.31%)	64 (1.38%)
Osteoporosis	47 (3.13%)	260 (3.39%)	559 (1.52%)	409 (2.89%)	9027 (3.06%)	143 (3.11%)
Osteoarthritis[3]	51 (0.12%)	211 (0.37%)	936 (0.94%)	467 (1.35%)	7570 (5.49%)	150 (7.06%)
Rheumatoid arthritis	22 (1.55%)	55 (0.71%)	502 (1.41%)	264 (1.82%)	1921 (0.64%)	52 (1.11%)
Intestinal polyps	35 (2.41%)	140 (1.89%)	727 (2.04%)	245 (1.69%)	5724 (1.97%)	91 (2.00%)
Lupus	4 (0.26%)	6 (0.07%)	68 (0.18%)	19 (0.13%)	384 (0.12%)	5 (0.10%)
Kidney stones[3]	9 (0.02%)	28 (0.04%)	112 (0.08%)	56 (0.10%)	918 (0.52%)	17 (0.61%)
Cataracts[3]	65 (0.15%)	292 (0.44%)	1383 (1.12%)	565 (1.45%)	12500 (7.75%)	208 (8.25%)
Pills for hypertension	56 (5.42%)	271 (4.93%)	1258 (6.58%)	569 (5.01%)	10225 (4.48%)	155 (4.74%)

[1] Inpatient DVT only.
[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.
[3] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 6.13
Locally Confirmed Other Cancers (Annualized Percentages): CT and OS Participants

Data as of: August 31, 2002

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	67.2		60.8	
Ppts with other cancer	1810	(0.47%)	2374	(0.50%)
Accessory sinus	0	(0.00%)	0	(0.00%)
Adrenal gland	2	(<0.01%)	4	(<0.01%)
Anus	8	(<0.01%)	9	(<0.01%)
Biliary tract, parts of (other/unspecified)	26	(0.01%)	17	(<0.01%)
Bladder	104	(0.03%)	132	(0.03%)
Bones/joints/articular cartilage (limbs)	4	(<0.01%)	4	(<0.01%)
Bones/joints/articular cartilage (other)	2	(<0.01%)	2	(<0.01%)
Brain	51	(0.01%)	60	(0.01%)
Cervix	39	(0.01%)	31	(0.01%)
Connective/subcutaneous/soft tissues	7	(<0.01%)	12	(<0.01%)
Endocrine glands, related structures	2	(<0.01%)	1	(<0.01%)
Esophagus	16	(<0.01%)	24	(0.01%)
Eye and adnexa	3	(<0.01%)	3	(<0.01%)
Genital organs	18	(<0.01%)	9	(<0.01%)
Kidney	81	(0.02%)	105	(0.02%)
Larynx	9	(<0.01%)	7	(<0.01%)
Leukemia	78	(0.02%)	86	(0.02%)
Liver	22	(0.01%)	21	(<0.01%)
Lung	349	(0.09%)	421	(0.09%)
Lymph nodes	8	(<0.01%)	4	(<0.01%)
Lymphoma,Hodgkins	10	(<0.01%)	9	(<0.01%)
Lymphoma,Non-Hodgkins	152	(0.04%)	206	(0.04%)
Melanoma of the skin	227	(0.06%)	312	(0.07%)
Multiple myeloma	72	(0.02%)	58	(0.01%)
Oral (mouth)	11	(<0.01%)	11	(<0.01%)
Palate	3	(<0.01%)	4	(<0.01%)
Pancreas	88	(0.02%)	106	(0.02%)
Parotid gland (Stensen's duct)	3	(<0.01%)	14	(<0.01%)
Peripheral nerves and autonomic nervous system	0	(0.00%)	3	(<0.01%)
Pyriform sinus	0	(0.00%)	1	(<0.01%)
Respiratory system, intrathoracic, other	5	(<0.01%)	8	(<0.01%)
Salivary glands, major (other/unspecified)	2	(<0.01%)	5	(<0.01%)
Stomach	19	(<0.01%)	30	(0.01%)
Thyroid	56	(0.01%)	67	(0.01%)
Tongue, part of (other/unspecified)	15	(<0.01%)	13	(<0.01%)
Urinary organs (other/unspecified)	5	(<0.01%)	12	(<0.01%)
Uterus, not otherwise specified	23	(0.01%)	45	(0.01%)
Other/unknown site of cancer	215	(0.06%)	287	(0.06%)
Other/unknown cancers reported on death form	102	(0.03%)	258	(0.05%)

Table 6.14
Locally Confirmed Other Fractures (Annualized Percentages): CT and OS Participants

Data as of: August 31, 2002

	CT		OS[1]	
Locally confirmed				
Number of participants	68132		6365	
Mean follow-up time (months)	67.2		69.1	
Ppts with other fractures	5179	(1.36%)	487	(1.33%)
Ankle	915	(0.24%)	80	(0.22%)
Carpal bone(s) in wrist	130	(0.03%)	8	(0.02%)
Clavicle or collar bone	84	(0.02%)	8	(0.02%)
Elbow, not otherwise specified	11	(<0.01%)	0	(0.00%)
Humerus, shaft/unspecified	56	(0.01%)	5	(0.01%)
Humerus, upper end	541	(0.14%)	44	(0.12%)
Humerus, lower end	68	(0.02%)	6	(0.02%)
Metacarpal bone(s)	185	(0.05%)	13	(0.04%)
Patella	234	(0.06%)	23	(0.06%)
Pelvis	189	(0.05%)	27	(0.07%)
Radius or ulna	1443	(0.38%)	150	(0.41%)
Sacrum and coccyx	58	(0.02%)	8	(0.02%)
Scapula	23	(0.01%)	4	(0.01%)
Shaft of femur	68	(0.02%)	5	(0.01%)
Tarsal/metatarsal bones	898	(0.24%)	94	(0.26%)
Tibia and fibula	443	(0.12%)	27	(0.07%)
Tibial plateau	103	(0.03%)	7	(0.02%)
Upper radius/ulna	274	(0.07%)	27	(0.07%)
Unknown other fracture	2	(<0.01%)	2	(0.01%)
Self-Reports				
Number of participants			93676	
Mean follow-up time (months)			60.8	
Elbow			430	(0.09%)
Foot			1564	(0.33%)
Hand			286	(0.06%)
Knee			524	(0.11%)
Lower Arm			2239	(0.47%)
Lower Leg			1751	(0.37%)
Pelvis			381	(0.08%)
Tailbone			114	(0.02%)
Upper Arm			910	(0.19%)
Upper Leg			216	(0.05%)
Vertebra			967	(0.20%)
Other Fracture			1920	(0.40%)

[1] Other fractures for OS Participants are only confirmed in the three bone density clinics.

Table 6.15
Cross-tabulation of ECG Codes Suggesting an Incident MI and Locally Confirmed and Self-Reported MI for All CT Participants

Data as of: August 31, 2002

	No Locally Confirmed MI or Open Self-Report of MI	Locally Confirmed MI[1]	Total
All CT Participants			
No significant Q or ST-T evolution[2]	55101	287	55388
Borderline Q-wave change[3]	1695	38	1733
Ischemic ST-T evolution[4]	1020	37	1057
Possible evolving Q-wave MI[5]	135[6]	19	154
Evolving Q-wave MI[7]	27[8]	18	45
Total	57978	399	58377
HRT Participants			
No significant Q or ST-T evolution[2]	22002	135	22137
Borderline Q-wave change[3]	726	16	742
Ischemic ST-T evolution[4]	467	15	482
Possible evolving Q-wave MI[5]	63[6]	8	71
Evolving Q-wave MI[7]	9[8]	11	20
Total	23267	185	23452
DM Participants			
No significant Q or ST-T evolution[2]	39570	191	39761
Borderline Q-wave change[3]	1175	26	1201
Ischemic ST-T evolution[4]	695	25	720
Possible evolving Q-wave MI[5]	83[6]	16	99
Evolving Q-wave MI[7]	20[8]	9	29
Total	41543	267	41810
CaD Participants			
No significant Q or ST-T evolution[2]	31204	94	31298
Borderline Q-wave change[3]	985	14	999
Ischemic ST-T evolution[4]	543	13	556
Possible evolving Q-wave MI[5]	78[6]	7	85
Evolving Q-wave MI[7]	18[8]	8	26
Total	32828	136	32964

[1] Includes only locally confirmed MIs that took place before the latest follow-up ECG.
[2] Novacode Incident MI code I 5.0.
[3] Novacode Incident MI code I 5.7.
[4] Novacode Incident MI code I 5.5, I 5.6.1, and I.5.6.2.
[5] Novacode Incident MI code I 5.3 and I.5.4.
[6] Cases in this cell are possible evolving Q-wave MIs.
[7] Novacode Incident MI code I 5.1 and I.5.2.
[8] Cases in this cell are definite evolving Q-wave MIs.

Table 6.16
Cause of Death (Annualized Percentages): CT and OS Participants

Data as of: August 31, 2002

	CT		OS	
Number Randomized	68132		93676	
Mean Follow-up Time (months)	67.2		60.8	
Total death	1929	(0.51%)	2981	(0.63%)
Adjudicated death	1763	(0.46%)	2677	(0.56%)
Final adjudicated death	1617	(0.42%)	2417	(0.51%)
Temporary adjudicated death	146	(0.04%)	259	(0.05%)
Identified by NDI search	0	(0.00%)	1	(<0.01%)
Cardiovascular				
Atherosclerotic cardiac	271	(0.07%)	329	(0.07%)
CHD deaths adjudicated before 10/99	86	(0.02%)	82	(0.02%)
Definite CHD deaths adjudicated after 10/99	105	(0.03%)	126	(0.03%)
Possible CHD deaths adjudicated after 10/99	80	(0.02%)	121	(0.03%)
Cerebrovascular	127	(0.03%)	184	(0.04%)
Pulmonary embolism	12	(<0.01%)	21	(<0.01%)
Other cardiovascular	104	(0.03%)	171	(0.04%)
Unknown cardiovascular	29	(0.01%)	42	(0.01%)
Total cardiovascular deaths	543	(0.14%)	747	(0.16%)
Cancer				
Breast cancer	31	(0.01%)	165	(0.03%)
Ovarian cancer	66	(0.02%)	85	(0.02%)
Endometrial cancer	7	(<0.01%)	24	(0.01%)
Colorectal cancer	84	(0.02%)	97	(0.02%)
Other cancer	609	(0.16%)	811	(0.17%)
Unknown cancer site	45	(0.01%)	72	(0.02%)
Total cancer deaths	842	(0.22%)	1254	(0.26%)
Accident/injury				
Homicide	5	(<0.01%)	5	(<0.01%)
Accident	45	(0.01%)	59	(0.01%)
Suicide	7	(<0.01%)	17	(<0.01%)
Other injury	4	(<0.01%)	4	(<0.01%)
Total accidental deaths	61	(0.02%)	85	(0.02%)
Other				
Other known cause	221	(0.06%)	391	(0.08%)
Unknown cause	96	(0.03%)	200	(0.04%)
Total deaths – other causes	317	(0.08%)	591	(0.12%)

Table 6.17
Results of NDI Search[1]

	Known dead[2]		Lost to follow-up[3]		Known alive[4]	
	N	%	N	%	N	%
Submitted to NDI	1252		2249		500	
NDI returned matches	1235	98.6	731	32.5	149	29.8
Matches satisfying WHI criteria	1224	97.8	53	2.4	0	0.0
Reported dead to WHI after 8/31/2000	N/A		27	1.2[5]	N/A	
Only identified using NDI	N/A		26	1.2[6]	N/A	

[1] Analysis has not been updated from that of August 31, 2001.
[2] Participants having a Form 120 or Form 124 with date of death before 1/1/2000.
[3] Participants who were lost-to-follow-up or no-follow-up by 8/31/2000, for whom contact was before 1/1/2000.
[4] Randomly selected participants with whom there was clinic contact after 1/1/2000.
[5] 1 of these participants was a CT participant, 26 were OS participants.
[6] 8 of these participants were CT participants, 18 were OS participants.

Table 6.18
Lost-to-Follow-up and Vital Status by Clinic: CT Participants

Data as of: August 31, 2002

	Deceased		Alive: Current Participation[1]		Alive: Recent Participation[2]		Alive: Past/Unknown Participation[3]		Stopped Follow-up[4]		Lost to Follow-up[5]		Total
	N	%	N	%	N	%	N	%	N	%	N	%	N
Clinic													
Atlanta	50	2.9	1621	94.2	13	0.8	1	0.1	28	1.6	7	0.4	1720
Birmingham	62	3.4	1701	92.8	23	1.3	1	0.1	34	1.9	11	0.6	1832
Bowman	42	2.8	1364	89.3	35	2.3	0	0.0	57	3.7	29	1.9	1527
Brigham	54	2.3	2199	95.5	27	1.2	3	0.1	1	0.0	19	0.8	2303
Buffalo	50	3.1	1526	95.1	6	0.4	0	0.0	20	1.2	3	0.2	1605
Chapel Hill	41	2.7	1467	95.3	1	0.1	0	0.0	30	1.9	0	0.0	1539
Chicago	53	3.3	1495	92.1	8	0.5	0	0.0	45	2.8	23	1.4	1624
Chi-Rush	43	3.2	1197	90.3	16	1.2	4	0.3	32	2.4	34	2.6	1326
Cincinnati	29	2.1	1275	91.7	28	2.0	1	0.1	48	3.5	10	0.7	1391
Columbus	48	3.1	1458	94.1	4	0.3	0	0.0	29	1.9	10	0.6	1549
Detroit	19	1.4	1184	86.0	52	3.8	1	0.1	88	6.4	33	2.4	1377
GWU-DC	36	2.4	1426	94.3	26	1.7	2	0.1	15	1.0	7	0.5	1512
Gainesville	59	2.8	1933	93.2	20	1.0	0	0.0	50	2.4	11	0.5	2073
Honolulu	30	2.1	1275	90.6	39	2.8	0	0.0	41	2.9	22	1.6	1407
Houston	27	2.1	1128	88.8	37	2.9	2	0.2	60	4.7	16	1.3	1270
Iowa City	75	3.1	2319	95.3	4	0.2	0	0.0	17	0.7	18	0.7	2433
Irvine	34	2.1	1478	91.1	19	1.2	0	0.0	45	2.8	47	2.9	1623
L.A.	42	2.5	1572	93.8	16	1.0	2	0.1	34	2.0	10	0.6	1676
La Jolla	69	3.2	1839	85.1	77	3.6	10	0.5	25	1.2	140	6.5	2160
Madison	31	2.0	1500	96.4	4	0.3	0	0.0	18	1.2	3	0.2	1556
Medlantic	52	3.5	1340	89.6	39	2.6	1	0.1	42	2.8	21	1.4	1495
Memphis	74	4.2	1543	88.6	44	2.5	3	0.2	45	2.6	33	1.9	1742
Miami	30	2.0	1189	80.2	56	3.8	1	0.1	50	3.4	157	10.6	1483
Milwaukee	42	2.5	1546	93.6	12	0.7	0	0.0	45	2.7	6	0.4	1651
Minneapolis	59	3.0	1889	95.0	20	1.0	0	0.0	19	1.0	2	0.1	1989
NY-City	50	2.7	1734	92.2	43	2.3	9	0.5	19	1.0	26	1.4	1881
Nevada	55	3.7	1403	94.6	6	0.4	1	0.1	14	0.9	4	0.3	1483
Newark	64	2.6	2137	87.2	108	4.4	2	0.1	112	4.6	28	1.1	2451
Oakland	39	2.5	1493	95.2	10	0.6	0	0.0	18	1.1	8	0.5	1568
Pawtucket	70	2.6	2460	93.0	27	1.0	1	0.0	53	2.0	33	1.2	2644
Pittsburgh	58	3.5	1578	95.1	6	0.4	0	0.0	17	1.0	0	0.0	1659
Portland	48	2.9	1485	90.9	31	1.9	0	0.0	40	2.4	30	1.8	1634
San Antonio	21	1.5	1240	89.5	3	0.2	0	0.0	94	6.8	28	2.0	1386
Seattle	58	3.2	1605	88.9	87	4.8	5	0.3	28	1.6	22	1.2	1805
Stanford	40	2.3	1656	94.4	12	0.7	2	0.1	33	1.9	12	0.7	1755
Stonybrook	36	2.7	1282	94.6	12	0.9	0	0.0	25	1.8	0	0.0	1355
Torrance	25	2.5	872	86.6	41	4.1	1	0.1	34	3.4	34	3.4	1007
Tucson	98	4.7	1831	87.8	18	0.9	1	0.0	51	2.4	87	4.2	2086
U.C. Davis	74	3.8	1765	91.8	32	1.7	1	0.1	24	1.2	27	1.4	1923
Worcester	42	2.6	1546	94.7	27	1.7	0	0.0	9	0.6	8	0.5	1632
Total	1929	2.8	62551	91.8	1089	1.6	55	0.1	1489	2.2	1019	1.5	68132

[1] Participants who have filled in a Form 33 within the last 9 months.
[2] Participants who last filled in a Form 33 between 9 and 18 months ago.
[3] Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

Table 6.19
Lost-to-Follow-up and Vital Status by Clinic: OS Participants

Data as of: August 31, 2002

	Deceased		Alive: Current Participation[1]		Alive: Recent Participation[2]		Alive: Past/Unknown Participation[3]		Stopped Follow-up[4]		Lost to Follow-up[5]		Total
	N	%	N	%	N	%	N	%	N	%	N	%	N
Clinic													
Atlanta	64	2.6	2277	92.4	98	4.0	1	0.0	7	0.3	16	0.6	2463
Birmingham	103	4.1	2223	87.9	93	3.7	0	0.0	63	2.5	47	1.9	2529
Bowman	61	2.7	1932	86.8	90	4.0	0	0.0	33	1.5	111	5.0	2227
Brigham	46	1.6	2822	95.8	55	1.9	1	0.0	1	0.0	21	0.7	2946
Buffalo	108	4.8	2091	93.0	31	1.4	0	0.0	14	0.6	4	0.2	2248
Chapel Hill	55	2.6	1981	95.1	30	1.4	0	0.0	12	0.6	5	0.2	2083
Chicago	62	3.3	1727	91.4	44	2.3	4	0.2	26	1.4	26	1.4	1889
Chi-Rush	73	3.6	1713	83.6	150	7.3	5	0.2	36	1.8	72	3.5	2049
Cincinnati	71	3.2	1971	87.6	71	3.2	8	0.4	50	2.2	78	3.5	2249
Columbus	54	2.4	2122	95.6	27	1.2	1	0.0	11	0.5	4	0.2	2219
Detroit	43	2.0	1822	86.3	75	3.6	58	2.7	64	3.0	50	2.4	2112
GWU-DC	73	3.2	2134	95.0	31	1.4	2	0.1	5	0.2	2	0.1	2247
Gainesville	93	3.3	2534	90.8	86	3.1	1	0.0	58	2.1	20	0.7	2792
Honolulu	49	2.3	1851	87.6	117	5.5	2	0.1	62	2.9	32	1.5	2113
Houston	85	4.0	1921	90.2	33	1.5	7	0.3	73	3.4	11	0.5	2130
Iowa City	77	2.5	2954	94.7	28	0.9	0	0.0	31	1.0	30	1.0	3120
Irvine	66	3.0	2071	92.9	10	0.4	0	0.0	45	2.0	38	1.7	2230
L.A.	58	2.6	2073	94.4	14	0.6	2	0.1	28	1.3	20	0.9	2195
La Jolla	126	3.6	2842	82.1	188	5.4	25	0.7	17	0.5	265	7.7	3463
Madison	68	3.4	1888	95.3	13	0.7	0	0.0	9	0.5	3	0.2	1981
Medlantic	70	3.2	1958	89.3	97	4.4	7	0.3	30	1.4	31	1.4	2193
Memphis	81	3.2	2095	83.3	149	5.9	5	0.2	76	3.0	110	4.4	2516
Miami	45	3.3	1041	75.8	65	4.7	0	0.0	34	2.5	189	13.8	1374
Milwaukee	60	2.7	2038	90.7	59	2.6	1	0.0	27	1.2	61	2.7	2246
Minneapolis	71	2.6	2530	92.8	58	2.1	0	0.0	26	1.0	42	1.5	2727
NY-City	95	3.3	2554	88.0	153	5.3	11	0.4	21	0.7	69	2.4	2903
Nevada	121	5.6	2003	92.1	30	1.4	0	0.0	17	0.8	3	0.1	2174
Newark	79	2.3	2919	86.5	141	4.2	2	0.1	58	1.7	174	5.2	3373
Oakland	81	3.9	1906	92.8	37	1.8	0	0.0	25	1.2	4	0.2	2053
Pawtucket	105	2.9	3274	91.2	73	2.0	72	2.0	38	1.1	26	0.7	3588
Pittsburgh	86	4.5	1705	88.9	41	2.1	2	0.1	56	2.9	27	1.4	1917
Portland	54	2.4	2008	90.0	92	4.1	3	0.1	39	1.7	36	1.6	2232
San Antonio	52	2.7	1729	89.0	25	1.3	0	0.0	113	5.8	23	1.2	1942
Seattle	74	4.4	1462	87.9	59	3.5	28	1.7	19	1.1	21	1.3	1663
Stanford	95	3.6	2476	92.8	36	1.3	3	0.1	51	1.9	8	0.3	2669
Stonybrook	47	2.3	1878	92.6	48	2.4	2	0.1	14	0.7	39	1.9	2028
Torrance	53	3.5	1280	85.2	41	2.7	1	0.1	27	1.8	101	6.7	1503
Tucson	129	4.6	2362	84.9	55	2.0	1	0.0	37	1.3	198	7.1	2782
U.C. Davis	89	3.9	2086	91.9	53	2.3	2	0.1	30	1.3	9	0.4	2269
Worcester	59	2.6	2055	91.8	95	4.2	3	0.1	10	0.4	17	0.8	2239
Total	2981	3.2	84308	90.0	2691	2.9	260	0.3	1393	1.5	2043	2.2	93676

[1] Participants who have filled in a Form 33 within the last 15 months.
[2] Participants who last filled in a Form 33 between 15 and 24 months ago.
[3] Participants without a Form 33 within the last 24 months, who have been located (as indicated on Form 23) within the last 6 months.
[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.
[5] Participants not in any of the above categories.

7. Laboratory Studies

7.1 Overview

Blood samples are collected on all CT participants at baseline and year 1 and on a 6% subsample of participants at years 3, 6, and 9. Blood samples are collected on all OS participants at baseline and Year 3. All blood samples are obtained in the fasting state (at least 12 hours), maintained at 4°C until plasma or serum is separated. In addition, urine samples are collected on both CT and OS participants at the three Bone Density sites at baseline, year 1 and year 9 for CT, and baseline and year 3 for OS participants. Plasma, serum, RBCs, buffy coat, and urine aliquots are frozen at -70°C and sent on dry ice to the central repository (McKesson Biological Services, Rockville, MD) where storage at -70°C is maintained.

7.2 Status of Analyses

Core Analytes

The analyses of the twenty core analytes are done by Medical Research Laboratories, Highland Heights, Kentucky (MRL). MRL has completed the analyses of the CT 6% subsample core analytes for baseline, Year 1, and Year 3 samples. Analysis of Year 6 bloods will begin later this year. See *Sections 2* and *3* in this report for presentation of the laboratory results for HRT and DM.

MRL has also completed the analysis of the 1% OS Measurement Precision Study (OS-MPS) participants. See *Section 5.3* in the February 1, 1999 to August 25, 1999 Semi-Annual Progress Report for the results.

DNA Extraction

DNA extraction for WHI is done by BioServe Biotechnologies, Laurel, MD. For each buffy coat sample, BioServe prepares up to four daughter aliquots containing 3 micrograms DNA each and divides the remaining DNA into parent aliquots containing up to 200 micrograms DNA each, depending on the quantity of DNA extracted. BioServe sends the extracted DNA aliquots to McKesson for storage and/or distribution to DNA testing laboratories.

To date, BioServe has completed the DNA extraction of over 1,700 samples, including all of the samples for the CVD Biomarker Case Control Study of CHD, Stroke, and VTE in the HRT Clinical Trial and for ancillary study #83, Paul Ridker, Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study.

CVD Biomarker Case-Control Study of CHD, Stroke, and VTE in the HRT Clinical Trial

This study is divided into two phases, with phase I including all locally adjudicated cases of CHD, stroke, and VTE occurring within two years of randomization and phase II including similar types of cases occurring more than two years after randomization. The University of Leiden was contracted to perform the DNA testing for the study. All phase I and phase II DNA samples were sent to Leiden, and results from all but two polymorphisims have been received, with these final results expected in November. The University of Vermont was contracted to perform the thrombosis analyses for the study. The phase I and phase II samples were sent to Vermont in October 2001, and completion of the phase I thrombosis analyses Vermont is expected by the end of 2002 and completion of phase II analyses is expected in mid-2003.

MRL has completed the phase I and phase II lipid analyses for the study.

Hormones

Esoterix (Calabasas Hills, CA; formerly Endocrine Sciences) has completed hormone analyses on baseline and year 1 samples for 120 of the 300 participants included in the approved paper "Correlates of endogenous sex hormone concentrations in WHI". Samples from the remaining 180 participants will be sent in monthly batches of 30 participants by the end of the year.

In addition, serum samples were sent to Esoterix to conduct a pilot study of the correlation between the standard Esoterix assay for total estradiol, which uses 1.0 ml of serum, and the alternative Vitros IRA assay, which uses only 0.1 ml of serum. At the same time, aliquots of serum from the samples were sent to two other labs for an IGF validation study.

Ancillary Studies

Analyses of blood samples for ancillary study (AS) #83, Paul Ridker, Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study, were completed last year. The analyses of the lipid core analytes was also completed at the AS laboratory. Samples for core analytes will be sent to MRL for analyses at a later time. Analyses of bloods for AS #110, Kathryn Rexrode, Sex Steroid Hormones and Risk of Coronary Heart Disease: A nested Case Control Study were partially completed this fall. The analyses of samples for AS #129, Howard Strickler, Association of Diabetes and Insulin-like Growth Factor-I with Risks of Colorectal, Breast and Endometrial Cancers are on hold pending the results of the estradiol assay pilot study being conducted by Esoterix.

Currently, WHI has made available 1.8 ml baseline and 1.8 ml Year 3 serum, citrate plasma, and EDTA plasma samples for use by OS ancillary studies. Through August 30, 2002, WHI has approved 19 ASs using WHI blood specimens, with 7 funded and the other 12 pending funding. Six ASs were reviewed for the Spring 2002 OS blood competition, and review of 7 additional AS requesting blood specimens is planned for the Fall 2002 OS blood competition due in September. Table 1 gives a summary of the volume of OS blood samples committed to OS ancillary studies by disease type as of Aug. 30, 2002. To date, no more baseline serum is available for current CHD and hip fracture cases, and very limited baseline citrate and EDTA plasma is available for stoke cases (see volumes indicated in Table 7.1).

Table 7.1
OS Blood Committed to Ancillary Studies (AS)

Outcomes	# of AS	Cases reported as of 8/02	Max # of cases committed[1]	Volume committed (baseline/year 3) Serum (ml)	Citrate plasma (ml)	EDTA plasma (ml)	DNA (µg)
CHD	3	1,297	2,015	1.8[2]	1.0	0.8	9
Stroke	1	1,061	1,100		1.5	1.5	3
Hypertension	1	14,526	800			0.8	3
Type 2 diabetes	1	3,174	2,150			0.25	3
Hip fracture	1	540	400	1.7[2]			3
Breast cancer	5	2,570	5,400	1.3 – 1.7[2]			9
Colorectal cancer	3	554	1,984	0.5			12
Endometrial cancer	3	329	891	0.5			9
Leukemia	1	78	59				3
Ovarian cancer	3	226	546	1.5[2]/1.0			6
Pancreatic cancer	1	88	93			0.6	3
Eye disease	1	See note 3	1,700	1.1			

[1] Not all volume committed to all cases
[2] No more baseline sample available for these cases
[3] Determined by local ancillary study screening

8. Clinical Center Performance Monitoring

8.1 Performance Monitoring

A four step plan is used to identify clinic-specific performance issues in a timely fashion, to reinforce good performance, and to provide assistance or institute corrective action if performance is inadequate. CCC staff train, monitor, and communicate with CC staff on an ongoing basis.

8.2 PMC Committee Activity

The Performance Monitoring Committee (PMC) provides a facilitating and monitoring role for CCs. In July 1998, the PMC separated its monitoring activities into two separate groups, with one group addressing outcomes and one group addressing adherence/retention and other issues. Membership of the Adherence and Retention PMC (A&R PMC) includes: Sally Shumaker, CFC PI, chair; Shari Ludlum and Linda Pottern, Project Office; Gerardo Heiss, Chapel Hill Clinical Center PI; Betty Caan, Oakland Clinical Center PI (began in April, replacing Judy Hsia, George Washington Clinical Center PI in March 2002), Michelle Naughton, Steve Rapp, Sara Wilcox, CFC; and Barb Cochrane, Julie Hunt, Andrea LaCroix, Bernedine Lund, and Lesley Tinker, CCC. Membership of the Outcomes PMC (O-PMC) includes Anne McTiernan, CCC, chair; David Curb, Honolulu Clinical Center PI; Marian Limacher, Gainesville Clinical Center PI; Ronald Prineas, CFC; Jacques Rossouw, Project Office; and Charles Kooperberg, Bernedine Lund, and Lori Proulx-Burns, CCC.

Since March 1, 2002, the A&R PMC held six conference calls, reviewing 5-6 Clinical Centers on each call. Information reviewed about each Clinical Center includes: 1) cumulative and recent measures of participant intervention and follow-up status; 2) HRT and CaD adherence measures; 3) DM C-I and DM intervention measures; and 4) cumulative and recent measures of completion of required tasks. Each performance measure is compared to study goals, study-wide averages, and performance in the last 3-12 month period. At the request of the PMC, many of the CCs submitted copies of their Biannual Technical Reports and/or informational memos about their recent performance in the materials they sent to the PMC for review on the conference calls. The A&R PMC held separate targeted conference calls with two CCs.

Specific issues the PMC-A&R addressed since March 1, 2002:

- In March, at the request of the Adherence and Retention Working Group, the PMC-A&R reviewed the CC priorities for task completion, and agreed that the priorities established in 1993-4 should not be changed. Instead, the PMC suggested that the priorities be redistributed to the CCs.
- In May, the Committee reviewed tables showing the percent of HRT and CaD participants who had restarted taking study pills after they had previously stopped.
- In June, the PMC discussed the issue of participants not wanting to come into the CC for a visit, and agreed to investigate how CCs address getting distant participants into the CCs, and which sites use remote sites for those participants.
- In August, the Committee discussed possible strategies for helping CCs prioritize and carry out local implementation of the Estrogen plus Progestin update (including stopping study pills and unblinding).

In the same period, the O-PMC held six conference calls, reviewing 5-7 Clinical Centers on each call. A summary of each CC included: 1) recent and cumulative data on collection of required outcomes forms, outcomes packet assembly, and local adjudication; 2) a graph showing the timeliness of outcomes processing over time; 3) CC responsiveness to CCC queries for more information on cancer and CVD cases; and 4) a summary of number of staff and local adjudicators. In the letters to CCs, specific goals were listed for CCs. In addition, the O-PMC held separate targeted conference calls with four CCs to discuss issues with outcomes processing in more detail and to provide direction and interim goals for improving performance. Four CCs receiving the follow-up calls had made substantial progress on decreasing their backlog of outcomes cases.

In February, the Executive Committee asked for an outcomes catch-up plan similar to the recruitment catch-up plan the CCs used during recruitment. Using a backlog defined as the number of cases that were in process for more than two months, the following two reports were developed:

- A CC-specific catch-up 'worksheet' for the CCs to use as a tool to calculate the CC's average monthly and daily outcomes processing workload. The worksheet shows the number of cases the CC needs to process to eliminate the CC's backlog and/or to maintain the current workload. In May, CCs were sent a copy of the worksheet with data for their own CC filled in (data as of February 28, 2002). CCs are able to update their copy of the worksheet using data from their own CC-run reports on an on-going basis to monitor their status as close-out approaches. CCs with satellite sites are able to update the worksheet for each site.
- A one-page summary report titled "Outcomes Collection and Processing Backlog" showing the number of *Form 33/Form 33D - Medical History Update/(Detail)* completed, current outcomes processing workload, backlog, and the additional cases the CC would need to process each month to decrease the backlog by May 31, 2003. This date was selected to give time for CCs to evaluate their outcomes processing procedures and to eliminate any backlog they may have before CT and OS close-out begins. The final column in the report shows the percent increase in workload the CC needs to accomplish to eliminate the backlog by May 2003.
- As an additional aid to CCs, a current report showing timeliness of outcomes processing was enhanced to show data for the preceding last 12 months, allowing CCs to see more recent progress of outcomes case processing.

Plans over the next six months include having CCC Outcomes Liaisons attend 3-4 QA Visits to assist CCs having particular difficulty in processing outcomes efficiently.

The PMC report showing data as of August 30, 2002, is in *Tables 8.1-8.5*. Changes were made to the HRT table, dropping the adherence summary for the E-plus-P trial and including the adherence for only the E-Alone trial participants. The CCs also receive these tables quarterly.

Table 8.1
Performance Monitoring Committee Report
Data as of 8/31/02

DM

	Adjusted C-I[1]				Task Completeness Form 60 - FFQ[4]		% Stopped[5]	
	Average[2]		Sep 01 - Aug 02[3]		Dec 01 - May 02		Cum Aug 02	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Nevada	12.9	1	10.6	1	96.2	1	6.5	2
Oakland	11.6	1	10.5	1	94.9	1	4.4	1
Iowa City	11.0	1	8.0	2	96.9	1	4.7	1
Madison	10.9	1	9.0	1	94.9	1	4.3	1
Columbus	10.8	1	8.5	1	95.4	1	6.5	2
Stanford	10.7	1	8.5	1	92.9	2	5.7	1
Milwaukee	10.7	1	9.4	1	94.4	1	5.2	1
Pittsburgh	10.5	1	8.3	1	96.0	1	4.7	1
Seattle	10.4	1	8.1	2	85.6	3	8.0	2
Minneapolis	10.3	1	7.4	2	93.2	2	6.5	2
GWU-DC	10.2	2	8.1	2	89.0	3	6.2	1
Irvine	9.8	2	7.3	2	92.2	2	6.6	2
Chicago	9.7	2	8.7	1	91.3	2	9.9	3
Portland	9.4	2	6.6	3	87.0	3	8.2	2
Gainesville	9.3	2	8.4	1	89.1	3	6.6	2
Worcester	9.2	2	7.6	2	95.5	1	5.9	1
Torrance	9.2	2	7.2	2	77.0	4	11.5	4
Chapel Hill	9.1	2	8.1	2	93.5	2	4.7	1
UC Davis	8.9	2	6.9	3	87.3	3	8.8	3
LA	8.9	2	6.7	3	89.7	3	8.6	3
Brigham	8.7	3	6.4	4	91.1	2	6.3	2
Buffalo	8.7	3	6.3	4	93.8	1	7.1	2
Pawtucket	8.7	3	7.0	3	92.4	2	8.3	3
Tucson	8.6	3	7.7	2	90.0	3	11.4	4
Memphis	8.6	3	7.0	3	86.3	3	11.2	4
Newark	8.4	3	6.9	3	75.3	4	11.5	4
Stony Brook	8.4	3	8.2	1	84.2	4	7.4	2
Houston	8.4	3	6.4	4	90.1	3	9.1	3
Bowman	8.3	3	6.2	4	78.8	4	10.0	3
Chi-Rush	8.2	3	7.3	2	94.0	1	13.1	4
Atlanta	8.1	4	6.5	3	87.8	3	5.5	1
Cincinnati	8.0	4	6.3	4	90.9	2	8.7	3
Honolulu	8.0	4	6.9	3	90.6	2	9.4	3
LaJolla	7.7	4	6.5	3	85.1	4	12.1	4
NYC	7.6	4	6.5	3	79.6	4	9.9	3
Detroit	7.1	4	5.2	4	72.7	4	12.8	4
Birmingham	6.7	4	6.0	4	85.1	4	9.9	3
San Antonio	6.1	4	4.8	4	82.3	4	14.8	4
Medlantic	5.7	4	4.1	4	92.5	2	11.3	4
Miami	5.0	4	4.2	4	68.3	4	21.5	4
CC Average	**9.0**		**7.2**		**88.6**		**8.6**	
Ave F/U 5.7 yr	Design Assumption 11.8				Goal ≥ 90%		Design Assumption 15.8	

[1] Adjusted C-I defined as (C-I of collected FFQs) x (FFQ completion rate)
[2] Based on FFQs collected after randomization through AV7.
[3] Based on FFQs collected in the last 12 months
[4] From *WHIP 1445-Task Completeness*; complete if encounter date on *Form 60* is -6/+12 months from visit target date, using 6 month period ending 3 months before the data as of date; excludes deaths
[5] From *WHIP0751- DM Intervention & F/U Status*, includes stopped intervention, stopped F/U, lost-to-F/U, and deaths

Table 8.2
Performance Monitoring Committee Report
Data as of 8/31/02

HT

	E-Alone Adherence Summary ≥ 80%				Task Completeness Dec 01 – May 02				% Stopped[5]	
	Average[1]		Sep 01 - Aug 02[2]		Form 10[3]		Form 85[4]		Cum Aug 02	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Oakland	78.9	1	75.9	1	98.4	2	92.5	1	11.3	1
Iowa City	70.2	1	62.2	1	98.3	2	95.7	1	13.0	1
LA	69.5	1	50.0	3	95.2	3	91.5	2	15.2	1
Minneapolis	67.7	1	64.5	1	98.2	2	94.6	1	13.5	1
Pittsburgh	67.7	1	58.8	1	95.4	3	93.6	1	19.5	2
Cincinnati	65.6	1	62.3	1	98.7	1	94.7	1	22.0	3
Stanford	64.7	1	59.0	1	98.6	1	75.4	4	15.3	1
Portland	63.4	1	56.0	1	95.4	3	84.2	3	18.5	2
Nevada	62.9	1	59.8	1	99.5	1	91.6	2	22.2	3
Milwaukee	62.4	1	55.8	1	97.2	2	94.2	1	16.1	1
Chapel Hill	62.2	2	51.6	2	98.9	1	95.6	1	16.3	2
Gainesville	61.4	2	52.1	2	98.9	1	93.2	1	23.9	3
Brigham	60.7	2	59.2	1	99.5	1	90.9	2	14.5	1
Columbus	60.7	2	54.4	2	98.7	1	92.4	2	21.5	2
Pawtucket	59.9	2	54.7	2	99.0	1	91.4	2	21.8	3
Worcester	58.3	2	55.1	2	93.9	4	95.9	1	16.0	1
Birmingham	56.4	2	47.1	3	95.6	3	87.5	3	24.6	4
Honolulu	56.3	2	54.4	2	95.2	3	91.5	2	15.3	1
Madison	55.8	2	52.0	2	96.3	2	94.9	1	19.6	2
GWU-DC	55.0	2	48.1	3	96.1	3	88.8	3	12.9	1
Seattle	54.7	3	50.7	2	94.3	3	69.4	4	22.6	3
Chicago	53.5	3	54.2	2	99.7	1	91.5	2	20.3	2
Bowman	52.1	3	47.6	3	93.1	4	81.8	4	22.7	3
Newark	51.8	3	41.7	4	90.1	4	89.1	3	19.0	2
Buffalo	51.7	3	45.5	4	98.9	1	91.3	2	21.3	2
UC Davis	51.5	3	46.8	3	94.7	3	89.0	3	23.5	3
Irvine	51.1	3	47.0	3	93.9	4	83.1	4	23.0	3
Stony Brook	51.1	3	46.3	4	97.2	2	91.1	2	16.7	2
LaJolla	51.0	3	48.3	3	89.5	4	77.7	4	24.0	3
Chi-Rush	50.2	3	47.4	3	96.9	2	91.5	2	26.0	4
Torrance	50.0	4	50.9	2	97.6	2	84.1	3	22.5	3
NYC	49.4	4	45.9	4	96.1	3	80.3	4	19.6	2
Memphis	49.0	4	48.2	3	94.2	4	81.4	4	29.4	4
Tucson	47.2	4	43.5	4	92.3	4	86.1	3	29.7	4
Atlanta	46.3	4	45.5	4	97.7	2	88.6	3	27.3	4
San Antonio	45.1	4	46.4	3	97.1	2	84.5	3	29.3	4
Detroit	45.1	4	38.2	4	86.4	4	73.0	4	26.1	4
Medlantic	42.4	4	40.4	4	96.3	3	87.5	3	27.6	4
Houston	39.9	4	30.0	4	88.4	4	77.8	4	32.1	4
Miami	28.7	4	26.9	4	87.5	4	74.1	4	35.6	4
CC Average	**55.9**		**50.8**		**96.0**		**88.0**		**20.9**	
Ave F/U 5.5 yr	-		-		Goal ≥ 90%		Goal ≥ 90%		Design Assump. 30.9	

[1] Adherence from randomization through 1) 12 months before data as of date 2) last adherence collection within the last 12 months before the data as of date, or 3) death; women off intervention are considered non-adherent

[2] Adherence in previous 12 months; excludes deaths; women off intervention are considered non-adherent

[3] From *WHIP 1445-Task Completeness*,complete if encounter date on *Form 10 - HRT Management and Safety* is -3/+3 months from target date

[4] From *WHIP 1445-Task Completeness*, complete if mammogram date on *Form 85 - Mammogram* date is -12/+6 months from AV target date

[5] From *WHIP CCC750-HRT Intervention & F/U Status*; includes E-Alone stopped intervention (excludes E-plus-P stop intervention), stopped F/U, lost-to-F/U, and deaths

Table 8.3
Performance Monitoring Committee Report
Data as of 8/31/02

CaD

	Adherence Summary ≥ 80%				Task Completeness Form 17[3]		% Stopped[4]	
	Average[1]		Sep 01 - Aug 02[2]		Dec 01 - May 02		Cum Aug 02	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Oakland	80.8	1	83.1	1	99.2	1	10.4	1
Iowa City	71.7	1	71.8	1	98.3	2	15.7	1
Stanford	71.5	1	72.5	1	98.7	1	20.6	2
Minneapolis	68.8	1	69.2	1	96.8	3	17.1	1
Nevada	67.6	1	70.2	1	99.5	1	19.1	1
Columbus	67.2	1	66.1	1	99.3	1	23.3	2
Gainesville	64.8	1	63.7	1	98.2	2	26.9	3
Portland	63.6	1	64.1	1	96.1	3	22.7	2
Brigham	63.1	1	62.9	2	99.1	1	23.9	2
Pittsburgh	62.6	1	59.6	3	97.0	2	25.4	2
Chi-Rush	62.5	2	62.3	2	98.6	2	27.6	3
Pawtucket	62.0	2	65.7	1	99.4	1	24.1	2
Chapel Hill	61.7	2	62.1	2	98.2	2	15.3	1
Milwaukee	60.6	2	62.1	2	98.7	1	19.1	1
Honolulu	60.2	2	61.6	2	94.4	3	28.5	4
Worcester	60.1	2	61.3	2	95.8	3	17.0	1
Madison	59.5	2	57.3	3	97.8	2	19.6	1
Cincinnati	59.3	2	66.4	1	99.0	1	26.6	3
GWU-DC	58.9	2	55.6	3	96.3	3	23.7	2
LA	58.8	2	57.7	3	96.2	3	26.9	3
Torrance	57.9	3	60.0	2	92.3	4	25.6	3
Buffalo	57.0	3	62.5	2	98.6	1	20.2	1
UC Davis	56.8	3	59.9	3	94.7	3	26.0	3
Bowman	56.5	3	60.1	2	93.3	4	24.8	2
Birmingham	56.3	3	60.3	2	96.2	3	20.4	1
Seattle	56.3	3	57.1	3	93.9	4	26.7	3
Stony Brook	55.8	3	53.3	4	98.2	2	29.3	4
LaJolla	55.2	3	55.1	4	89.4	4	23.7	2
Atlanta	53.8	3	57.8	3	98.4	2	26.7	3
Tucson	52.8	3	59.5	3	93.3	4	33.5	4
Chicago	52.6	4	55.2	3	99.3	1	29.3	4
Irvine	52.1	4	51.0	4	95.5	3	28.0	4
San Antonio	51.7	4	55.4	3	97.8	2	27.5	3
NYC	49.7	4	53.9	4	96.3	3	29.5	4
Memphis	48.2	4	51.6	4	94.3	4	34.1	4
Detroit	46.9	4	48.2	4	89.8	4	31.5	4
Houston	46.8	4	45.5	4	87.5	4	32.0	4
Newark	46.2	4	50.6	4	90.8	4	26.6	3
Medlantic	43.3	4	48.0	4	97.5	2	24.3	2
Miami	31.2	4	36.9	4	87.0	4	44.2	4
CC Average	**58.3**		**60.0**		**96.3**		**24.5**	
Ave F/U 4.6 yr	-		-		Goal ≥ 90%		Design Assump. 22.0	

[1] Adherence from randomization through 1) 12 months before data as of date 2) last adherence collection within the last 12 months before the data as of date, or 3) death; women off intervention are considered non-adherent

[2] Adherence in previous 12 months; excludes deaths; women off intervention are considered non-adherent

[3] From *WHIP 1445-Task Completeness*, complete if encounter date on *Form 17 - CaD Management and Safety* is -3/+3 months from target date

[4] From *WHIP CCC750-CaD Intervention & F/U Status*; includes stopped intervention, stopped F/U, lost-to-F/U, and deaths

Table 8.4
Performance Monitoring Committee Report
Data as of 8/31/02

OS

	Task Completeness - Year 3[1] May 00-Oct 01[2]				% Stopped[3]	
	Form 100		Form 143		Cum Aug 02	
	%	Quartile	%	Quartile	%	Quartile
Iowa City	-	-	-	-	4.4	1
UC Davis	-	-	-	-	5.6	2
Buffalo	-	-	-	-	5.6	2
Chicago	-	-	-	-	6.1	2
Irvine	-	-	-	-	6.7	3
Seattle	-	-	-	-	6.9	3
Bowman	-	-	-	-	9.2	4
Pittsburgh	-	-	-	-	9.9	4
Gainesville	95.4	1	99.1	1	6.2	2
Madison	95.2	1	100.0	1	4.0	1
Nevada	93.3	1	96.0	1	6.5	3
Brigham	91.7	1	96.8	1	2.3	1
Worcester	91.5	1	92.3	2	3.8	1
Oakland	89.6	1	98.7	1	5.4	2
Stanford	89.5	1	94.6	2	5.8	2
Columbus	89.1	1	95.5	1	3.2	1
Pawtucket	89.1	1	95.1	1	4.7	1
GWU-DC	88.5	1	94.3	2	3.6	1
NYC	88.1	2	91.1	2	6.4	3
Milwaukee	86.7	2	89.5	2	6.6	3
Cincinnati	86.3	2	93.0	2	9.1	4
Atlanta	85.9	2	93.1	2	3.6	1
Mediantic	85.2	2	87.4	3	6.0	2
Portland	84.9	2	94.8	1	5.9	2
Minneapolis	84.4	2	95.1	1	5.2	2
Birmingham	84.2	2	85.7	3	8.4	3
Honolulu	83.8	2	86.5	3	6.9	3
Chapel Hill	83.1	2	94.7	1	3.5	1
LaJolla	83.0	3	86.6	3	11.9	4
Stony Brook	82.9	3	91.6	2	5.0	1
LA	80.8	3	87.5	2	5.0	1
Chi-Rush	79.4	3	90.1	2	8.9	3
Torrance	77.8	3	86.1	3	12.2	4
San Antonio	75.8	3	86.6	3	9.7	4
Newark	73.1	3	74.2	3	10.0	4
Tucson	71.5	3	78.9	3	13.2	4
Memphis	69.7	3	76.1	3	10.7	4
Detroit	66.3	3	72.1	3	7.4	3
Houston	59.9	4	70.4	4	8.2	3
Miami	24.0	4	32.0	4	19.5	4
CC Average	**83.6**		**89.5**		**6.9**	
Ave F/U 5.1 yr	Goal ≥ 90%		Goal ≥ 90.9%		-	

[1] From *WHIP1445-Task Completeness;* complete if encounter date is -3/+15 months from AV3 target date. Six CCs have no OS Year 3 visits due in the time period.

[2] 6-month period ending 10 months before data as of date to allow for 10 month lag in completeness

[3] From *WHIP CCC752 Intervention & F/U Status*; includes stopped F/U, lost-to-F/U, and deaths

Table 8.5
Performance Monitoring Committee Report
Data as of 8/31/02

Outcomes

	Task Completeness						Outcomes Processing (Sept 01 – Aug 02)							
	CT Form 33[1] Dec 01- May 02		OS Form 33[2] May 01 - Oct 01		Form 33D[3] Jun 01- Aug 02		Cases Assembled ≤ 12 weeks[4]		Cases Adjudicated ≤ 14 days[5]		Cases Open > 16 weeks[6]		Cases Closed ≤ 16 weeks[7]	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Buffalo	97.9	1	95.1	2	98.4	1	95.2	1	99.7	1	29.7	4	92.1	1
Iowa City	97.4	1	96.1	2	91.6	4	91.6	2	78.2	3	13.5	1	86.9	2
Nevada	98.1	1	99.0	1	99.4	1	92.4	2	86.6	3	8.1	1	86.6	2
Oakland	96.4	1	98.3	1	93.8	3	95.1	1	85.2	3	16.0	2	83.3	3
Chapel Hill	97.4	1	98.8	1	98.5	1	98.0	1	91.9	2	0.0	1	98.1	1
Madison	97.3	1	98.8	1	96.6	2	94.7	1	65.1	4	10.3	1	87.7	2
Stanford	96.2	1	96.9	1	97.4	2	89.8	3	85.8	3	23.2	3	84.7	2
Atlanta	95.5	2	97.5	1	98.8	1	93.8	1	82.9	3	33.1	4	84.2	2
Columbus	96.8	1	98.7	1	95.9	2	90.9	2	68.9	4	27.6	3	78.4	3
Milwaukee	95.8	2	94.6	2	95.3	3	91.3	2	56.5	4	25.9	3	66.7	4
Brigham	96.8	1	96.3	2	99.4	1	93.3	2	72.1	4	14.7	2	87.7	2
Gainesville	95.1	2	97.2	1	96.9	2	89.7	3	98.6	1	17.4	2	87.7	2
Stony Brook	95.1	2	94.4	2	92.1	4	83.2	3	93.8	2	19.2	2	78.1	3
Minneapolis	95.5	2	95.6	2	94.8	3	95.5	1	78.1	3	10.8	1	90.8	1
GWU-DC	94.9	2	99.3	1	95.8	3	83.6	3	99.8	1	12.4	1	77.1	3
Pawtucket	95.1	2	95.0	2	96.0	2	89.3	3	34.2	4	25.3	3	69.9	3
Worcester	95.3	2	96.6	1	97.0	2	97.3	1	87.5	3	16.9	2	92.5	1
Pittsburgh	97.4	1	88.9	4	99.8	1	89.3	3	100.0	1	19.4	2	89.4	1
Chicago	94.4	2	93.5	3	93.1	4	90.9	2	98.7	1	27.9	3	73.1	3
Cincinnati	92.2	3	92.5	3	97.9	1	85.4	3	98.9	1	10.2	1	53.1	4
Birmingham	95.1	2	92.1	3	93.0	4	60.2	4	98.6	1	40.4	4	45.6	4
LA	94.2	3	96.5	2	97.1	2	67.9	4	97.5	1	46.6	4	46.9	4
Irvine	91.6	3	93.7	3	88.6	4	83.2	4	88.8	2	25.0	3	70.3	3
Portland	92.1	3	95.2	2	87.6	4	92.1	2	93.3	2	21.4	2	88.9	1
Seattle	90.1	4	89.7	3	94.6	3	92.5	2	89.7	2	24.0	3	83.2	3
Chi-Rush	91.4	3	89.0	4	95.9	3	94.5	1	96.5	2	10.9	1	90.2	1
NYC	92.2	3	93.7	3	98.8	1	92.4	2	85.8	3	47.1	4	83.5	2
UC Davis	92.6	3	96.4	2	98.6	1	81.0	4	100.0	1	31.6	4	84.3	2
Medlantic	91.3	3	92.4	3	97.0	2	89.1	3	84.9	3	28.8	3	86.4	2
Memphis	90.6	3	89.7	4	95.7	3	99.1	1	95.2	2	8.4	1	94.3	1
Bowman	90.1	3	89.3	4	92.7	4	80.1	4	86.0	3	33.6	4	46.9	4
San Antonio	89.7	4	92.8	3	89.4	4	96.9	1	90.6	2	10.8	1	87.9	1
Tucson	88.3	4	88.8	4	96.9	2	93.2	2	93.6	2	22.2	2	90.3	1
Newark	86.4	4	87.8	4	95.9	3	90.4	3	63.4	4	21.2	2	69.9	3
Honolulu	88.0	4	92.1	3	91.7	4	81.3	4	71.6	4	23.0	3	55.4	4
Houston	86.0	4	93.9	3	94.6	3	57.2	4	58.4	4	29.4	4	40.2	4
Detroit	84.5	4	86.9	4	93.4	3	70.1	4	98.4	1	27.4	3	61.8	4
Torrance	83.2	4	86.4	4	97.0	2	81.9	4	96.8	2	13.8	2	74.9	3
LaJolla	83.1	4	86.1	4	43.9	4	88.0	3	68.8	4	54.3	4	59.3	4
Miami	76.4	4	76.1	4	97.9	1	69.7	4	58.6	4	38.5	4	55.4	4
CC Ave	**92.6**		**93.5**		**94.0**		**88.2**		**84.4**		**26.3**		**77.0**	
Goals	≥ 95.7%		≥ 96.0%		≥ 96.8%		≥ 80%		≥ 80%		< 20%		≥ 80%	

[1] From *WHIP 1445-Task Completeness;* complete if encounter date is -3/+3 months from target date
[2] From *WHIP 1445-Task Completeness;* complete if encounter date is -2/+10 months from AV1,4+ target date, -2/+9 from AV2, and -3/+15 for AV3
[3] From *WHIP 2030-Timeliness of Outcomes Processing*; includes both CT and OS
[4] From *WHIP 1263-Timeliness of Outcomes Packet Assembly;* percent of assembled cases that were assembled (assigned) within 12 weeks
[5] From *WHIP 1264-Timeliness of Local Adjudications;* percent of adjudicated cases that were adjudicated within 14 days
[6] From *WHIP 2030-Timeliness of Outcomes Processing*; percent of open cases that were open more than 16 weeks
[7] From *WHIP 2030-Timeliness of Outcomes Processing*; percent of closed cases that were closed within 16 weeks

9. Other Study Activities

A number of WHI-related scientific endeavors have been initiated by study investigators. Publications in scholarly journals are approved through the Presentations and Publications Advisory Committee and the Project Office. Ancillary studies are approved by the Design and Analysis Advisory Committee and the Project Office. Those initiatives that could potentially threaten the integrity of the Clinical Trial results before the completion of the study are to be referred to the DSMB for review. A full statement of the relevant policies may be found in the *WHI Manuals, Vol. 1 – Study Protocol and Policies, Section 3 – Study Policies.*

Table 9.1 – Publications presents current and proposed publications that have been approved by the Publications and Presentations Committee.

Table 9.2 – Ancillary Studies lists all ancillary study proposals received by the Design and Analysis Committee along with some key features of the studies and their current status.

These tables represent the current information available to the relevant committees. Updates are clearly needed. Status reports for papers or ancillary studies may be sent to the CCC, attention Sundara Murphy. The CCC requests one reprint from each published manuscript for study archives.

Table 9.1
Publications

MS ID	Title	Authors	Data Focus	Stage	Reference
1	Informed Consent in the Women's Health Initiative Clinical Trial and Observational Study	**McTiernan**, Rossouw, Manson, Franzi, Taylor, Carleton, Johnson, Nevitt	Gen.	11	Journal of Women's Health 4(5):519-29, 1995
4	The Women's Health Initiative: Overview of the Nutrition Component	**Tinker**, Burrows, Henry, Patterson, Van Horn, Rupp	Gen.	11	Nutrition and Women's Health, pp. 510-542, 1996.
5	Women Health Initiative: Why Now? What is it? What's New?	**Matthews**, Shumaker, Bowen, Langer, Hunt, Kaplan, Klesges, Ritenbaugh	Gen.	11	American Psychologist. 52(2):101-116, 1997 Feb.
6	Low-fat Diet Practices of Older Women: "Prevalence and Implication for Dietary Assessment"	**Patterson**, Kristal, Coates, Ritenbaugh, Van Horn, Caggiula, Snetselaar, Tylavsky	Gen.	11	Journal of the American Dietetic Association. 96(7):670-9, 1996 Jul.
7	The Evolution of the Women's Health Initiative: Perspectives from the NIH	**Rossouw**, Finnegan, Harlan, Pinn, Clifford, McGowan	Gen.	11	Journal of the American Medical Women's Association. 50(2):50-5, 1995 Mar-Apr
8	Design of the WHI Clinical Trial and Observational Study	**Prentice**, Rossouw, Furberg, Johnson, Henderson, Cummings, Manson, Freedman, Oberman, Kuller, Anderson	Gen.	11	Controlled Clinical Trials 19:61-109, 1998
9	Approaches to Monitoring the Results of Long-term Disease Prevention Trials: Examples from the Women's Health Initiative	**Freedman**, Anderson, Kipnis, Prentice, Wang, Rossouw, Wittes, DeMets	CT	11	Controlled Clinical Trials. 17(6):509-25, 1996 Dec.
11	The Role of Randomized Controlled Trials in Assessing the Benefits and Risks of Long-term Hormone Replacement Therapy: Example of the Women's Health Initiative	**Prentice**, Rossouw, Johnson, Freedman, McTiernan	CT	11	Menopause 3(2):71-76, 1996
12	Factors Associated with Insurance Status among Participants in the WHI	**Hsia**, Sofaer, Kiefe, Zapka, Bowen, Mason, Limacher, Pettinger, Lillington	Gen.	11	Journal of Women's Health & Gender-Based Medicine 9(8):881-889, 2000
17	Sexual Orientation and Health: Comparisons in the Women's Health Initiative Sample	**Valanis**, Bowen, Bassford, Whitlock, Charney, Carter	CT	11	Archives of Family Medicine. 9(9):843-53 , 2000 Sep-Oct
19	Ethnic, Socioeconomic, and Lifestyle Correlates of Obesity in U.S. Women: The Women's Health Initiative	**Manson**, Lewis, Kotchen, Allen, Johnson, Stefanick, Foreyt, Klesges, Tinker, Noonan, Perri, Hall	Gen.	11	Clinical Journal of Women's Health. 1(5):225-34, 2001 Dec
21	Hypertension and It's Treatment in Postmenopausal Women: Baseline Data from the Women's Health Initiative	**Wassertheil-Smoller**, Anderson, Black, Psaty, Manson, Wong, Francis, Grimm, Kotchen, Langer, Lasser	OS	11	Hypertension 2000;36:780-89
22	Pelvic Organ Prolapse: Gravity and Gravidity	**Hendrix**, Clark, Nygaard, Aragaki, Barnabei, McTiernan	CT	11	Am J Obstet Gynecol 2002;186:1160-6

MS ID	Title	Authors	Data Focus	Stage	Reference
24	Estimation of the Correlation between Nutrient Intake Measures Under Restricted Sampling	**Wang**, Anderson, Prentice	Gen.	11	Biometrics. 55, 711-717 (1999)
27	The Effects of Insurance Coverage and Ethnicity on Mammography Utilization in a Postmenopausal Population	**Bush**, Langer	Gen.	11	Western Journal of Medicine 168:236-40, 1998
35	Measurement Characteristics of the WHI Food Frequency Questionnaire	**Patterson**, Kristal, Carter, Tinker, Bolton, Agurs-Collins	Gen.	11	Annals of Epidemiology 1999:9:178-197
37	Depression as Mediated by Social Support, Life Events, and Sexual Activity in Postmenopausal Non-Hispanic White and Latina Women	**Larisch**, Talavera, Langer, Velasquez, Elder	Gen.	11	
40	The Health Impact of Domestic Violence in Older Women	**Mouton**, Furniss, Lasser, Rovi	OS	11	Journal of Women's Health & Gender-Based Medicine 1999:8(9):1173-1179
43	Sleep Complaints of Postmenopausal Women	**Kripke**, Freeman, Masaki, Brunner, Jackson, Hendrix, Carter	CT	11	Clinical Journal of Women's Health 1:244-252, 2001
59	Risk Factors for Kidney Stones in Postmenopausal Women in the Southern United States	**Hall**, Pettinger, Oberman, Watts, Johnson, Paskett, Limacher, Hays	Gen.	11	Am J Med Sci 2001;322 (1):1-7
60	WHIMS: a Trial of the Effect of Estrogen Therapy in Preventing and Slowing the Progression of Dementia	**Shumaker**, Bowen	WHIMS	11	Controlled Clinical Trials 19:604-621
63	Health Insurance as a Determinant of Cancer Screening in WHI OS Participants	**Hsia**, Kemper, Kiefe, Zapka, Sofaer, Pettinger, Bowen, Limacher, Lillington, Mason	OS	11	Preventive Medicine 2000;31:261-270
66	Walking, Vigorous Exercise, and Incidence of Cardiovascular Disease in an Ethnically Diverse Cohort of Women	**Manson**, Greenland, LaCroix, Stefanick, Mouton, Oberman, Perri, Sheps, Pettinger, Siscovick	OS	11	N Engl J Med, Vol. 347, No. 10
67	Yogurt Consumption is Associated with Healthy Behaviors in Post-Menopausal Women	**Mossavar-Rahmani**, Garland, Caan, Hebert, Wodarski, Vitolins, Himes, Parker	OS	11	In Press: Clinical Journal of Women's Health
69	Correlates of Serum Lypocene in Older Women	**Casso**, White, Patterson, Agurs-Collins, Kooperberg, Haines	CT	11	Nutrition and Cancer 2000:36:163-69.
70	Correlates of Serum Alpha- and Gamma-Tocopherol in the WHI	**White**, Masaki, Chen, Shikany, Caan, Mares-Perlman, Wilson, Kristal	CT	11	Annals of Epidemiology 2001;11:136-144
71	The Women's Health Initiative: Goals, Rationale, and Current Status	**Liu**	Gen.	11	Menopausal Medicine, Vol.6(2), p.1-4, 1998
86	The Effects of Physical and Emotional Status on Adherence to a Low-fat Dietary Pattern in the Women's Health Initiative	**Tinker**, Perri, Bowen, Patterson, Parker, Wodarski, McIntosh, Sevick	CT	11	

MS ID	Title	Authors	Data Focus	Stage	Reference
88	Estimating Normal Hemogram Values for Postmenopausal Women	**Assaf**, Carleton, Miller, Coccio	Gen.	11	Clinical Journal of Women's Health Vol. 1, No. 1, December 2000, 23-28
91	Compliance with National Cholesterol Education Program Dietary and Lifestyle Guidelines Among Older Women with Self-reported Hypercholesterolemia: The Women's Health Initiative	**Hsia**, Rodabough, Rosal, Cochrane, Howard, Snetselaar, Frishman, Stefanick	OS	11	In Press: American Journal of Medicine
99	Risk Factor Clustering in the Insulin Resistance Syndrome and its Relationship to Cardiovascular Disease In White, Black, Hispanic, and Asian Postmenopausal Women	**Howard**, Criqui, Curb, Rodabough, Safford, Santoro, Wilson, Wylie-Rosette	OS	11	In Press: Metabolism
103	The Women's Health Initiative: Recruitment Complete - Looking Back and Looking Forward (Guest Editorial)	**Rossouw**, Hurd	CT	11	Journal of Women's Health 8:3-5, 1999.
104	Promoting Adherence and Retention to Clinical Trials in Special Populations: A Women's Health Initiative Workshop	**Wilcox**, Shumaker, Bowen, Naughton, Rosal, Ludlam, Dugan, Hunt, Stevens	Gen.	11	Controlled Clinical Trials, 22 (3), 279-289
107	Vigorous Leisure Activity Through Women's Adult Life: The Women's Health Initiative	**Wilcox**, Heiss, Pettinger, Brunner, Daugherty, King, McTiernan	OS	11	In Press: American Journal of Epidemiology
108	Cross-Sectional Geometry and Bone Mass in the Proximal Femur in African-American and White Postmenopausal Women	**Nelson**, Hendrix	CT	11	
128	Inflammatory Biomarkers, Hormone Replacement Therapy, and Incident Coronary Heart Disease: A Prospective Analysis from the Women's Health Initiative Observational Study	**Pradhan**, Manson, Rossouw, Siscovick, Mouton, Wallace, Jackson, Pettinger, Ridker	OS	11	JAMA 2002;288:980-987
155	Changes in Food Sources of Dietary Fat in Response to an Intensive Low-Fat Dietary Intervention: Early Results from the Women's Health Initiative	**Patterson**, Kristal, Caan, Lillington, Mossavar-Rahmani, Simon, Snetselaar, Van Horn, Rodabough	CT	11	
10	A Comprehensive Data Management System for Multicenter Studies	**Anderson**, Davis, Koch	Gen.	10	
13	Depression and Cardiovascular Sequelae in Post-Menopausal Women	**Wassertheil-Smoller**, Shumaker, Ockene, Talavera, Greenland, Cochrane, Robbins, Aragaki, Dunbar	Gen.	10	
30	Completeness of Purchase Mailing Lists for Identifying Older Women	**Falkner**, Wactawski-Wende, Trevisan	CT	10	
39	Hormone Replacement Therapy and Dietary Fat Intake Influence on Blood Lipids and Insulin in Postmenopausal Women	**Chlebowski**, Sparks, Stefanick, Howard, Mossavar-Rahmani, McTiernan	Gen.	10	

MS ID	Title	Authors	Data Focus	Stage	Reference
61	WHI Halfway Paper (100K Paper)	**Langer**, Kotchen, Daugherty, Lewis, Elmer, Trevisan, Noonan, Hendrix, Adams-Campbell	Gen.	10	
72	Post-Menopausal Bone Loss and its Relationship to Oral Bone Loss	**Jeffcoat**, Lewis, Reddy, Wang, Redford	Gen.	10	Periodontics 2000
76	Labeling as a Predictor of Dietary Maintenance	**Hopkins**, Burrows, Bowen, Tinker	CT	10	
93	Fat Intake in Husbands of Women in the Dietary Component of the Women's Health Initiative	**Shikany**	Gen.	10	
95	The Effects of Widowhood on Physical Health, Mental Health, and Health Behaviors; the Women's Health Initiative	**Wilcox**, Evenson, Aragaki, Wassertheil-Smoller, Mouton, Loevinger, Cochrane	OS	10	
98	Patterns of Antioxidant Supplement Use in Participants in the Women's Health Initiative	**Shikany**, Patterson, Agurs-Collins, Anderson	Gen.	10	
100	The Yield of Six-Month Recall Mammography on Screening Mammograms	**Yasmeen**, Romano, Pettinger, Chlebowski, Robbins, Lane, Hendrix	Gen.	10	
115	Prevalence and 3-year Incidence of Abuse in Older Women	**Mouton**, Rodabough, Rovi, Hunt, Brzyski		10	
120	Obesity, Body Size, and Risk of Postmenopausal Breast Cancer: The Women's Health Initiative	**Morimoto**, White, McTiernan, Chlebowski, Hays, Stefanick, Margolis, Manson, Kuller, Chen, Muti, Lopez	OS	10	
122	Does Statin Use Reduce Risk of Osteoporotic Fracture or Improve Bone Density in Postmenopausal Women? Results from the Women's Health Initiative Observational Study	**LaCroix**, Cauley, Pettinger, Hsia, Bauer, McGowan, Chen, Lewis, McNeeley, Pasaro, Jackson	OS	10	
132	Second Malignancy and Nonmelanoma Skin Cancer: The Women's Health Initiative Observational Study	**Rosenberg**, Greenland, Khandekar, Ascensao, Lopez	Gen.	10	
134	Alternative Self-Monitoring Tools in the Dietary Modification Component of the Women's Health Initiative	**Mossavar-Rahmani**, Henry, Rodabough, Bragg, Brewer, Freed, Kinzel, Pederson, Soule, Vosburg	CT	10	
142	Coronary Artery Calcification in African-American and White Women	**Khurana**, Rosenbaum, Howard, Adams-Campbell, Detrano, Hsia, Klouj	OS	10	
166	Is Tea Drinking Related to Bone Mineral Density and Osteoporotic Fractures? ---Results from the Women's Health Initiative Observational Study	**Chen**, Pettinger, Ritenbaugh, LaCroix, Robbins, Caan, Barad, Hakin	OS	10	
16	Caloric Requirements and Dietary Self-report	**Hebert**, Patterson, Gorfine, Ebbeling, St. Jeor, Chlebowski	Gen.	9	
25	Hormone Replacement Therapy and the QT Interval	**Kadish**, Greenland, Limacher, Frishman, Daugherty, Parker, Schwartz	CT	9	

MS ID	Title	Authors	Data Focus	Stage	Reference
26	Special Populations Recruitment for the WHI: Success and Limitations	**Fouad**, Corbie- Smith, Curb, Howard, Mouton, Simon, Talavera, Thompson, Wang, White, Young	Gen.	9	
34	The Relationship between Smoking Status, Body Weight, and Waist-to-Hip Ratio: the WHI	**Johnson**, Klesges, Hays, Noonan, Black, Curb, Liu, Manson	Gen.	9	
55	Factor Structure and Factor Invariance of the Women's Health Initiative Insomnia Rating Scale	**Levine**, Shumaker, Naughton, Kaplan, Kripke, Bowen	Gen.	9	
73	Innovative Strategies for Monitoring and Enhancing Clinic Performance in the WHI Clinical Trial: The Creation of the Performance Monitoring Committee	**Pottern**, Naughton, Lund, Cochrane, Brinson, Kotchen, McTiernan, Shumaker	Gen.	9	
83	A Prospective Study of Physical Activity and the Risk of Breast Cancer in Women Aged 50 - 79 Years	**McTiernan**, Kooperberg, White, Wilcox, Coates, Adams-Campbell, Woods, Ockene	Gen.	9	
84	Research Staff Turnover and Participant Adherence in the WHI	**Jackson**, Berman, Snetselaar, Granek, Boe, Huber, Milas, Spivak, Chlebowski	CT	9	
85	Women's Health Initiative: Rationale, Design and Progress Report	**Johnson**, Anderson, Barad, Stefanick, McNagny	CT	9	
102	Cardiovascular Outcomes Related to Anti-Hypertensive Drug Therapy in Older Women: The Women's Health Initiative Observational Study	**Wassertheil-Smoller**, Psaty, Greenland, Margolis, Oberman, Kotchen, Mouton, Hilkert, Black, Anderson, Trevisan, Aragaki	OS	9	
105	Retention of Low Income and Minority Women in Clinical Trials: A Focus Group Study	**Johnson**, Williams, Fouad	CT	9	
109	NCI Monograph: Approaches to Research Trials Recruitment in Hispanic Communities: Review and Recommendations	**Larkey**	Gen.	9	
111	Effects of Fat Intake on Fat Hedonics: Cognition or Taste?	**Bowen**, Green, Vizenor, Vut, Kreuter, Rolls	OS	9	
112	Results of an Adjunct Dietary Intervention Program in the Women's Health Initiative	**Bowen**, Ehret, Pedersen, Snetselaar, Johnson, Tinker, Hollinger, Lichty, Sivertsen, Ocken, Staats, Beedoe	OS	9	
126	Influences on Older Women's Adherence to a Low-Fat Diet in the Women's Health Initiative	**Kearney**, Rosal, Ockene, Churchill	CT	9	
135	Radiographic Measurements, Bone Mineral Density and the Singh Index in the Proximal Femur of White and African-American Postmenopausal Women	**Barondess**, Singh, Hendrix, Nelson		9	

MS ID	Title	Authors	Data Focus	Stage	Reference
149	Health Status of Postmenopausal White Women with Back and Leg Pain Living in the Community: A Pilot Study	**Vogt**, Lauerman, Chirumbole, Kuller	OS	9	
187	Estrogens and Cardiovascular Disease	**Rossouw**	OS	9	
198	Aspects of the Management and Coordination of The Women's Health Initiative	**Cochrane**, Lund, Anderson, Prentice	Gen.	9	
38	Relationship of Select Dietary Components and Colorectal Cancer among Postmenopausal Women: The Women's Health Initiative	**Frank**, Pettinger, Paskett, Wylie-Rosett, Agurs-Collins	Gen.	8	
62	Self-reported Urogential Symptoms in Postmenopausal Women: The Women's Health Initiative	**Pastore**, Carter, Hulka, Wells	Gen.	8	
29	Effects of Diet Intervention on Motivation to make other Health Related Changes	**Langer**, Lo	CT	7	
41	Determinants of Fasting Hyperinsulinemia	**Manson**, LaCroix, Haan, Rodrigues, Johnson, Allen, Hendrix	Gen.	7	
57	Regional Differences in Stroke Morbidity at Baseline in the WHI	**Johnson**, Hall, Oberman, Sheps, Hulka, Hays, Baum, Schenken, Burke, Limacher, Anderson, Jeppson	Gen.	7	
79	Databased Tracking and Statistical Models of the Clinical Trial Recruitment Process	**Creech**	CT	7	
80	Insulin Resistance and Weight Change in Postmenopausal Black and White Women	**Howard**, Adams-Campbell, Pasaro, Black, Stevens, Wagenknecht, Rodrigues, Safford, Allen, Snetselaar	Gen.	7	
81	The Prevalence of Urinary Incontinence in WHI Women	**Hendrix**, Clark, Ling, Dugan, Salmieri, Hurtado, McNeeley, Laube, McTiernan, Francis	Gen.	7	
140	Is Hysterectomy Status an Independent Determinant of Framingham Risk?	**Hsia**, Rossouw, Limacher, Wassertheil-Smoller, McGovern, Oberman, Barad	Gen.	7	
145	Inverse Association of Breast Cancer with the Use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDS): Prospective Results from the Women's Health Initiative	**Harris**, Jackson, Frid, McTiernan, Anderson, White, Chlebowski, Ascensao	OS	7	
164	Leukocyte Count as a Predictor of Cardiovascular Events in Post-Menopausal Women	**Margolis**, Prentice, Greenland, Manson, Assaf, Safford, Howard, Grimm, Bray	OS	7	
177	Validity of Self-Reports of Fractures among Postmenopausal Women in a Prospective Study Results from the Women's Health Initiative	**Chen**, Bassford, LaCroix, Kooperberg, Jackson, Cauley, Kipersztok, Borne	Gen.	7	

MS ID	Title	Authors	Data Focus	Stage	Reference
189	Dietary Adherence in the WHI Dietary Modification Trial	**Unauthored**	CT	7	
31	Comparisons between Never Smokers, Former Smokers, and Current Smokers in the WHI	**Ockene**, Bowen, Brunner, Robbins, Shikany	OS	6	
36	Prevalence of Silent MI	**Sagar**, Kotchen, Wong, Graettinger, Burke, Van Vorhees, McIntosh	CT	6	
53	Dietary, Physical Activity, and Exercise Patterns Among Diabetics	**Agurs-Collins**, Adams-Campbell, Pasaro, Howard	Gen.	6	
68	Reliability and Physiologic Correlates of the Physical Activity Questionnaire in the WHI	**Morimoto**, White, Wang, Stefanick, Siscovick, Cauley, Strickland, Rebar, Rodrigues, Going, Frid	CT	6	
78	Association Between Antioxidants and BMD in an Ethnically Diverse Population of Older Women	**Wolf**, Cauley, Stone, Nevitt, Simon, Jackson, LaCroix, Lewis, Wactawski-Wende, LeBoff	Gen.	6	
113	Prior Use of Oral Contraceptives and Fracture Risk in Menopausal Women	**Barad**, Kooperberg, Wactawski-Wende, Hendrix, Watts, Liu	Gen.	6	
163	Racial/Ethnic Differences in Breast Cancer Incidence Rates	**Chlebowski**, Prentice, Patterson, Paskett, Lane, Hubbell, Rohan, Dolan	OS	6	
49	Patterns of Use and Characteristics Associated with HRT among Postmenopausal Women	**Dunn**, Greenland, Woods, Stovall, Bartholow, Francis	Gen.	5	
51	The Relationship of Quality of Social Support to Frequency of Cancer Screening Behaviors among Postmenopausal Women	**Lane**, Taylor, Glanz, Elam, Klaskala, Powell, Messina, Smith	Gen.	5	
52	Nutrient Intake of Women with Diabetes in the WHI Observational Study Cohort	**Tinker**, Gams, Lee, Smith, West, Snetselaar, Caggiula	Gen.	5	
74	Baseline Characteristics of the WHI-OS Breast Cancer Survivor Cohort	**Paskett**, Sherman, Anderson, Hays, McDonald, Naughton	OS	5	
87	Incidence and Correlates of Hip and Knee Replacement in the WHI	**Wallace**, Chang, Nevitt, LaCroix, Kaplan, Sturm	Gen.	5	
92	Comparison of Self-report, Discharge Diagnosis, and Adjudication of Cardiovascular Events in the WHI	**Heckbert**, Hsia, Kooperberg, McTiernan, Curb, Barbour, Gaziano, Safford, Psaty, Frishman	Gen.	5	
106	Utility of Body Mass Index (BMI) as a Proxy for Obesity Among White, Black, Asian, Native American and Hispanic Post-menopausal Women	**Going**, Chen, Tinker, Stefanick, St. Jeor, Lewis	Gen.	5	
127	Plasma Homocysteine Levels and Coronary Heart Disease in Women	**Siscovick**, Manson, Trevisan, Wallace, Howard, Burke, Ridker	OS	5	

MS ID	Title	Authors	Data Focus	Stage	Reference
129	Thrombotic Markers for Coronary Heart Disease in Women	**LaCroix**, Trevisan, Langer, Lewis, Hsia, Oberman, Kotchen, Ridker	OS	5	
130	Cross-sectional Analysis of Association Between Hormone Replacement Therapy and Thrombotic and Inflammatory Markers for CHD in Women	**Langer**, Manson, LaCroix, Lewis, Hendrix, Rossouw, Pradhan, Ridker	OS	5	
148	Outcomes of Pap Smears on Postmenopausal Women	**Yasmeen**, Romano, Barad, Hubbell, La Valluer, Johnson, Lane, McIntosh, Hendrix		5	
151	History of Estrogen and Oral Contraceptive Use and Cognitive Function: Results from the Women's Health Initiative Memory Study	**Rapp**, Dailey, Gass, Wactawski-Wende, Hendrix, Hogan, Jones, Murphy, Shumaker	WHIMS	5	
152	The Impact of Magnesium Intake on Bone Mass and Risk of Fracture in the Women's Health Initiative Observational Study	**Jackson**, LaCroix, Lewis, Wactawski-Wende, Cauley, Chen, Bassford	OS	5	
153	Metabolic Syndrome and Depression	**Wylie-Rosette**, Cochrane, Perri, Rapp, Rosal	CT	5	
154	Does Acidogenic Diet Contribute to the Incidence of Hip Fracture?	**Barzel**, Wylie-Rosette, Ritenbaugh, Aickin, LeBoff	OS	5	
156	Incidence of Systemic Lupus Erythematosus in the Women's Health Initiative	**Assaf**, Cyr, Crowley, Coccio	OS	5	
174	HMG Co-A Reductase Inhibitor (Statin) Use and the Risk of Breast Cancer in the Women's Health Initiative Observational Study	**Cauley**, LaCroix, Chlebowski, Margolis, McTiernan, Vitolins, Furberg, Bauer	OS	5	
190	Predictors of LVH	**Oberman**, Ko, Lasser, LaCroix, Wylie	CT	5	
197	Presentation of Acute Coronary Syndromes in Women	**Hsia**, Rossouw, Brunner, LaCroix, Wallace	OS	5	
20	Correlates of Endogenous Sex Hormone Concentrations in WHI	**McTiernan**, Wactawski-Wende, Chen, Meilahn, La Valluer, Cummings, Hiatt, Baum, Hulka, Wang, McNagny	CT	4	
178	Three Year Change in BMD	**Lewis**, Robbins, LaCroix, Chen, Wactawski-Wende, Nevitt, Jackson, Cauley	OS	4	
193	Predictors of Adherence to the Women's Health Initiative Clinical Trial Interventions: A Conceptual Framework	**Rosal**, Shumaker, Snetselaar, Tinker, Cochrane, Bowen, Brunner, Ockene	CT	4	
194	Predictors of Adherence to the Hormone Replacement Therapy Clinical Trial in the Women's Health Initiative	**Cochrane**, Stefanick, Wallace, Granek, Lillington, Andesron, Woods, Naughton	CT	4	

MS ID	Title	Authors	Data Focus	Stage	Reference
195	Predictors of Calcium/Vitamin D Supplementation Adherence in the Women's Health Initiative	**Brunner**, Cauley, Snetselaar, Jackson, LeBoff, Cochrane, Granek, Wactawski-Wende	CT	4	
196	Intrapersonal, Interpersonal, Treatment, and Organizational Adherence Predictors in the Women's Health Initiative Dietary Modification Clinical Trial	**Tinker**, Van Horn, Perri, Rosal, Ockene, Patterson, Assaf, Hays	CT	4	
18	The Relationship of Dietary Phytoestrogens to Menopausal Symptoms and Major Morbidity in Postmenopausal Women	**Assaf**, Cyr, Coccio, Hixson	CT	3	
45	Socio-demographic Determinants of Folic Acid Intake	**Beresford**, Kritchevsky, Vitolins	Gen.	3	
47	Is a "Too Low" Fat Diet a Marker of Health or Disease	**Gilligan**, Snetselaar, St. Jeor, Van Horn, Stefanick, Kotchen, Patterson	CT	3	
54	Current Treatment Patterns in Women with Hypercholesterolemia	**Manson**, Freed, Chae	Gen.	3	
56	Psychometric Evaluation of the Urinary Incontinence Scale	**Levine**, Shumaker, Naughton, Kaplan, Bowen	Gen.	3	
90	Passive Smoke Exposure in Childhood and Adulthood and Prevalent Coronary Heart Disease in Women Enrolled in the WHI	**Wagenknecht**, Frishman, Wong, Ockene	OS	3	
117	Correlates of Session Completion and Self-monitoring of Food Intake among Minority Participants Enrolled in the Women's Health Initiative (WHI) Dietary Modification Intervention during the First Year of Intervention	**Rosal**, Ockene, Mossavar-Rahmani, Margolis, Paskett, Thomson		3	
118	Association Between Depressive Symptomatology and Physical Activity in Post-menopausal Women	**Ockene**, Rosal, Haan, Brunner, Mouton, Lopez, Perri, Cochrane, Matthews, Jackson	Gen.	3	
121	Quality of Life in Healthy Women and in Breast Cancer Survivors	**Haan**		3	
141	The Association of Food and Nutrient Intake with the Incidence of Stroke in the WHI Observational Study	**Beresford**, Shikany, St. Jeor, Torrens, Mossavar-Rahmani, Heiss, Patterson, Van Horn	OS	3	
157	Type 2 Diabetes and Cognitive Functioning in WHIMS	**Haan**	WHIMS	3	
159	Endogenous Sex Steroid Hormone and Risk of Coronary Heart Disease in Postmenopausal Women	**Rexrode**, Manson, Kuller, McTiernan, Stefanick, Heckbert, White	OS	3	

MS ID	Title	Authors	Data Focus	Stage	Reference
160	Correlation of Endogenous Sex Steroid Hormones with Inflammatory and Thrombotic Markers in Postmenopausal Women	**Rexrode**, Manson, Ridker, Cochrane, Ockene, Kotchen, Margolis, McGovern	OS	3	
173	Relationships Between Blood Pressure, Hypertension, and Hypertension Therapy and Measures of Cognition Among WHIMS Women At Baseline	**Johnson**, Espeland, Mouton, Margolis, Masaki, Murphy, Wassertheil-Smoller, Prineas	WHIMS	3	
186	Diabetes Prevention with Statins, ACE Inhibitors and HRT	**Hsia**, Howard, Limacher, Oberman, Safford, Allen, Torrens, Lawson	Gen.	3	
192	Risk Factors for Low Bone Mineral Density in American Indian and Alaska Native Women in the Women's Health Initiative	**Whampler**, Howard, Rossouw, Chen	Gen.	3	
200	Repression of Negative Emotion and Ambivalence about Negative Emotion: Associations with Psychosocial and Health-related Outcomes in the Women's Health Initiative	**Michaels**, Perrin, O'Connor, Wisdom, Ritenbaugh, Bowen, Brzyski, Cochrane	Gen.	3	

Stage
3=Writing group approved
4=Analysis proposed
5=Analysis in progress
6=Analysis completed
7=Draft manuscript
8=Final ms submitted to P&P & PO
9=Final ms approved
10=Submitted
11=In press/published
86=Dropped

Table 9.2
Ancillary Studies

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Speci-mens?	Proposed Funding Dates	Funding Status
163	Hormone Use Following the WHI E+P Trial Termination: A Pilot Study	Jennifer Hays	Jennifer Hays	yes	yes	none	CT & OS	405	no	1/03-12/04	pending
161	Bone Mass Response to Termination of Estrogen + Progestin	Jane Cauley	Lew Kuller	yes	yes	none	CT	350	no	7/10/02-10/01/02	funded
160	An Assessment of Symptoms and Symptom Self-Management for Women Abruptly stopping Hormone Replacement Study Pills	Barbara Valanis	Cheryl Ritenbaugh	yes	yes	none	CT	250	no	7/02-8/17/02	funded
159	The Insulin-like Growth Factor (IGF) System and Coronary Heart Disease	Robert Kaplan	S. Wassertheil-Smoller	no		none	2002A OS Blood Comp	650/650	no		dropped
158	Potential Mediators of the Association of Depression with CVD	Judith Wylie-Rosett	S. Wassertheil-Smoller	no		none	2002A OS Blood Comp	220/220	no		dropped
156	The Effect of Domestic Violence on Health Care Costs and Utilization	Charles Mouton	Robert Schenken	yes	yes	none	OS	217/217	no		pending
155	Carotenoids, Transforming Growth Factors, and Breast Cancer Risk	Tom Rohan	S. Wassertheil-Smoller	yes	yes	none	OS	3500/3500	yes		pending
154	Serum and DNA Precursors of Colorectal Cancer	Cedric Garland	Robert Langer	no		none	OS	400/400	yes		dropped
152	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Gloria Ho	S. Wassertheil-Smoller	yes	yes	none	2002A OS Blood Comp	1700/900	yes		pending

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Speci-mens?	Proposed Funding Dates	Funding Status
150	Effect of Airborne Particulate Matter and Other Air Pollutants on the Incidence of Cardiovascular Events in the Women's Health Initiative Observational Study	Joel Kaufman		yes	yes	none	OS	all OS women	no	5/02-4/04	funded
149	DNA Repair Genetic Polymorphisms and Breast Cancer Risk	Jennifer Hu	Electra Paskett	yes	yes	none	2001 OS Blood Comp	800/800	yes		pending
148	Relationship Between Monoclonal Hemopoiesis and other Molecular Abnormalities and the Development of Leukemia in Older Women	Harvey Priesler		yes	yes	none	2001 OS Blood Com	59/177	yes		pending
147	Gene-gene and gene-environment interactions and breast cancer risk	Charis Eng	Rebecca Jackson	no		none	2002A OS Blood Comp	200/200	yes		dropped
146	A Prospective Study of Pancreatic Cancer Pathogenesis	Charles Fuchs	JoAnn Manson	yes	yes		2001 OS Blood Com	93/279	yes		pending
141	Periodontal Disease and Subclinical Cardiovascular Disease in Post-Menopausal Women	Joan Dorn	Maurizio Trevisan	yes	yes	none	OS	80	no	04/01-06/01	funded
140	Environmental Epidemiology of Arrhythmogenesis in WHI	Eric Whitsel		yes	yes	none	CT	all CT women	no		pending
139	Follow-up of Healthy Breast Cancer Survivors in the WHI Observational Study	Electra Paskett	Electra Paskett	yes	yes	none	OS	416	no	8/01-8/02	funded
137	Platelet Polymorphisms as Risk Factors for Myocardial Infarction in Postmenopausal Women and their Interactions with Hormone Replacement Therapy	Paul Bray	Jennifer Hays	yes	yes	none	OS	1060/2120	yes		pending
135	Natural History of Pelvic Organ Prolapse in WHI Women	Ingrid Nygaard	Robert Wallace	yes	yes	none	HRT	400	no	7/01-6/06	funded

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Speci-mens?	Proposed Funding Dates	Funding Status
134	Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer	Francesmary Modugno	Lew Kuller	yes	yes	none	2000 OS Blood Comp	400	yes		funded
133	Biochemical and Genetic Markers of Hypertension in White and Black Women	Howard Sesso, JoAnn Manson	JoAnn Manson	yes	yes	none	2000 OS Blood Comp	800/800	yes		pending
132	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Simin Liu, JoAnn Manson	JoAnn Manson	yes	yes	none	2000 OS Blood Comp	3840	yes	7/02-6/07	funded
130	A Randomized Controlled Trial of Fat Reduction, Calcium/Vitamin D Supplementation, Hormone Replacement Therapy, and risk of Proliferative Forms of Benign Breast Disease	Thomas Rohan	S. Wassertheil-Smoller	yes	yes	none	DM, HRT		no	7/01-06/06	funded
129	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Howard Strickler	S. Wassertheil-Smoller	yes	yes	none	2000 OS Blood Comp	5775	yes	2/02-2/06	funded
128	DNA Mismatch Repair Gene Associated Colorectal, Endometrial and Ovarian Cancer in Postmenopausal Women: a Novel Prospective Population-Based Study	Tom Weber	S. Wassertheil-Smoller	yes	yes	none	2000 OS Blood Comp	6500	yes		pending
127	Impact of Risk Perception on Preventive Health Behaviors, Process of Care and Outcomes Among a Diverse Cohort of Women at High Risk of Ischemic Heart Disease	Janice Barnhart	S. Wassertheil-Smoller	yes	yes	none	OS	350	no	4/1/2002-3/31/2006	funded

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Speci-mens?	Proposed Funding Dates	Funding Status
126	Molecular and Genetic Determinants of Stroke in the Women's Health Initiative Observational Study	Sylvia Smoller	S. Wassertheil-Smoller	yes	yes	none	OS Umbrella Study	2100	yes		pending
124	Sociocultural Influences on Motivation for and Maintenance of Health-Related Dietary Change Among Women	Joylin Namie	Robert Langer	yes	yes	none	DM	90-150	no	6/00-12/00	funded
122	Feasibility Study of Computerized Tailored Dietary Feedback	Karen Glanz, David Curb	David Curb	yes	yes	none	DM	36	no	3/10/00-9/00	funded
121	Hyperinsulinemia and Ovarian Cancer	Carrie Cottreau, Lewis Kuller	Lew Kuller	yes	yes	none	OS Blood Comp	206	yes		pending
120	Epidemiology of Cervical and Lumbar Stenosis	Molly T. Vogt	Lew Kuller	yes	yes	Pittsburgh, Arizona	OS	4000	no		pending
118	Accuracy of Food Portion Estimation Among Postmenopausal Women	Chrisitine L. Coy		yes	yes	none	DM	191	no	12/1999-4/2000	funded
117	Risk Factors for Dry Eye Syndrome in Postmenopausal Women	Kelley A. Kinney	Rebecca Jackson	yes	yes	none	OS	400	no	2/01-1/04	funded
113	Some Aspects of Mediterranean Diet in Relation to Risk of Chronic Diseases among Postmenopausal Women	Iman Hakim	Tamsen Bassford	yes	yes	none	OS	1000	yes	8/1/99 - 7/31/02	funded
110	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Kathryn Rexrode/Jo Ann Manson	JoAnn Manson	yes	yes	none	1998 OS Blood Comp	700	yes	4/1/00 - 3/31/03	funded
108	Gene-environment effects and colorectal cancer	Rowan Chlebowski/ Henry Lin	Rowan Chlebowski Harbor UCLA	yes	yes	none	2001 OS Blood Comp	800/800	yes		pending
105	Carotenoids in Age-Related Eye Disease Study	Julie Mares-Perlman	Catherine Allen	yes	yes	Iowa, Portland, Wisconsin	1998 OS Blood Comp	2880	yes	4/1/00 - 3/31/04	funded

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Speci-mens?	Proposed Funding Dates	Funding Status
104	Tamoxifen Prevention: Is it acceptable to women at risk?	Joy Melnikow	John Robbins	yes	yes	none	OS	150	no	7/1/99 - 6/30/02	funded
103	Effects of Hormone Replacement Therapy on Cognitive Aging: Women's Health Initiative Study of Cognitive Aging (WHISCA)	Sally Shumaker		yes	yes		HRT	1800	no	4/1/99 - 3/31/05	funded
102	Quality of Life Improvements and Willingness to Pay: An Investigation of Selective Estrogen Receptor Modulators	Mona Fouad	Albert Oberman	yes	yes	none	OS	120	no	10/98 - 9/98	funded
100	Genetic, Biochemical and Behavioral Determinants of Obesity	Jennifer Hays	Jennifer Hays	yes	yes		OS	775	yes	through 9/01	funded
99	GENNID Study	Rowan Chlebowski	Rowan Chlebowski Harbor UCLA	yes	yes	none	ALL	40	yes	12/1/98 - 3/31/00	funded
98	Bone mineral density as a predictor for periodontitis	Jean Wactawski-Wende	Maurizio Trevisan	yes	N/A	none	OS	1000	yes	4/2002-4/2006	funded
97	Modeling serum markers for cost-effective ovarian cancer screening	Garnet Anderson		yes	yes	none	1998 OS Blood Comp	720	yes	4/1/00 - 3/31/04	funded
95	Work organization, psychological distress, and health among minority older women	Beatriz Rodriguez	David Curb	yes	N/A	none	OS	500	no	till 6/01	funded
93	The Epidemiology of Venous Disease	Michael Criqui	Robert Langer	yes	no		OS	725	no	3/11/98 - 6/30/99	funded
92	Fasting glucose in baseline plasma from all CT participants	Barbara Howard					CT		no	N/A	pending
90	Biomarkers and Hip Fracture	Steve Cummings	Steve Cummings	yes	yes	none	OS Umbrella Study	400/400	yes		pending

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Speci-mens?	Proposed Funding Dates	Funding Status
86	A Pilot Study to Determine the Sensitivity of Form 39 to Impaired Executive Control Function (ECF) as measured by the CLOX: an Executive Clock-Drawing Task	M.J. Polk	Robert Schenken	yes	yes	none	HRT	50	no	N/A	funded
84	Apolipoprotein E genotype, ERT use, and fat-soluble vitamin intake: Effects on Cognitive Function in Older Women	Julie E. Dunn	Philip Greenland	yes	yes	none	DM+OS	260	yes	11/98 - 12/03	funded
83	Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study	Paul Ridker	JoAnn Manson	yes	yes	none	OS Umbrella Study	1300	yes	7/1/99 - 6/30/03	funded
82	Extension of Bone Mineral Density Assessment in WHI Native American Women	Zhao Chen	Cheryl Ritenbaugh	yes	yes	none	OS	200	no	7/1/97 - 6/30/01	funded
78	Community Strategy to Retain Women Enrolled in Research	Mona Fouad	Al Oberman	yes	N/A	none	CT	40	no	7/1/97 - 9/30/97	funded
76	Tailored Messages to Enhance Adherence of Older Women to Dietary Programs for Breast Cancer control	Rowan Chlebowski	Rowan Chlebowski Harbor UCLA	yes	yes	none	DM	28	no	9/1/97 - 8/13/98	funded
75	Adherence to Dietary Modification in the WHI	Milagros C. Rosal	Judith Ochene	yes	N/A	6 (does not specify which CC's)	DM	480	no	9/1/97 - 8/30/02	funded
74	The Effectiveness of Individual Versus Group Behavioral Strategies to Increase Participants Adherence	Lois Wodarski	Maurizio Trevisan	yes	yes	none	DM	50	no	7/1/97 - 9/30/97	funded
73	Psychosocial and Cultural Determinants of NIDDM in Latinas	Deborah Parra-Medina	Robert Langer	yes	yes	La Jolla, San Antonio, Tucson	OS	228	yes	5/1/97 - 4/30/98	funded
72	Ethnicity, Body Composition, Bone Density and Breast Cancer	Zhao Chen	Cheryl Ritenbaugh	yes	yes	none	OS	800	no	9/1/97 - 8/30/02	funded

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Speci-mens?	Proposed Funding Dates	Funding Status
70	The Prevalence & Prognostic Importance of Myocardial Ischemia During Daily Life, & its Relationship to Migraine Status:WHI	David Sheps		yes	yes	10	OS	3200	no	9/1/97 - 8/31/00	funded
68	Coronary artery calcification detected with Ultrafast CT as an indication of CAD in OS participants	Judith Hsia	Judith Hsia	yes	yes	51	OS	782	no	1/1/97 - 12/31/05	funded
67	Prevalence and Natural History of Autoimmune Thyroid Disease in Postmenopausal Women	Marjita Zakarija		yes	N/A	51	OS	1040	no	ongoing	funded
65	Incidence of Benign breast disease in the DM CT - Pilot	Tom Rohan	A. McTiernan	yes	yes	all	DM	200	no	4/1/98 - 6/30/99	funded
63	Development and Evaluation of Eating Style Index	Pam Haines		yes	yes		OS	800	no	10/1/96 - 6/30/99	funded
62	Prevention of age-related maculopathy in the WHI HRT CT: WHI-SE	Mary Haan	Mary Haan	yes	yes		HRT	3300	no	1/99 - 1/07	funded
61	Longitudinal Assessment of Memory Functioning in the WHI Clinical Trial	Beth Ober	Mary Haan	yes	yes		HRT	110	no	on-going	funded
60	Fat Intake in Husbands of WHI Dietary Arm Participants	James Shikany	Al Oberman	yes	yes	none	DM Partners		no	12/1/96	funded
57	Hispanic Women's Advocacy and Retention Strategies	Cheryl Ritenbaugh	Cheryl Ritenbaugh	yes	yes	none	OS	120	no	9/1/96 - 8/31/98	funded
56	Behavioral and psychosocial predictors of dietary change in postmenopausal women	Joan Pleuss	Alice Thomson	yes	yes	none	DM	260	no	9/1/96 - 8/31/98	funded
50	Nutrition Practice Guidelines for Maintaining Low-Fat Dietary Change in Post Menopausal Women	Beth Burrows	Ross Prentice	yes	yes	none	DM	200	no	10/1/96 - 9/30/97	funded
48	Prostate Ca Survey of Spouses of WHI Screened Women	Sylvia Smoller	Sylvia Smoller	yes	yes	none	All	1607	no	2/1/96 - 6/30/96	funded

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Speci-mens?	Proposed Funding Dates	Funding Status
47	Effect of diet intervention on motivation to make other health-related changes	Langer/Lo	Robert Langer	yes	yes	none	DM	150	no	5/1/96 - 4/30/97	funded
40	Ethnic and age differences in use of Mammography	S. Wassertheil -Smoller	S. Wassertheil-Smoller	yes	yes	none	All	All	no	N/A	funded
39	The Effects of HRT on the Development and Progression of Dementia (WHIMS)	Sally Shumaker	Sally Shumaker	yes	yes	all except #18	HRT	4800	no	5/1/96 - 4/30/02	funded
36	Hormone Replacement Therapy and Changes in Mammographic Density	Gerardo Heiss		yes	yes		HRT	NA	no	1/98 - 12/01	funded
34	Ethnic Differences in Hip Bone Geometry by DXA and QCT	Dorothy Nelson	Susan Hendrix	yes	yes	none	HRT	330	no	12/1/96 - 12/31/02	funded
33	The Association of HRT with Abdominal and Total Body Fat in Postmenopausal Women	Charlotte Mayo	Al Oberman	yes	yes	none	OS	690	no	7/31/95 - 3/31/96	funded
31	Eye Care Use	Robert Kleinstein	Al Oberman	yes	yes	none	OS	300	no	N/A	funded
25	Ankle-Arm Blood Pressure Index Measurement	Kamal Masaki	David Curb	yes	yes	none	OS	2700	no	2/96 - 1/98	funded
24	Cross-ethnic Comparisons of Skeletal Health of Postmenopausal Women in San Diego County	Diane Schneider	Robert Langer	yes	yes	none	OS	168	no	1/3/95 - 1/2/97	funded
17	Domestic Violence in Older Women	Charles Mouton	Norm Lasser	yes	yes	none	OS	1000	no	10/25/94 - 10/24/96	funded
15	The Relationship between Osteopenia and Periodontitis	Jean Wactawski-Wende	Maurizio Trevisan	yes	yes	none	OS	1300	no	9/16/96 - 09/15/01	funded
14	High Density Lipoprotein Metabolism	Scott Going, Tamsen Bassford	Tom Moon	yes	N/A	none	OS	200	no	7/1/94 - 6/30/96	funded
13	Prevalence and Correlates of Lumbar Spinal Stenosis	Molly Vogt	Lew Kuller	yes	N/A	none	CT	150	no	on-going	funded
11	Validation and Exploration of Sleep and Mood Predictors	Daniel Kripke	Robert Langer	yes	N/A	none	OS	600	yes	8/1/95 - 7/31/99	funded

AS #	Title	Study's PI(s)	WHI Investigator	D&A Approval	PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Speci-mens?	Proposed Funding Dates	Funding Status
9	An investigation of oral hard tissue status in relation to skeletal bone mineral density measures and osteoporosis	Marjorie Jeffcoat	Al Oberman	yes	N/A	none	OS	650	no	6/1/95 - 5/31/02	funded
5	Explanations for the Development of Fat Distaste	Pamela Green	Deb Bowen	yes	N/A	none	DM	160	no	4/1/95 - 9/30/96	funded