Women's Health Initiative
Clinical Trial and Observational Study

Semi-Annual Progress Report
September 1, 2002 to February 28, 2003

Prepared by
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Funded by National Institutes of Health Contract No. N01-WH-2-2110

May 15, 2003

WHI Semi-Annual Progress Report

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Executive Summary

This report, summarizing data accumulated through February 28, 2003 presents the current status of the three clinical trial components and the observational study of the Women's Health Initiative (WHI). The focus of this report is adherence to the interventions, completeness of follow-up, safety and event rate comparisons for each clinical trial component.

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 2002, at the recommendation of the DSMB. The average follow-up is nearing 6 years. Drop-out rates in the ERT trial are somewhat higher than design assumptions with some evidence of increase in the last 6-12 months. "Drop-in" rates are also larger than projected. Vital status is known within the last 18 months for all but 4% of women. 3.6% of HRT participants are deceased. The current event rates for CHD, breast cancer, colorectal cancer, and hip fractures are approximately 70%, 90%, 80%, and 40%, respectively, of projected rates. Event rates are provided by age, race/ethnicity, and hysterectomy status. Brief updates are also provided for the ancillary studies in HRT women looking at cognitive function (WHIMS) and eye disease (WHI-SE).

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 7.4% at AV-8. The corresponding design assumptions for the C-I comparisons were 13% at year 1, diminishing by 0.25% per year. 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-third serving at AV-8. Currently 3.9% of the DM participants are lost-to-follow-up or have stopped follow-up and 3.0% of participants are deceased. The average follow-up time for DM women is approximately 6.1 years. The current incidence rates of breast cancer, colorectal cancer, and CHD are approximately 115%, 70%, 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 55%-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 2.1% of participants are lost-to-follow-up or have stopped follow-up, and 2.5% of the participants are known to be deceased. Treatment arm contrasts of intermediate outcomes (blood results, bone mineral density measures, and blood pressures) are presented. With approximately 5 years of average follow-up, the current rates of hip fractures, invasive breast cancer, and colorectal cancer are approximately 40%, 120%, and 80%, respectively, of what was assumed in the study design. Comparisons of event rates by age and race/ethnicity are presented for all monitored outcomes.

Observational Study recruitment ended with 93,676 women enrolled. Follow-up rates suggest strong retention overall as only 3.8% 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.

The Performance Monitoring Committee (PMC) is focusing its review and performance enhancement activities on outcomes collections and related activities. The Adherence and Retention subgroup is focusing on completeness of medical history collection and reasons it is not collected, such as undeliverable addresses and participants lost-to-follow-up, while the Outcomes subgroup is providing more frequent and focused assistance to CCs on outcomes investigation and adjudication.

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) through February 28, 2003. Topics include intervention adherence, follow-up, safety, outcomes, study power, 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 emanating from the historic events of the early stopping and publication of results of the randomized trial of combined estrogen plus progestin (PERT)[1]. The highest priority efforts were in informing the women, collecting final outcomes data and developing the final trial dataset, data analyses and scientific reports of trial results. At the time of this writing, one additional paper has appeared on the New England Journal of Medicine website describing findings on quality of life and cognitive function. Additional papers providing final, centrally adjudicated results on CHD, stroke, fractures, breast cancer, and gynecologic cancers have been submitted to journals, and in the case of stroke, accepted. Additional manuscripts describing PERT effects on venous thromboembolic disease, colorectal cancer, diabetes and gynecologic symptoms are in various stages of development. Two papers describing results for the WHI Memory ancillary study have also been accepted. The investigators have also been active in presenting the initial results at professional and lay meetings, including a national workshop on hormone therapy, sponsored by NIH and FDA in October, 2002.

The closure of the PERT trial has stimulated more rapid planning for biomarker studies. To facilitate this, the Case-Control Analyte Working Group (Dr. Rebecca Jackson, OSU, Chair) organized a workshop on genomics and proteomics on April 3, 2003. Experts in the new molecular technologies were invited to describe the potential of these approaches to develop and/or test hypotheses in the WHI specimens in the near future. A report from this activity, proposing a strategic plan for use of CT biospecimens, is under development.

Additional special efforts of the last few months included:

- Further development of close-out planning, including special emphasis on possible early close-out of other trial components. (Close-out Working Group, Dr. Rebecca Jackson, chair)

- Revision and submission to NHLBI of the extended follow-up proposal to continue scientific activities and participant follow-up without intervention through 2010 (Dr. Marcia Stefanick, chair). This proposal received a concept review on April 4, 2003, the results of which are expected to be known soon.

- Modifications to the PERT trial protocol acknowledging the stopping of intervention activities (HT Advisory Committee, Dr. David Barad, Chair).

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[1] Writing Group for the Women's Health Initiative Investigators. Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women, JAMA 2002: 288: 321-333.

- Completion of the 2002 Personalized Evaluation of Fat Intake (PEFI) intervention in the DM and planning for an optional re-administration in 2003.

All reports summarize Clinical Center (CC) data provided to the CCC by February 28, 2003. 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*).

The WHI Clinical Coordinating Center (CCC) is located at Fred Hutchinson Cancer Research Center, in Seattle, WA. Several other groups contribute to the coordinating center effort through a contractual relationship with the CCC: University of Washington (Bruce Psaty, PI) for cardiovascular expertise; Wake Forest University (Sally Shumaker, PI) for clinical facilitation and behavioral expertise; Wake Forest University (Ron Prineas, PI) for centralized ECG reading; University of California, San Francisco (Steve Cummings, PI) for centralized bone densitometry reading and osteoporosis expertise; McKesson Bioservices (Frank Cammarata, PI) for drug distribution on specimen repository; Medical Research Laboratories (Evan Stein, PI), biospecimen analysis.

Clinical Center locations and Principal Investigators (PI) are listed in Table 1.1. We note that two changes in Clinical Center Principal Investigators have been made since the last report. Drs. Maurizio Trevisan and Robert Schenken and have stepped down from their leadership roles in the Buffalo and San Antonio Clinical Centers, respectively. We thank for their years of service to WHI. Drs. Jean Wactawski-Wende and Robert Brzyski are the newly named Principal Investigators for those sites.

Table 1.1
WHI Clinical Centers and Principal Investigators

Institution	Principal Investigator	Location
Albert Einstein College of Medicine	Sylvia 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 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 and Evanston, IL
Ohio State University	Rebecca Jackson, MD	Columbus, OH
Research Foundation SUNY, Stony Brook	Dorothy Lane, MD MPH	Stony Brook, NY
Rush Presbyterian/St. Luke's Medical Ctr	Henry Black, MD	Chicago, IL
Stanford University	Marcia Stefanick, PhD	San Jose, CA
State University of New York, Buffalo	Jean Wactawski-Wende, PhD	Buffalo, NY
University of Alabama at Birmingham	Cora Lewis, MD MSP	Birmingham, AL
University of Arizona	Tamsen Bassford, MD	Tucson and 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
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, 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, NE
University of North Carolina, 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 Brzyski, 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 most of 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 pills, 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 – Hormone Replacement Therapy Component* 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 for Participants Without a Uterus* gives descriptive data on all women who are considered due for each contact for participants with hysterectomy (ERT vs. placebo) trial. At this point 91% were randomized more than five years ago , and 59% more than six years, 29% more than seven years and 1203 (11%) have been in the study more than eight years The current estimates of rates of stopping pills in follow-up years five through eight are between 5% and 6% per year. The adherence summaries for AV-5 through AV-8 are 54%, 50%, 47% and 46%, each 1-2% lower than the last report. *Figure 2.1 – HRT Adherence Summary* 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. These trends also suggest a possible reduction in adherence in the last 6-12 months.

Drop-out and drop-in rates for the ERT trial are presented in *Table 2.3 – HRT Drop-Out and Drop-In Rates by Follow-up Time* 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-5 through AV-8 the difference between the observed and projected cumulative stopping intervention rates appear to be somewhat divergent. Overall, 52% of women in the ERT trial have stopped their study pills at some point but 53% 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. The observed "drop-in" rates continue to be 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 30% 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 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 2.8 – Bone Mineral Density Analysis: HRT Participants* 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. *Table 2.9 – Bone Mineral Density Analysis: HRT Participants by Race/Ethnicity* presents BMD data for Black/African American, Hispanic/Latino, and White women participating in the HRT component at these three centers.

2.5 Vital Status

Table 2.10 – Lost-to-Follow-up and Vital Status 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 (2.1%) and the women with a uterus (0.9%). The difference was much smaller 12 months ago. Presumably this is the result of the closure of the intervention of the PERT component. Currently, 3.9% of the HRT participants are lost-to-follow-up or have stopped follow-up, and 3.6% 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 dead. Currently, the average follow-up for HRT participants is about 5.9 years, suggesting that approximately 16.4% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

2.6 Outcomes

Table 2.11 – Locally Verified Outcomes (Annualized Percentages) 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 3% 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, 90% of the expected number of breast cancers, 80% of the expected number of colorectal cancers, and about 40% 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 2.12 – Locally Verified Outcomes (Annualized Percentages) for HRT Participants Without and With Uterus 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 2.13 – Frequency of Various Subcategories of Stoke Diagnosis 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 2.14 – Frequency of Disability Levels Following Stroke 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 2.15 – Counts (Annualized Percentages) of Participants with Self-Reported Outcomes 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.

2.7 WHI Memory Study (WHIMS)

The WHI Memory Study is an ancillary study in the HRT component, funded until now 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 2.16* by hysterectomy status. With the closure of the PERT trial, the corresponding results from WHIMS have been analyzed and two reports will be published in the Journal of the American Medical Association in late May. Wyeth has informed the WHIMS investigators that they will not continue to support this study for additional follow-up.

2.8 WHI Sight Examination (WHI-SE)

The WHI-SE is an ancillary study in the HRT component, sponsored by Wyeth Ayerst through a grant to Dr. Mary Haan, University of Michigan. The aim of this study is to evaluate whether postmenopausal hormone replacement therapy can prevent age-related macular degeneration (ARM), or slow the progression of this disease in women who already have ARM, and/or reduces the risk of late forms of age-related maculopathy, including geographic atrophy, retinal pigment epithelial detachments and choroidal neovascular membranes. HRT participants are eligible if they are 65 years or older, read and speak English or Spanish, consent to study procedures including two eye exams with fundus photography, and have at least one eye that could be dilated for the retinal fundus photography. Women are excluded if they have allergies or other known contraindications for administering eye drops or cannot be subjected to retinal fundus photography. Recruitment began in May 2000 with a target sample size of 4500. Currently 3742 women have been enrolled in the 19 participating centers representing approximately 19.35% of the age eligible cohort and 13.7% of the entire HRT study. Baseline characteristics of WHI-SE participants are shown in *Table 2.17* by hysterectomy strata.

Follow-up consists of an annual questionnaire sent to participants to assess development or worsening of vision problems. Follow-up eye exams, photos, and repeated questionnaires were intended during 2004-2005.

Table 2.18 – Prevalence of WHI-SE Outcomes in HRT Participants at WHI-SE Baseline Exam presents the prevalence of various diagnoses of eye conditions at the time of entry into WHI-SE by hysterectomy strata. Note this entry time is generally at least 2 years months after randomization to HRT.

As with WHIMS, Wyeth has informed the WHI-SE investigators that they will not continue to support this study.

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, respond to criticisms of the initial report, complete the trial database, and develop additional reports on the final, centrally adjudicated outcome data (through July 7, 2003) on each disease area: CHD,

stroke, venous thromboembolism, fractures, breast cancer, colorectal cancer, gynecologic cancers, diabetes, gynecologic symptoms, and quality of life and cognitive function. The latter was published on the New England Journal of Medicine website in March of 2003. At the time this report is being written, five other articles have been submitted to journals and two have been accepted. In addition, specific analyses and selected datasets have been provided to the FDA and Wyeth in response to their request for more specific information.

One of the primary concerns of the investigators is in maintaining the integrity of the ERT trial. The data presented here suggest that there has been a modest increase in the rate of women dropping out of this trial. Adherence was already at a relatively low level, and so this loss is concerning. Study investigators continue their efforts to indicate the importance of the ERT trial continuing until the risks and benefits become clear.

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

Data as of: February 28, 2003

HRT Participants	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age				
Overall	**27,347**			
50-54	3,425	125%	13%	10
55-59	5,408	99%	20%	20
60-69	12,364	100%	45%	45
70-79	6,150	90%	22%	25
Without Uterus	**10,739**			
50-54	1,396	113%	13%	10
55-59	1,916	78%	18%	20
60-69	4,852	88%	45%	45
70-79	2,575	84%	24%	25
With Uterus	**16,608**			
50-54	2,029	135%	12%	10
55-59	3,492	116%	21%	20
60-69	7,512	111%	45%	45
70-79	3,575	95%	22%	25
Race/Ethnicity				
Overall	**27,347**			
American Indian	130		<1%	
Asian	527		2%	
Black	2,738		10%	
Hispanic	1,537		6%	
White	22,030		81%	
Unknown	385		1%	
Without Uterus	**10,739**			
American Indian	75		1%	
Asian	164		2%	
Black	1,616		15%	
Hispanic	651		6%	
White	8,084		75%	
Unknown	149		1%	
With Uterus	**16,608**			
American Indian	55		<1%	
Asian	363		2%	
Black	1,122		7%	
Hispanic	886		5%	
White	13,946		84%	
Unknown	236		1%	

Table 2.2
HRT Adherence Summary for Participants Without a Uterus

Data as of: February 28, 2003

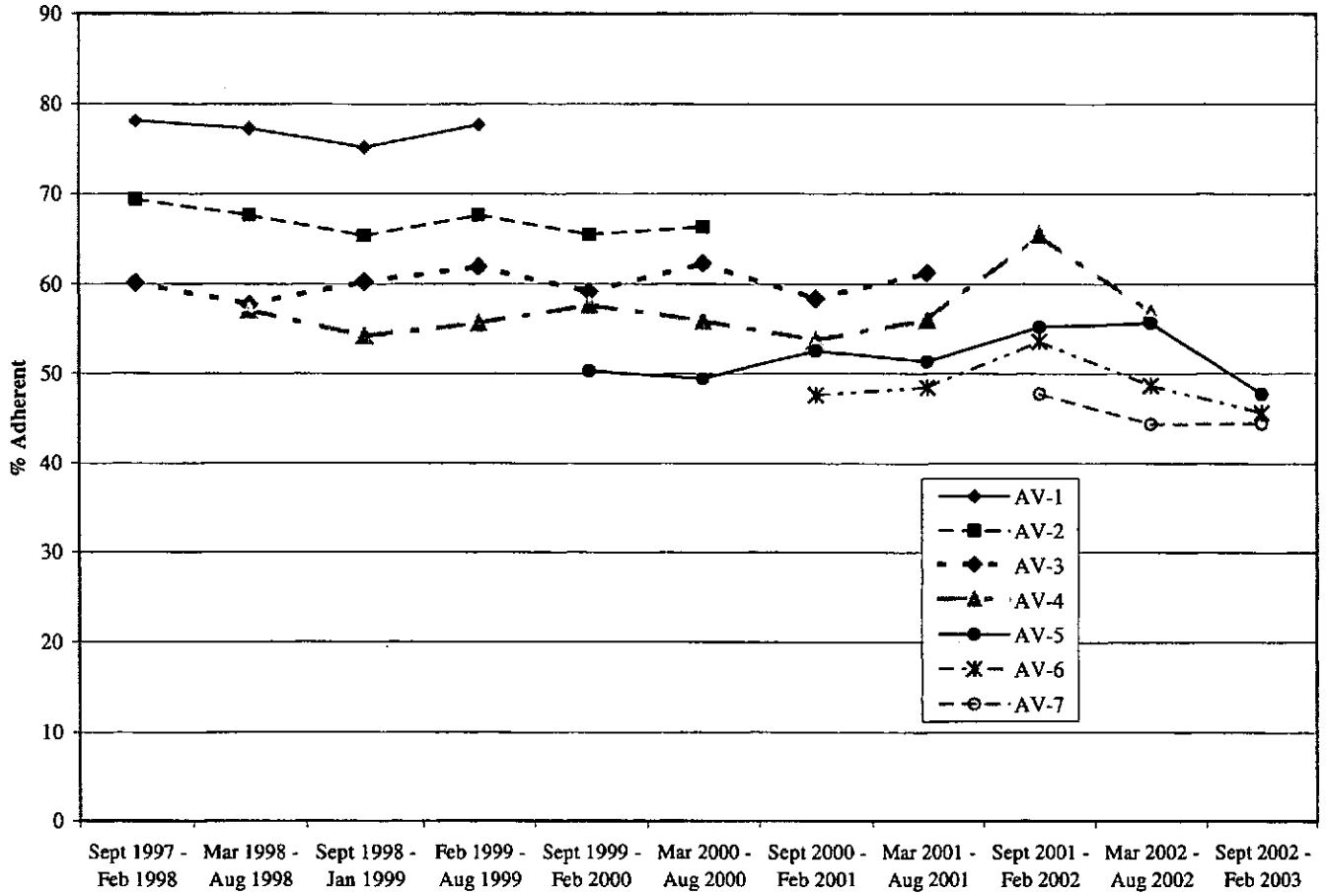
Contact	Due N	Conducted[1] N	%	Conducted in Window N	%	Stopped HRT during interval N	%	Missed Pill Collection N	%	Total with Collections N	%	Medication Rate[2,3] <50% N	%	Medication Rate[2,3] 50%-80% N	%	Medication Rate[2,3] 80% + N	%	Adherence Summary[4] %
Annual Visit - 1	10739	10352	96	8538	80	885	8	87	1	10613	99	810	8	1272	12	8531	80	80
Annual Visit - 2	10739	10061	94	7944	75	1047	10	209	2	9600	98	976	10	1190	12	7434	76	70
Annual Visit - 3	10739	10046	94	7445	70	856	8	218	2	8538	98	855	10	1046	12	6637	76	63
Annual Visit - 4	10739	9839	92	6778	65	712	7	188	2	7717	98	645	8	945	12	6127	78	58
Annual Visit - 5	9742	8817	91	5858	62	596	6	147	2	6418	98	509	8	815	12	5094	78	54
Annual Visit - 6	6303	5635	89	3481	57	348	6	111	3	3808	97	272	7	465	12	3071	78	50
Annual Visit - 7	3073	2698	88	1645	56	141	5	47	3	1753	97	141	8	208	12	1404	78	47
Annual Visit - 8	1203	1023	85	599	52	55	5	26	4	645	96	50	7	66	10	529	79	46

[1] Based on Form 33 collection.
[2] Medication rate calculated as number of pills taken divided by number of days since bottle(s) were dispensed.
[3] Percentage calculated based on denominator of total dispensation which is the sum of missed pill collection and total with collection.
[4] 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 February 28, 2003

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 (ERT Trial)

Data as of: February 28, 2003

	Design		Without Uterus			
	Int	Cum	Stopped[1]	Dead/ Lost[2]	Int[3]	Cum[4]
Drop-Outs[5]						
AV-1	8.8	8.8	8.3	0.4	8.3	8.3
AV-2	5.9	14.2	9.8	0.5	9.8	18.0
AV-3	5.9	19.2	8.1	0.8	8.1	26.0
AV-4	5.9	24.0	6.8	0.9	6.8	32.6
AV-5	5.9	28.5	6.3	0.8	6.3	38.7
AV-6	5.9	32.7	5.7	1.0	5.7	44.1
AV-7	5.9	36.7	4.8	1.2	4.8	48.5
AV-8	5.9	40.4	4.8	1.7	4.8	52.7
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			1.8	8.7

[1] Estimated rate of stopping hormones in the interval.
[2] Death or lost to follow-up rate in the interval.
[3] The first event of stopping or death or lost to follow-up in the interval.
[4] Estimated cumulative rate of stopping or death or lost to follow-up. Cumulative rates calculated as Kaplan-Meier estimates
[5] Drop-out rates derived from Form 7 by date..
[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 February 28, 2003

Reasons[2]	(N = 5122)	
Personal/family		
Demands of work	87	1.7%
Family illness, emergency or other family demands[3]	215	4.2%
Financial problems	9	0.2%
Lack of cooperation/support from family/friends[4]	53	1.0%
Living in nursing home	16	0.3%
Issues of interest in study[5]	123	2.4%
Travel		
Too far to CC	180	3.5%
Moved out of area or refuses to be followed to another CC	42	0.8%
Other travel issues[6]	105	2.0%
Visits & Procedures		
Doesn't like visits, calls	62	1.2%
Mammogram Issues[7]	30	0.6%
Doesn't like gynecologic procedures	13	0.3%
Doesn't like required forms or safety procedures[8]	87	1.7%
Problems with other procedures[9]	13	0.3%
Worried about health effects of medical tests/procedures	22	0.4%
Wants test results[10]	1	<0.1%
Problems with CC[11]	32	0.6%

(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 February 28, 2003

Reasons[2]	(N = 5122)	
Symptoms		
Vaginal Bleeding	6	0.1%
Breast Symptoms[3]	200	3.9%
Vaginal Changes	16	0.3%
Hot flashes/night sweats	33	0.6%
Other[4]	1058	20.7%
Health Conditions		
Breast Cancer	101	2.0%
Complex or atypical hyperplasia	0	0.0%
Endometrial cancer	2	<0.1%
Venous thromboembolism[5]	65	1.3%
High triglycerides (> 1000 mg/dL)	2	<0.1%
Malignant melanoma	13	0.3%
Gallbladder disease	14	0.3%
Heart Attack	77	1.5%
Stroke	106	2.1%
Meningioma	6	0.1%
Depression	13	0.3%
Cholesterol (high or concern about levels)	10	0.2%
Osteoporosis	37	0.7%
Cognitive/memory changes	39	0.8%
Other[6]	556	10.9%

(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 February 28, 2003

Reasons[2]	(N = 5122)	
Intervention		
Doesn't like randomized nature of intervention	93	1.8%
Expected some benefit from intervention	43	0.8%
Feels guilty, unhappy, or like a failure for not meeting study goals of intervention	3	0.1%
Takes too many pills	43	0.8%
Other pill issues[3]	143	2.8%
CaD Issues[4]	32	0.6%
DM Issues[5]	5	0.1%
Taking active HRT[6]	207	4.0%
Will not be on any HRT[7]	526	10.3%
Taking SERMs or other hormone medications[8]	45	0.9%
Other Health Issues		
Worried about cost if adverse effects occur	12	0.2%
Expected more health care	14	0.3%
Advised not to participate by health care provider[9]	646	12.6%
Study conflicts with other health issues[10]	601	11.7%
Other		
Other reasons not listed above	1080	21.1%
Refuses to give a reason	81	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 February 28, 2003

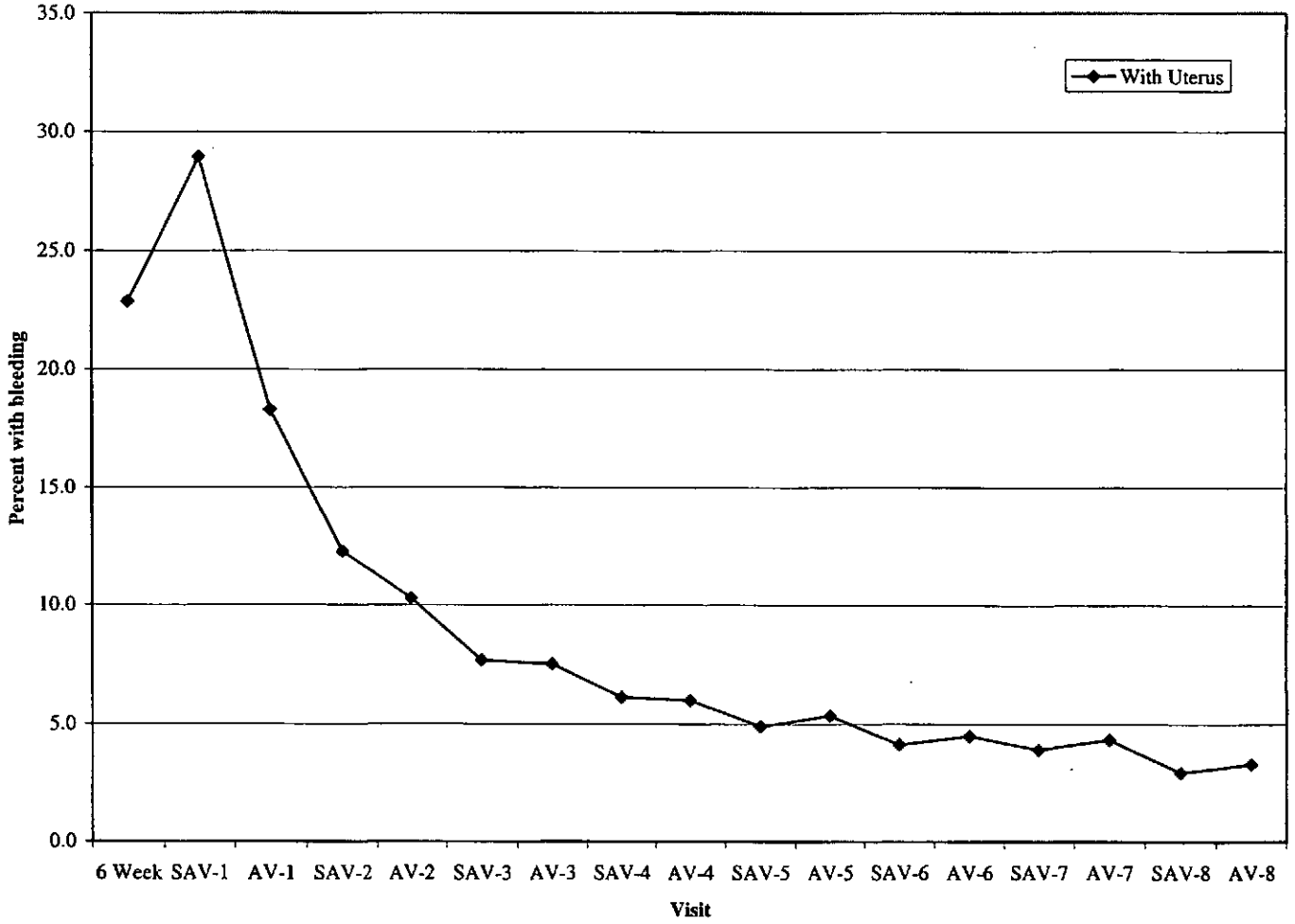
	All (N = 10,739)		Age at Screening: 50 – 54 (N = 1,396)		55 – 59 (N = 1,916)		60 – 69 (N = 4,852)		70 –79 (N = 2,575)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping HRT	5122	47.7%	664	47.6%	871	45.5%	2237	46.1%	1350	52.4%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	215	4.2%	28	4.2%	43	4.9%	98	4.4%	46	3.4%
Vaginal bleeding	6	0.1%	2	0.3%	2	0.2%	1	<0.1%	1	0.1%
Breast symptoms[6]	200	3.9%	14	2.1%	28	3.2%	79	3.5%	79	5.9%
Taking active HRT[7]	207	4.0%	33	5.0%	48	5.5%	84	3.8%	42	3.1%
Will not be on any HRT[8]	526	10.3%	45	6.8%	78	9.0%	248	11.1%	155	11.5%
Advised not to participate by health care provider[9]	646	12.6%	87	13.1%	101	11.6%	277	12.4%	181	13.4%
Study conflicts with other health issues[10]	601	11.7%	82	12.3%	98	11.3%	270	12.1%	151	11.2%

	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	35	46.7%	66	40.2%	799	49.4%	360	55.3%	3794	46.9%	68	45.6%
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	2.9%	2	3.0%	47	5.9%	26	7.2%	136	3.6%	3	4.4%
Vaginal bleeding	0	0.0%	0	0.0%	2	0.3%	1	0.3%	3	0.1%	0	0.0%
Breast symptoms[6]	2	5.7%	2	3.0%	28	3.5%	15	4.2%	151	4.0%	2	2.9%
Taking active HRT[7]	1	2.9%	1	1.5%	23	2.9%	13	3.6%	166	4.4%	3	4.4%
Will not be on any HRT[8]	2	5.7%	8	12.1%	80	10.0%	28	7.8%	401	10.6%	7	10.3%
Advised not to participate by health care provider[9]	5	14.3%	10	15.2%	70	8.8%	37	10.3%	514	13.5%	10	14.7%
Study conflicts with other health issues[10]	5	14.3%	11	16.7%	68	8.5%	30	8.3%	479	12.6%	8	11.8%

[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

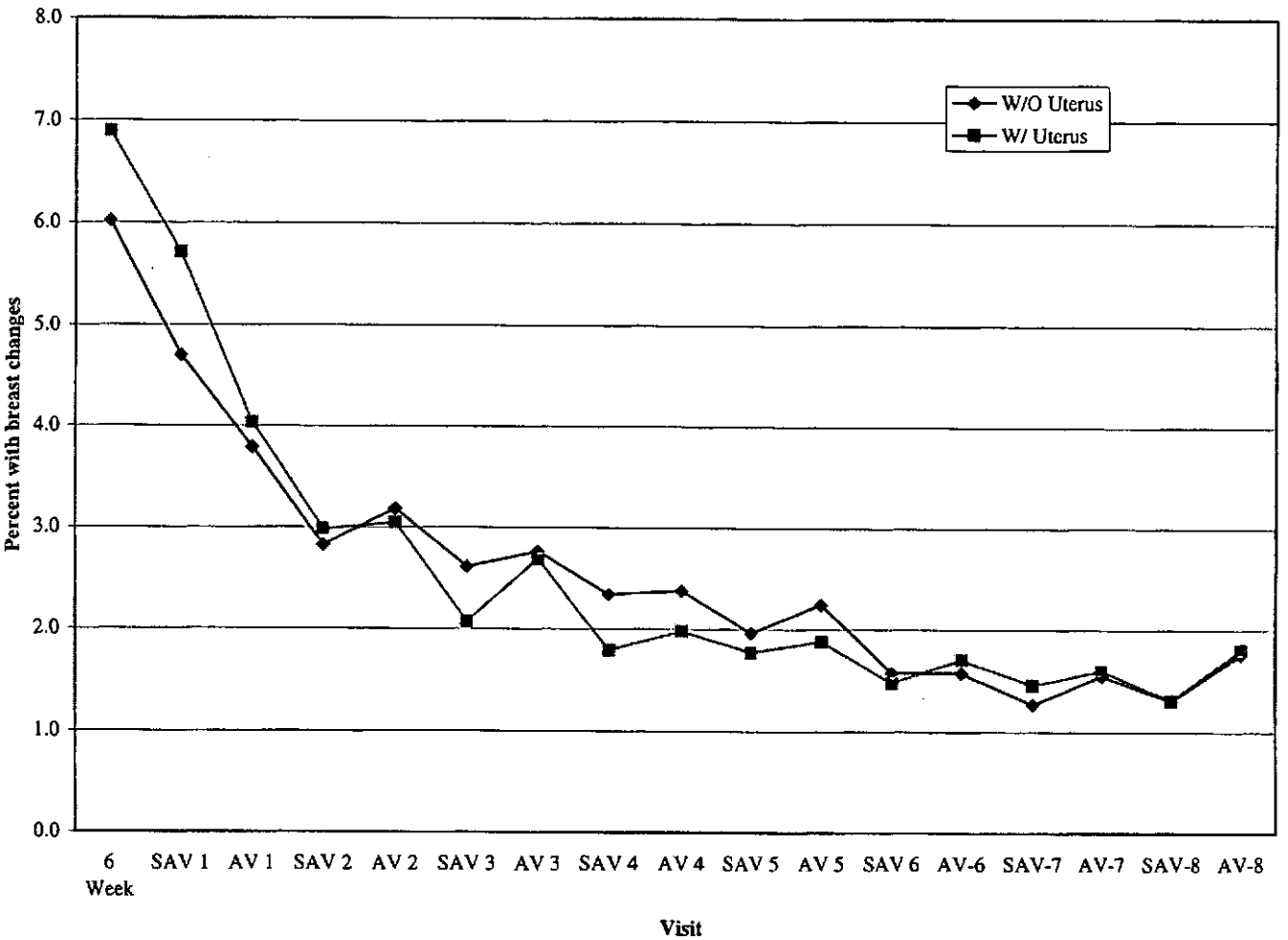
Data as of: February 28, 2003



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	950	(6.1%)
Annual Visit 4 – Number with Bleeding	936	(6.0%)
Semi-Annual Visit 5 – Number with Bleeding	751	(4.9%)
Annual Visit 5 – Number with Bleeding	745	(5.4%)
Semi-Annual Visit 6 – Number with Bleeding	475	(4.1%)
Annual Visit 6 – Number with Bleeding	394	(4.5%)
Semi-Annual Visit 7 – Number with Bleeding	237	(3.9%)
Annual Visit 7 – Number with Bleeding	180	(4.3%)
Semi-Annual Visit 8 – Number with Bleeding	74	(2.9%)
Annual Visit 8 – Number with Bleeding	49	(3.3%)

Table 2.7
Reports of Breast Changes

Data as of: February 28, 2003



Contact	Without Uterus		With Uterus	
Semi-Annual Visit 3 – Number with Breast Changes	220	(2.6%)	276	(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	179	(2.4%)	243	(2.0%)
Semi-Annual Visit 5 – Number with Breast Changes	141	(2.0%)	206	(1.8%)
Annual Visit 5 – Number with Breast Changes	145	(2.2%)	196	(1.9%)
Semi-Annual Visit 6 – Number with Breast Changes	83	(1.6%)	125	(1.5%)
Annual Visit 6 – Number with Breast Changes	62	(1.6%)	108	(1.7%)
Semi-Annual Visit 7 – Number with Breast Changes	35	(1.3%)	64	(1.5%)
Annual Visit 7 – Number with Breast Changes	28	(1.5%)	46	(1.6%)
Semi-Annual Visit 8 – Number with Breast Changes	15	(1.3%)	23	(1.3%)
Annual Visit 8 – Number with Breast Changes	12	(1.8%)	18	(1.8%)

Table 2.8
Bone Mineral Density[1] Analysis: HRT Participants

Data as of: February 28, 2003

	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	767	1.03	0.12	854	1.02	0.10
AV6	512	1.03	0.12	546	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]	762	2.08	4.28	846	1.97	3.79
AV6 % Change from baseline BMD[4]	508	2.29	5.66	539	2.78	5.65
Spine Scan						
Baseline	905	0.97	0.16	989	0.95	0.16
AV1	816	0.99	0.16	894	0.97	0.16
AV3	753	1.00	0.17	832	0.99	0.17
AV6	497	1.01	0.17	533	0.99	0.17
AV1 % Change from baseline BMD[2]	812	1.91	4.54	891	2.06	4.33
AV3 % Change from baseline BMD[3]	749	3.51	6.17	827	4.08	6.04
AV6 % Change from baseline BMD[4]	493	4.61	7.75	531	5.21	7.57
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	775	0.88	0.15	860	0.86	0.14
AV6	520	0.87	0.14	557	0.85	0.13
AV1 % Change from baseline BMD[2]	838	0.72	3.31	925	0.63	3.17
AV3 % Change from baseline BMD[3]	769	2.20	4.86	854	2.16	4.78
AV6 % Change from baseline BMD[4]	516	0.59	5.61	548	1.01	5.72

[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 2.9
Bone Mineral Density[1] Analysis: HRT Participants by Race/Ethnicity

Data as of: February 28, 2003

	Black/African American						Hispanic/Latino						White					
	Without Uterus			With Uterus			Without Uterus			With Uterus			Without Uterus			With Uterus		
	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	174	1.06	0.10	97	1.08	0.11	65	1.03	0.10	61	1.02	0.11	679	0.99	0.10	837	0.98	0.09
AV1	153	1.07	0.11	86	1.08	0.11	43	1.04	0.10	50	1.03	0.10	631	0.99	0.10	773	0.99	0.09
AV3	150	1.09	0.11	87	1.10	0.12	50	1.05	0.12	45	1.06	0.11	559	1.01	0.11	705	1.00	0.10
AV6	114	1.08	0.11	57	1.09	0.11	35	1.08	0.12	29	1.10	0.15	357	1.01	0.11	449	1.01	0.11
AV1 % Change from baseline BMD[2]	153	0.75	2.95	86	0.91	2.86	43	-0.16	2.33	49	-0.07	2.42	626	0.37	2.76	769	0.21	2.28
AV3 % Change from baseline BMD[3]	150	2.06	3.45	87	2.15	3.18	50	1.61	4.61	44	3.15	5.43	554	2.12	4.45	698	1.85	3.74
AV6 % Change from baseline BMD[4]	114	0.76	3.96	57	0.41	3.79	35	4.35	7.45	28	6.86	7.28	353	2.56	5.82	443	2.83	5.63
Spine Scan																		
Baseline	171	1.04	0.15	96	1.08	0.19	64	0.96	0.13	60	0.92	0.14	658	0.95	0.16	811	0.93	0.15
AV1	150	1.05	0.16	85	1.09	0.19	43	0.97	0.11	48	0.95	0.16	612	0.97	0.16	744	0.96	0.16
AV3	147	1.07	0.17	86	1.11	0.20	50	0.95	0.12	43	0.95	0.14	548	0.98	0.17	686	0.97	0.16
AV6	105	1.09	0.17	56	1.10	0.19	35	0.97	0.14	27	0.95	0.17	351	0.99	0.16	439	0.98	0.17
AV1 % Change from baseline BMD[2]	150	1.92	4.39	84	1.73	4.84	43	-0.44	4.18	48	1.81	6.89	608	2.09	4.56	742	2.11	4.09
AV3 % Change from baseline BMD[3]	147	3.43	6.16	85	3.00	6.35	50	-0.09	5.37	43	3.15	6.89	544	3.89	6.12	682	4.28	5.93
AV6 % Change from baseline BMD[4]	105	3.45	6.70	55	2.77	7.34	35	1.22	7.02	27	4.02	8.41	347	5.36	8.04	438	5.59	7.53
Hip Scan																		
Baseline	174	0.96	0.13	98	0.97	0.15	65	0.87	0.11	61	0.84	0.13	683	0.83	0.13	843	0.82	0.12
AV1	153	0.97	0.13	86	0.97	0.14	43	0.87	0.11	50	0.85	0.12	634	0.83	0.13	775	0.83	0.12
AV3	150	0.98	0.14	87	0.99	0.15	50	0.89	0.13	45	0.88	0.13	567	0.85	0.14	711	0.84	0.13
AV6	115	0.95	0.13	59	0.96	0.13	35	0.90	0.14	29	0.85	0.11	364	0.84	0.13	458	0.84	0.13
AV1 % Change from baseline BMD[2]	153	1.16	2.97	86	1.14	3.43	43	0.31	3.62	49	1.09	3.47	631	0.65	3.37	773	0.54	3.13
AV3 % Change from baseline BMD[3]	150	1.87	3.91	87	1.38	3.94	50	2.74	5.32	44	4.51	5.97	561	2.25	5.04	706	2.08	4.77
AV6 % Change from baseline BMD[4]	115	-1.49	5.48	58	-2.13	5.14	35	2.93	6.16	28	4.16	6.51	360	1.06	5.42	451	1.23	5.62

[1] Measured in (g/cm2).
[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 2.10
Lost-to-Follow-up and Vital Status: HRT Participants by Hysterectomy Status

Data as of: February 28, 2003

	Without Uterus (N=10,739)		With Uterus (N=16,608)		HRT Participants (N=27,347)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	433	4.0	556	3.3	989	3.6
Alive: Current Participation[1]	9568	89.1	15453	93.0	25021	91.5
Alive: Recent Participation[2]	208	1.9	29	0.2	237	0.9
Alive: Past/Unknown Participation[3]	16	0.1	8	0.0	24	0.1
Stopped Follow-Up[4]	287	2.7	420	2.5	707	2.6
Lost to Follow-Up[5]	227	2.1	142	0.9	369	1.3

[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 2.11
Locally Verified Outcomes (Annualized Percentages) by Age for Hormone Replacement Therapy

Data as of: February 28, 2003

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)	71.2	76.4	73.4	70.2	68.2
Cardiovascular					
CHD[1]	641 (0.40%)	37 (0.17%)	53 (0.16%)	288 (0.40%)	263 (0.75%)
CHD death[2]	154 (0.09%)	7 (0.03%)	13 (0.04%)	61 (0.08%)	73 (0.21%)
Total MI[3]	535 (0.33%)	32 (0.15%)	42 (0.13%)	242 (0.33%)	219 (0.63%)
Clinical MI	511 (0.31%)	31 (0.14%)	41 (0.12%)	231 (0.32%)	208 (0.59%)
Evolving Q-wave MI[4]	24 (0.01%)	1 (<0.01%)	1 (<0.01%)	11 (0.02%)	11 (0.03%)
Possible evolving Q-wave MI[4]	106 (0.07%)	12 (0.06%)	13 (0.04%)	41 (0.06%)	40 (0.11%)
Angina	847 (0.52%)	33 (0.15%)	108 (0.33%)	403 (0.56%)	303 (0.87%)
CABG/PTCA	848 (0.52%)	35 (0.16%)	96 (0.29%)	411 (0.57%)	306 (0.88%)
Carotid artery disease	153 (0.09%)	4 (0.02%)	16 (0.05%)	85 (0.12%)	48 (0.14%)
Congestive heart failure	506 (0.31%)	28 (0.13%)	53 (0.16%)	206 (0.28%)	219 (0.63%)
Stroke	510 (0.31%)	20 (0.09%)	49 (0.15%)	229 (0.32%)	212 (0.61%)
Non-disabling stroke	300 (0.18%)	15 (0.07%)	29 (0.09%)	139 (0.19%)	117 (0.33%)
Fatal/disabling stroke	121 (0.07%)	4 (0.02%)	6 (0.02%)	48 (0.07%)	63 (0.18%)
Unknown status from stroke	89 (0.05%)	1 (<0.01%)	14 (0.04%)	42 (0.06%)	32 (0.09%)
PVD	145 (0.09%)	7 (0.03%)	12 (0.04%)	73 (0.10%)	53 (0.15%)
DVT	285 (0.18%)	15 (0.07%)	39 (0.12%)	127 (0.18%)	104 (0.30%)
Pulmonary embolism	178 (0.11%)	9 (0.04%)	26 (0.08%)	84 (0.12%)	59 (0.17%)
CHD[1]/Possible evolving Q-wave MI	741 (0.46%)	49 (0.22%)	66 (0.20%)	327 (0.45%)	299 (0.86%)
Coronary disease[5]	1878 (1.16%)	101 (0.46%)	213 (0.64%)	864 (1.19%)	700 (2.00%)
DVT/PE	378 (0.23%)	18 (0.08%)	51 (0.15%)	180 (0.25%)	129 (0.37%)
Total cardiovascular disease	2805 (1.73%)	142 (0.65%)	315 (0.95%)	1318 (1.82%)	1030 (2.95%)
Cancer					
Breast cancer[6]	680 (0.42%)	60 (0.28%)	120 (0.36%)	333 (0.46%)	167 (0.48%)
Invasive breast cancer	538 (0.33%)	45 (0.21%)	95 (0.29%)	261 (0.36%)	137 (0.39%)
Non-invasive breast cancer	144 (0.09%)	15 (0.07%)	25 (0.08%)	74 (0.10%)	30 (0.09%)
Ovarian cancer	65 (0.04%)	2 (0.01%)	12 (0.04%)	36 (0.05%)	15 (0.04%)
Endometrial cancer[7]	59 (0.06%)	2 (0.02%)	12 (0.06%)	29 (0.07%)	16 (0.08%)
Colorectal cancer	233 (0.14%)	13 (0.06%)	25 (0.08%)	117 (0.16%)	78 (0.22%)
Other cancer[8]	869 (0.54%)	65 (0.30%)	120 (0.36%)	402 (0.56%)	282 (0.81%)
Total cancer	1851 (1.14%)	141 (0.65%)	283 (0.86%)	886 (1.22%)	541 (1.55%)
Fractures					
Hip fracture	212 (0.13%)	4 (0.02%)	7 (0.02%)	73 (0.10%)	128 (0.37%)
Vertebral fracture	212 (0.13%)	6 (0.03%)	25 (0.08%)	89 (0.12%)	92 (0.26%)
Other fracture[8]	2430 (1.50%)	278 (1.27%)	377 (1.14%)	1144 (1.58%)	631 (1.80%)
Total fracture	2746 (1.69%)	285 (1.31%)	401 (1.21%)	1259 (1.74%)	801 (2.29%)
Deaths					
Cardiovascular deaths	296 (0.18%)	11 (0.05%)	25 (0.08%)	117 (0.16%)	143 (0.41%)
Cancer deaths	431 (0.27%)	21 (0.10%)	45 (0.14%)	209 (0.29%)	156 (0.45%)
Other known cause	155 (0.10%)	10 (0.05%)	21 (0.06%)	54 (0.07%)	70 (0.20%)
Unknown cause	59 (0.04%)	3 (0.01%)	4 (0.01%)	27 (0.04%)	25 (0.07%)
Not yet adjudicated	48 (0.03%)	3 (0.01%)	8 (0.02%)	21 (0.03%)	16 (0.05%)
Total death	989 (0.61%)	48 (0.22%)	103 (0.31%)	428 (0.59%)	410 (1.17%)

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

Data as of: February 28, 2003

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)	68.9	67.3	70.6	68.4	71.6	67.5
Cardiovascular						
CHD[1]	4 (0.54%)	8 (0.27%)	58 (0.36%)	16 (0.18%)	542 (0.41%)	13 (0.60%)
CHD death[2]	2 (0.27%)	3 (0.10%)	24 (0.15%)	3 (0.03%)	119 (0.09%)	3 (0.14%)
Total MI[3]	3 (0.40%)	7 (0.24%)	42 (0.26%)	14 (0.16%)	458 (0.35%)	11 (0.51%)
Clinical MI	3 (0.40%)	7 (0.24%)	41 (0.25%)	14 (0.16%)	436 (0.33%)	10 (0.46%)
Evolving Q-wave MI[4]	0 (0.00%)	0 (0.00%)	1 (0.01%)	0 (0.00%)	22 (0.02%)	1 (0.05%)
Possible evolving Q-wave MI[4]	0 (0.00%)	1 (0.03%)	12 (0.07%)	4 (0.05%)	88 (0.07%)	1 (0.05%)
Angina	4 (0.54%)	13 (0.44%)	92 (0.57%)	35 (0.40%)	695 (0.53%)	8 (0.37%)
CABG/PTCA	5 (0.67%)	9 (0.30%)	77 (0.48%)	33 (0.38%)	715 (0.54%)	9 (0.42%)
Carotid artery disease	1 (0.13%)	1 (0.03%)	6 (0.04%)	1 (0.01%)	144 (0.11%)	0 (0.00%)
Congestive heart failure	3 (0.40%)	7 (0.24%)	72 (0.45%)	15 (0.17%)	403 (0.31%)	6 (0.28%)
Stroke	5 (0.67%)	9 (0.30%)	68 (0.42%)	17 (0.19%)	405 (0.31%)	6 (0.28%)
Non-disabling stroke	2 (0.27%)	6 (0.20%)	34 (0.21%)	13 (0.15%)	241 (0.18%)	4 (0.18%)
Fatal/disabling stroke	1 (0.13%)	2 (0.07%)	17 (0.11%)	2 (0.02%)	98 (0.07%)	1 (0.05%)
Unknown status from stroke	2 (0.27%)	1 (0.03%)	17 (0.11%)	2 (0.02%)	66 (0.05%)	1 (0.05%)
PVD	2 (0.27%)	0 (0.00%)	14 (0.09%)	2 (0.02%)	127 (0.10%)	0 (0.00%)
DVT	1 (0.13%)	1 (0.03%)	26 (0.16%)	4 (0.05%)	252 (0.19%)	1 (0.05%)
Pulmonary embolism	3 (0.40%)	1 (0.03%)	17 (0.11%)	1 (0.01%)	155 (0.12%)	1 (0.05%)
CHD[1]/Possible evolving Q-wave MI	4 (0.54%)	9 (0.30%)	69 (0.43%)	20 (0.23%)	625 (0.48%)	14 (0.65%)
Coronary disease[5]	10 (1.34%)	25 (0.85%)	208 (1.29%)	68 (0.78%)	1542 (1.17%)	25 (1.15%)
DVT/PE	4 (0.54%)	1 (0.03%)	33 (0.20%)	4 (0.05%)	335 (0.25%)	1 (0.05%)
Total cardiovascular disease	17 (2.28%)	35 (1.18%)	303 (1.88%)	88 (1.00%)	2331 (1.77%)	31 (1.43%)
Cancer						
Breast cancer[6]	3 (0.40%)	16 (0.54%)	57 (0.35%)	24 (0.27%)	576 (0.44%)	4 (0.18%)
Invasive breast cancer	3 (0.40%)	11 (0.37%)	44 (0.27%)	17 (0.19%)	459 (0.35%)	4 (0.18%)
Non-invasive breast cancer	0 (0.00%)	5 (0.17%)	13 (0.08%)	7 (0.08%)	119 (0.09%)	0 (0.00%)
Ovarian cancer	0 (0.00%)	0 (0.00%)	5 (0.03%)	0 (0.00%)	59 (0.04%)	1 (0.05%)
Endometrial cancer[7]	1 (0.32%)	0 (0.00%)	0 (0.00%)	3 (0.06%)	55 (0.07%)	0 (0.00%)
Colorectal cancer	0 (0.00%)	7 (0.24%)	23 (0.14%)	13 (0.15%)	186 (0.14%)	4 (0.18%)
Other cancer[8]	6 (0.80%)	12 (0.41%)	70 (0.43%)	26 (0.30%)	742 (0.56%)	13 (0.60%)
Total cancer	10 (1.34%)	35 (1.18%)	149 (0.93%)	64 (0.73%)	1572 (1.20%)	21 (0.97%)
Fractures						
Hip fracture	0 (0.00%)	2 (0.07%)	7 (0.04%)	3 (0.03%)	199 (0.15%)	1 (0.05%)
Vertebral fracture	1 (0.13%)	2 (0.07%)	2 (0.01%)	2 (0.02%)	203 (0.15%)	2 (0.09%)
Other fracture[8]	11 (1.47%)	32 (1.08%)	128 (0.80%)	80 (0.91%)	2155 (1.64%)	24 (1.11%)
Total fracture	11 (1.47%)	35 (1.18%)	136 (0.84%)	83 (0.95%)	2456 (1.87%)	25 (1.15%)
Deaths						
Cardiovascular deaths	2 (0.27%)	5 (0.17%)	48 (0.30%)	3 (0.03%)	234 (0.18%)	4 (0.18%)
Cancer deaths	2 (0.27%)	11 (0.37%)	41 (0.25%)	12 (0.14%)	359 (0.27%)	6 (0.28%)
Other known cause	2 (0.27%)	1 (0.03%)	20 (0.12%)	1 (0.01%)	131 (0.10%)	0 (0.00%)
Unknown cause	2 (0.27%)	0 (0.00%)	5 (0.03%)	3 (0.03%)	48 (0.04%)	1 (0.05%)
Not yet adjudicated	0 (0.00%)	1 (0.03%)	7 (0.04%)	1 (0.01%)	39 (0.03%)	0 (0.00%)
Total death	8 (1.07%)	18 (0.61%)	121 (0.75%)	20 (0.23%)	811 (0.62%)	11 (0.51%)

[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 2.12
Locally Verified Outcomes (Annualized Percentages) for HRT Participants Without and With Uterus

Data as of: February 28, 2003

Outcomes	Without Uterus		With Uterus	
Number randomized	10739		16608	
Mean follow-up (months)	70.8		71.4	
Cardiovascular				
CHD[1]	294	(0.46%)	347	(0.35%)
CHD death[2]	82	(0.13%)	72	(0.07%)
Total MI[3]	240	(0.38%)	295	(0.30%)
Clinical MI	229	(0.36%)	282	(0.29%)
Evolving Q-wave MI[4]	11	(0.02%)	13	(0.01%)
Possible evolving Q-wave MI[4]	39	(0.06%)	67	(0.07%)
Angina	451	(0.71%)	396	(0.40%)
CABG/PTCA	413	(0.65%)	435	(0.44%)
Carotid artery disease	78	(0.12%)	75	(0.08%)
Congestive heart failure	268	(0.42%)	238	(0.24%)
Stroke	239	(0.38%)	271	(0.27%)
Non-disabling stroke	140	(0.22%)	160	(0.16%)
Fatal/disabling stroke	50	(0.08%)	71	(0.07%)
Unknown status from stroke	49	(0.08%)	40	(0.04%)
PVD	70	(0.11%)	75	(0.08%)
DVT	93	(0.15%)	192	(0.19%)
Pulmonary embolism	55	(0.09%)	123	(0.12%)
CHD[1]/Possible evolving Q-wave MI	331	(0.52%)	410	(0.41%)
Coronary disease[5]	917	(1.45%)	961	(0.97%)
DVT/PE	126	(0.20%)	252	(0.25%)
Total cardiovascular disease	1310	(2.07%)	1495	(1.51%)
Cancer				
Breast cancer[6]	230	(0.36%)	450	(0.46%)
Invasive breast cancer	178	(0.28%)	360	(0.36%)
Non-invasive breast cancer	53	(0.08%)	91	(0.09%)
Ovarian cancer	22	(0.03%)	43	(0.04%)
Endometrial cancer[7]	0	N/A	59	(0.06%)
Colorectal cancer	105	(0.17%)	128	(0.13%)
Other cancer[8]	332	(0.52%)	537	(0.54%)
Total cancer	672	(1.06%)	1179	(1.19%)
Fractures				
Hip fracture	71	(0.11%)	141	(0.14%)
Vertebral fracture	77	(0.12%)	135	(0.14%)
Other fracture[8]	933	(1.47%)	1497	(1.51%)
Total fracture	1042	(1.64%)	1704	(1.72%)
Deaths				
Cardiovascular deaths	145	(0.23%)	151	(0.15%)
Cancer deaths	182	(0.29%)	249	(0.25%)
Other known cause	56	(0.09%)	99	(0.10%)
Unknown cause	28	(0.04%)	31	(0.03%)
Not yet adjudicated	22	(0.03%)	26	(0.03%)
Total death	433	(0.68%)	556	(0.56%)

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

Data as of: February 28, 2003

	Without Uterus		With Uterus	
Number randomized	10739		16608	
Stroke Diagnosis				
Subarachoid hemorrhage	9	3.8%	13	4.8%
Intracerebral hemorrhage	32	13.4%	38	14.0%
Other intracranial hemorrhage	2	0.8%	3	1.1%
Occlusion of cerebral arteries with infarction	135	56.5%	157	57.9%
Acute cerebrovascular disease	42	17.6%	37	13.7%
Central nervous system complications	14	5.9%	11	4.1%
Report of cerebrovascular death only	5	2.1%	10	3.7%
Missing	0	0.0%	2	0.7%
Total	239	100%	271	100%

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

Table 2.14
Frequency (%)[1] of Disability Levels Following Stroke – Glasgow Scale: HRT Participants

Data as of: February 28, 2003

	Without Uterus		With Uterus	
Number randomized	10739		16608	
Glasgow scale				
Good recovery	77	32.2%	88	32.5%
Moderately disabled	63	26.4%	72	26.6%
Severely disabled	21	8.8%	32	11.8%
Vegetative survival	0	0.0%	4	1.5%
Death or death within 1 month	29	12.1%	35	12.9%
Unable to categorize stroke	14	5.9%	14	5.2%
Not yet categorized	35	14.6%	26	9.6%
Total	239	100%	271	100%

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

Table 2.15
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: February 28, 2003

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	27347	3425	5408	12364	6150
Mean follow-up (months)	71.2	76.4	73.4	70.2	68.2
Hospitalizations					
Ever	11418 (7.04%)	1011 (4.63%)	1801 (5.45%)	5311 (7.34%)	3295 (9.42%)
Two or more	5705 (3.52%)	448 (2.05%)	810 (2.45%)	2639 (3.65%)	1808 (5.17%)
Other					
Diabetes (treated)	1657 (1.08%)	224 (1.07%)	332 (1.06%)	754 (1.10%)	347 (1.05%)
Gallbladder disease[1]	1643 (1.21%)	226 (1.20%)	345 (1.22%)	770 (1.29%)	302 (1.07%)
Hysterectomy	527 (0.53%)	46 (0.35%)	98 (0.46%)	258 (0.58%)	125 (0.62%)
Glaucoma	2320 (1.49%)	195 (0.91%)	382 (1.18%)	1117 (1.61%)	626 (1.94%)
Osteoporosis	4593 (2.99%)	330 (1.54%)	671 (2.09%)	2222 (3.24%)	1370 (4.34%)
Osteoarthritis[2]	3763 (3.75%)	472 (2.88%)	740 (3.23%)	1715 (3.98%)	836 (4.71%)
Rheumatoid arthritis	1257 (0.81%)	165 (0.78%)	273 (0.86%)	546 (0.79%)	273 (0.83%)
Intestinal polyps	2865 (1.90%)	283 (1.34%)	487 (1.54%)	1467 (2.18%)	628 (2.03%)
Lupus	215 (0.13%)	29 (0.13%)	45 (0.14%)	100 (0.14%)	41 (0.12%)
Kidney stones[2]	523 (0.40%)	65 (0.38%)	99 (0.37%)	234 (0.39%)	125 (0.43%)
Cataracts[2]	6649 (5.70%)	338 (1.97%)	898 (3.41%)	3581 (6.72%)	1832 (9.23%)
Pills for hypertension	5749 (4.99%)	622 (3.54%)	1079 (4.23%)	2626 (5.23%)	1422 (6.49%)

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)	68.9	67.3	70.6	68.4	71.6	67.5
Hospitalizations						
Ever	65 (8.71%)	146 (4.94%)	1185 (7.36%)	500 (5.71%)	9371 (7.13%)	151 (6.97%)
Two or more	31 (4.16%)	63 (2.13%)	610 (3.79%)	207 (2.36%)	4730 (3.60%)	64 (2.95%)
Other						
Diabetes (treated)	11 (1.71%)	38 (1.41%)	280 (1.99%)	149 (1.85%)	1156 (0.92%)	23 (1.14%)
Gallbladder disease[1]	9 (1.57%)	24 (0.89%)	144 (0.99%)	93 (1.42%)	1350 (1.24%)	23 (1.29%)
Hysterectomy	2 (0.64%)	4 (0.20%)	29 (0.44%)	26 (0.52%)	460 (0.55%)	6 (0.45%)
Glaucoma	11 (1.57%)	46 (1.62%)	299 (2.01%)	142 (1.68%)	1788 (1.41%)	34 (1.69%)
Osteoporosis	20 (2.84%)	100 (3.52%)	229 (1.48%)	231 (2.83%)	3942 (3.17%)	71 (3.46%)
Osteoarthritis[2]	26 (5.12%)	75 (3.61%)	386 (3.97%)	264 (4.36%)	2945 (3.66%)	67 (4.82%)
Rheumatoid arthritis	9 (1.36%)	23 (0.81%)	205 (1.39%)	178 (2.14%)	820 (0.65%)	22 (1.07%)
Intestinal polyps	14 (2.03%)	41 (1.52%)	283 (1.88%)	143 (1.70%)	2359 (1.93%)	25 (1.25%)
Lupus	2 (0.27%)	4 (0.14%)	25 (0.16%)	13 (0.15%)	170 (0.13%)	1 (0.05%)
Kidney stones[2]	5 (0.87%)	17 (0.69%)	56 (0.43%)	31 (0.44%)	407 (0.38%)	7 (0.39%)
Cataracts[2]	32 (5.81%)	108 (5.01%)	602 (5.18%)	344 (5.02%)	5487 (5.84%)	76 (4.86%)
Pills for hypertension	36 (6.88%)	109 (5.28%)	536 (6.73%)	349 (5.32%)	4651 (4.81%)	68 (4.84%)

[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 2.16
Baseline Characteristics of HRT Participants Enrolled in WHIMS

Data as of: February 28, 2003

	HRT Participants Without Uterus		HRT Participants With Uterus	
Total HRT Participants	10739		16608	
Eligible HRT Population[1]	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	69	(2.3%)	68	(1.5%)
Some high school	213	(7.2%)	231	(5.1%)
High school diploma/GED	705	(23.7%)	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%)

[1] Includes 169 participants not eligible at screening (age<65), who later turned 65 prior to enrolling in WHIMS.

Table 2.17
Baseline Characteristics of HRT Participants Enrolled in WHI-SE

Data as of: February 28, 2003

	HRT Participants			
	Without Uterus		With Uterus	
Total HRT Participants	10739		16608	
Eligible HRT Population	7922		11873	
Enrolled in WHI-SE	1668		2679	
% Enrolled of Total HRT		15.5%		16.1%
% Enrolled of Eligible		21.1%		22.6%
WHI-SE Participants	**(N = 1668)**		**(N = 2679)**	
Age at Screening				
< 70	1128	67.6%	1947	72.7%
70-74	403	24.2%	546	20.4%
75+	137	8.2%	186	6.9%
Education				
Missing	8	0.5%	11	0.4%
0-8 years	37	2.2%	34	1.3%
Some high school	92	5.5%	100	3.7%
High school diploma/GED	414	24.8%	580	21.6%
School after high school	699	41.9%	995	37.1%
College degree or higher	418	25.1%	959	35.8%
Ethnicity				
White	1400	83.9%	2434	90.9%
Black	187	11.2%	134	5.0%
Hispanic	46	2.8%	66	2.5%
American Indian	8	0.5%	3	0.1%
Asian/Pacific Islander	8	0.5%	22	0.8%
Unknown	19	1.1%	20	0.7%
Family Income				
Missing	78	4.7%	149	5.6%
< $10,000	116	7.0%	98	3.7%
$10,000 - $19,999	347	20.8%	366	13.7%
$20,000 - $34,999	489	29.3%	811	30.3%
$35,000 - $49,999	325	19.5%	535	20.0%
$50,000 - $74,999	200	12.0%	447	16.7%
$75,000 +	113	6.8%	273	10.2%

Table 2.18
Prevalence of WHI-SE Outcomes[1] in HRT Participants at WHI-SE Baseline Exam

Data as of: February 28, 2003

	Without Uterus (N = 1668)		With Uterus (N = 2679)		All (N = 4347)	
Age-Related Maculopathy						
Left eye	245	15.3%	367	14.1%	612	14.6%
Right eye	245	15.3%	328	12.6%	573	13.6%
Both eyes	130	8.1%	182	7.0%	312	7.4%
Either eye	360	22.4%	513	19.8%	873	20.8%
Neovascular Age-Related Macular Degeneration						
Left eye	9	0.6%	12	0.5%	21	0.5%
Right eye	8	0.5%	17	0.7%	25	0.6%
Both eyes	2	0.1%	5	0.2%	7	0.2%
Either eye	15	0.9%	24	0.9%	39	0.9%
Geographical Age-Related Macular Degeneration						
Left eye	2	0.1%	6	0.2%	8	0.2%
Right eye	7	0.4%	8	0.3%	15	0.4%
Both eyes	1	0.1%	4	0.2%	5	0.1%
Either eye	8	0.5%	10	0.4%	18	0.4%
Early Age-Related Macular Degeneration						
Left eye	234	14.6%	349	13.4%	583	13.9%
Right eye	230	14.3%	303	11.7%	533	12.7%
Both eyes	111	6.9%	155	6.0%	266	6.3%
Either eye	353	22.0%	497	19.1%	850	20.2%
Diabetic Retinopathy						
Left eye	66	4.1%	52	2.0%	118	2.8%
Right eye	69	4.3%	53	2.0%	122	2.9%
Both eyes	45	2.8%	37	1.4%	82	2.0%
Either eye	90	5.6%	68	2.6%	158	3.8%
Large C/D Ratio[2]						
Present	88	5.3%	113	4.2%	201	4.6%
Questionable	79	4.7%	102	3.8%	181	4.2%
None	1500	89.9%	2464	92.0%	3964	91.2%
Do not know/cannot grade	1	0.1%	0	<0.1%	1	<0.1%
Glaucoma (self-reported)						
Yes	110	6.6%	148	5.5%	258	5.9%
No	1527	91.5%	2507	93.6%	4034	92.8%
Do not know	31	1.9%	24	0.9%	55	1.3%
Intraocular pressure at eye exam						
30+	2	0.1%	1	<0.1%	3	0.1%
<30	1650	98.9%	2635	98.4%	4285	98.6%
Do not know	16	1.0%	43	1.6%	59	1.4%
Cataract (self-reported)						
Yes	818	49.0%	1182	44.1%	2000	46.0%
No	770	46.2%	1366	51.0%	2136	49.1%
Do not know	80	4.8%	131	4.9%	211	4.9%

[1] Outcomes collected through July 7, 2002.
[2] A large C/D ratio indicates thinning of the edge of the nerve tissue inside the optic disc, and is possibly a sign of glaucoma.

3. DM Component

3.1 Recruitment

Age and race/ethnicity-specific DM recruitment data are presented in *Table 3.1 – Dietary Modification Component Age and Race/Ethnicity – Specific Recruitment*. 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 7.4% at AV-8. This report presents nutrient intake comparisons for each racial/ethnic group separately (*Table 3.3 – Nutrient Intake Monitoring in American Indian/Alaska Native Women*). 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 – Issues* 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-third serving 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 – Control – Intervention Difference in % Energy from Fat in WHI DM Participants Study Subject Characteristics and Session Participation from FFQs Collected in the Last Year*). The only participant characteristic that was consistently associated with a lower C-I difference was being Black compared to White ($p<0.01$). 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 – Body Weight*. 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 tended to decrease over time and there is not a statistically significant difference at AV-7 or AV-8, although the mean intervention body weight is less than in control women. Here we also describe the paired differences in weight change from baseline (Table 3.5 & Figure 3.2). From baseline to

AV-1, women in the intervention arm reduced body weight by an average of 2.2 kg in comparison to no change for women in the control arm. Although women in the intervention arm have gradually experienced a return to mean baseline weight by about AV-6, control women have gained weight over time and hence the difference between the arms of the trial is statistically significant at every annual visit ($p<0.01$). 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 – Reasons for Stopping DM give reasons for stopping DM Intervention activities categorized by general type and stratified by age and race/ethnicity. Overall, the major reasons for stopping given by participants were family responsibilities (11.2%), demands of work (9.5%), and issues of interest in the study (9.9%). 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 lack 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 Bone Density Analyses

Tables 3.8-3.9 – Bone Mineral Density Analysis 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 occurred with increases in mean bone mineral density in the whole body scan as well as the spine and hip scan. An increase in BMD is not expected from this intervention. There were, generally, similar trends by race/ethnicity. Possible reasons for these increases 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 3.10 – Adherence to Follow-up Contacts 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 3.11 – Lost-to-Follow-up and Vital Status: DM Participants 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 3.9% of the DM participants are lost-

to-follow-up or have stopped follow-up, and 3.0% 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 6.1 years, suggesting that approximately 17.0% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

3.6 Outcomes

Table 3.12 – Locally Verified Outcomes (Annualized Percentages) by Age and Race/Ethnicity for Dietary Modification contains counts of the number of locally verified major WHI outcomes for DM participants by race/ethnicity and age. Approximately 3% 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 115% of the expected number of breast cancers, 70% 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 3.13 - Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race//Ethnicity for DM Participants 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 percent energy from fat difference is less than the design assumptions. The WHI investigators and staff have undertaken regular, annual initiatives to improve adherence.

In 2000, the DM Intervention incorporated an Intensive Intervention Program (IIP) that consisted of a series of three interviews using motivational enhancement counseling techniques. A preliminary evaluation of the IIP among intervention participants indicated that 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 ($p<0.05$).

In 2001, we conducted a Targeted Message Campaign. Participants received a mailing designed to help them rediscover their intrinsic motivation(s) for participating in WHI, which was followed by a supportive motivational enhancement call. 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.

In 2002, 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 was performed using a questionnaire on usual fat-intake over the past 4 weeks. After scanning, computerized algorithms provide printed, individualized feedback on estimated grams of fat consumed (overall and by foods) and food-specific behavioral change suggestions. The dietary questionnaire was administered during summer

sessions and the written feedback was provided and reinforced in fall sessions. Overall, 74.6% of WHI intervention participants completed this protocol and the top five sources of fat were peanuts and other nuts; popcorn made with oil; beef, pork, lamb; peanut butter; and cheese.

At the Fall 2002 Steering Committee meeting, the WHI lead nutritionists conducted a workshop that provided a behavioral booster training aimed at re-energizing nutritionists by sharing information on effective adherence and retention strategies used by CCs, and identifying local options to support intervention participants' adherence to the low-fat dietary pattern.

For 2003, we are conducting a centralized PEFI protocol that will give women the opportunity to participate in a 2nd round of assessment and feedback. The CCC will mail a PEFI questionnaire to participants, scan returned forms, print the tailored feedback, and mail the printed feedback with interpretation guide to the participants. Thus, PEFI 2003 will be implemented in a self-help manner boosted by participants' familiarity with the questionnaire and feedback. Clinical Center nutritionists will also receive a copy of the feedback so that they can support this initiative.

In 2003 and 2004, the CCC is leading a series of dietary behavioral-focused conference calls with CC nutritionists, which are co-lead by the CCC Behaviorist and a CCC nutritionist. The intent of the calls is to support CC nutritionists in their motivational enhancement, group facilitation, or other behavioral approaches. During 2003, the focus will be adherence and during 2004, it will be close-out of the dietary intervention. Note that a similar series of calls were conducted in 1999, 2000 and 2001; and were well attended and very positively rated by CC nutritionists.

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

Data as of: February 28, 2003

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**48,835**			
50-54	6,961	149%	14%	10
55-59	11,041	118%	23%	20
60-69	22,712	108%	47%	45
70-79	8,121	70%	17%	25
Race/Ethnicity	**48,835**			
American Indian	202		<1%	
Asian	1,105		2%	
Black	5,262		11%	
Hispanic	1,845		4%	
White	39,762		81%	
Unknown	659		1%	

Table 3.2
Nutrient Intake Monitoring

Data as of: February 28, 2003

	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	26775	36.1	6.9	10.9	0.1	<.01
FFQ Year 2[4]	5926	26.3	7.6	8668	36.3	7.0	9.9	0.1	<.01
FFQ Year 3[5]	3241	27.7	7.9	4890	37.3	7.1	9.6	0.2	<.01
FFQ Year 4[6]	5050	28.6	8.1	7874	37.6	7.1	9.1	0.1	<.01
FFQ Year 5[7]	5551	29.0	8.2	8534	37.8	7.3	8.8	0.1	<.01
FFQ Year 6[8]	4763	29.5	8.1	7309	37.7	7.0	8.2	0.1	<.01
FFQ Year 7[9]	2168	29.9	8.1	3277	37.7	7.2	7.8	0.2	<.01
FFQ Year 8[10]	729	30.3	7.8	1165	37.6	7.2	7.4	0.4	<.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	210	25.7	9.3	237	33.1	8.6	7.5	0.8	<.01
24 Hr Recall, Year 5	118	26.4	9.5	175	34.3	8.3	7.9	1.0	<.01
24 Hr Recall, Year 6	80	26.4	10.0	97	34.9	8.3	8.4	1.4	<.01
24 Hr Recall, Year 6 Cohort	383	26.8	8.8	627	33.7	7.9	6.9	0.5	<.01
24 Hr Recall, Year 7	31	28.9	11.1	37	35.3	8.3	6.5	2.4	<.01
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	26775	1584.3	641.6	110.4	5.8	<.01
FFQ Year 2	5926	1479.6	534.8	8668	1575.8	625.5	96.3	10.0	<.01
FFQ Year 3	3241	1476.4	538.1	4890	1571.4	644.2	95.0	13.7	<.01
FFQ Year 4	5050	1443.5	536.5	7874	1562.0	635.0	118.5	10.8	<.01
FFQ Year 5	5551	1453.7	538.1	8534	1555.6	640.6	101.9	10.4	<.01
FFQ Year 6	4763	1432.4	544.1	7309	1533.5	625.5	101.1	11.1	<.01
FFQ Year 7	2168	1440.9	542.8	3277	1546.2	636.7	105.2	16.6	<.01
FFQ Year 8	729	1417.6	537.6	1165	1519.9	644.2	102.3	28.6	<.01
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	210	1439.8	401.9	237	1534.5	461.0	94.7	41.2	0.05
24 Hr Recall, Year 5	118	1442.6	472.1	175	1591.9	535.1	149.3	60.8	0.02
24 Hr Recall, Year 6	80	1423.9	537.0	97	1633.1	516.3	209.1	79.4	<.01
24 Hr Recall, Year 6 Cohort	383	1431.9	392.4	627	1554.8	492.9	122.8	29.7	<.01
24 Hr Recall, Year 7	31	1271.1	364.7	37	1553.2	495.7	282.1	107.4	0.03

(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] 1269 (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] 756 (14%) Intervention women had <=20% energy from fat at year 5.
[8] 524 (11%) Intervention women had <=20% energy from fat at year 6.
[9] 224 (10%) Intervention women had <=20% energy from fat at year 7.
[10] 69 (9%) Intervention women had <=20% energy from fat at year 8.

Table 3.2 (continued)
Nutrient Intake Monitoring

Data as of: February 28, 2003

	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	26775	64.5	31.8	23.0	0.3	<.01
FFQ Year 2	5926	43.5	22.3	8668	64.5	31.3	21.0	0.5	<.01
FFQ Year 3	3241	45.9	23.7	4890	66.0	32.5	20.2	0.7	<.01
FFQ Year 4	5050	46.2	23.9	7874	66.2	32.2	20.0	0.5	<.01
FFQ Year 5	5551	47.3	24.3	8534	66.4	33.0	19.1	0.5	<.01
FFQ Year 6	4763	47.2	23.9	7309	65.1	31.9	17.9	0.5	<.01
FFQ Year 7	2168	48.3	25.3	3277	65.8	32.6	17.5	0.8	<.01
FFQ Year 8	729	47.8	23.6	1165	64.5	32.8	16.6	1.4	<.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	210	41.5	20.5	237	58.2	25.8	16.7	2.2	<.01
24 Hr Recall, Year 5	118	42.8	22.2	175	62.5	28.8	19.6	3.1	<.01
24 Hr Recall, Year 6	80	43.2	28.9	97	64.7	29.0	21.5	4.4	<.01
24 Hr Recall, Year 6 Cohort	383	43.1	20.7	627	60.0	27.2	16.9	1.6	<.01
24 Hr Recall, Year 7	31	41.6	21.6	37	60.8	25.2	19.2	5.8	<.01
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	26775	22.5	11.9	8.4	0.1	<.01
FFQ Year 2	5926	14.8	8.2	8668	22.5	11.7	7.7	0.2	<.01
FFQ Year 3	3241	15.5	8.9	4890	22.9	12.2	7.4	0.2	<.01
FFQ Year 4	5050	15.7	8.9	7874	23.1	12.2	7.4	0.2	<.01
FFQ Year 5	5551	16.1	9.1	8534	23.2	12.5	7.1	0.2	<.01
FFQ Year 6	4763	16.0	8.7	7309	22.8	12.1	6.7	0.2	<.01
FFQ Year 7	2168	16.6	9.5	3277	23.1	12.6	6.4	0.3	<.01
FFQ Year 8	729	16.4	8.9	1165	22.9	13.0	6.4	0.5	<.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	210	13.5	7.7	237	19.5	10.0	6.0	0.9	<.01
24 Hr Recall, Year 5	118	13.7	7.4	175	21.1	10.7	7.4	1.1	<.01
24 Hr Recall, Year 6	80	13.4	9.4	97	21.1	10.7	7.8	1.5	<.01
24 Hr Recall, Year 6 Cohort	383	13.7	7.5	627	19.7	10.1	6.0	0.6	<.01
24 Hr Recall, Year 7	31	13.2	8.5	37	19.8	9.5	6.6	2.2	<.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: February 28, 2003

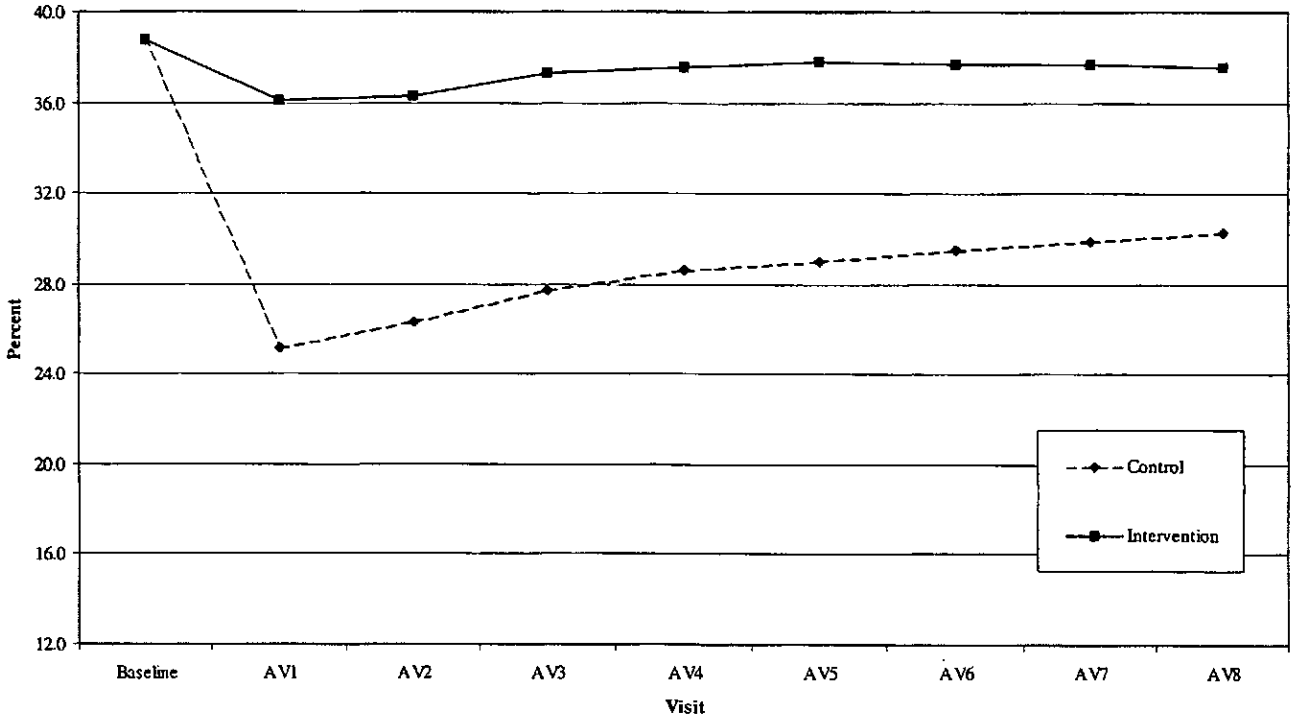
	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Polyunsaturated Fat (g)									
FFQ Baseline	19541	15.3	7.6	29294	15.3	7.6	0.0	0.1	0.79
FFQ Year 1	18098	7.9	4.4	26775	12.5	6.7	4.6	0.1	<.01
FFQ Year 2	5926	8.3	4.5	8668	12.4	6.5	4.1	0.1	<.01
FFQ Year 3	3241	8.8	4.7	4890	12.8	6.8	4.0	0.1	<.01
FFQ Year 4	5050	9.0	4.9	7874	12.8	6.7	3.8	0.1	<.01
FFQ Year 5	5551	9.2	5.0	8534	12.8	6.9	3.7	0.1	<.01
FFQ Year 6	4763	9.2	5.1	7309	12.6	6.5	3.3	0.1	<.01
FFQ Year 7	2168	9.3	5.2	3277	12.7	6.7	3.4	0.2	<.01
FFQ Year 8	729	9.2	4.8	1165	12.2	6.4	3.0	0.3	<.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	210	8.7	4.9	237	11.7	6.9	3.0	0.6	<.01
24 Hr Recall, Year 5	118	9.1	6.4	175	12.3	8.1	3.2	0.9	<.01
24 Hr Recall, Year 6	80	9.5	7.6	97	13.7	7.8	4.3	1.2	<.01
24 Hr Recall, Year 6 Cohort	383	9.0	4.8	627	12.3	6.4	3.3	0.4	<.01
24 Hr Recall, Year 7	31	8.8	4.8	37	12.9	6.0	4.1	1.3	<.01
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	26693	3.8	2.0	1.2	0.0	<.01
FFQ Year 2	5903	5.1	2.4	8636	3.9	2.0	1.2	0.0	<.01
FFQ Year 3	3235	5.2	2.5	4876	3.9	2.0	1.3	0.1	<.01
FFQ Year 4	5040	5.1	2.4	7860	3.8	2.0	1.3	0.0	<.01
FFQ Year 5	5528	5.1	2.5	8508	3.8	2.1	1.2	0.0	<.01
FFQ Year 6	4740	5.0	2.4	7284	3.8	2.0	1.2	0.0	<.01
FFQ Year 7	2152	4.9	2.4	3264	3.8	2.0	1.1	0.1	<.01
FFQ Year 8	724	5.0	2.4	1161	3.7	2.0	1.2	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	26683	4.2	2.3	0.8	0.0	<.01
FFQ Year 2	5902	4.9	2.5	8630	4.1	2.2	0.7	0.0	<.01
FFQ Year 3	3234	4.6	2.5	4871	4.0	2.2	0.7	0.1	<.01
FFQ Year 4	5036	4.4	2.4	7848	3.9	2.2	0.5	0.0	<.01
FFQ Year 5	5524	4.3	2.3	8499	3.8	2.2	0.5	0.0	<.01
FFQ Year 6	4738	4.2	2.4	7276	3.8	2.1	0.5	0.0	<.01
FFQ Year 7	2151	4.1	2.3	3262	3.8	2.1	0.4	0.1	<.01
FFQ Year 8	724	4.0	2.2	1160	3.7	2.1	0.3	0.1	<.01

[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: February 28, 2003

% Energy from Fat [1]



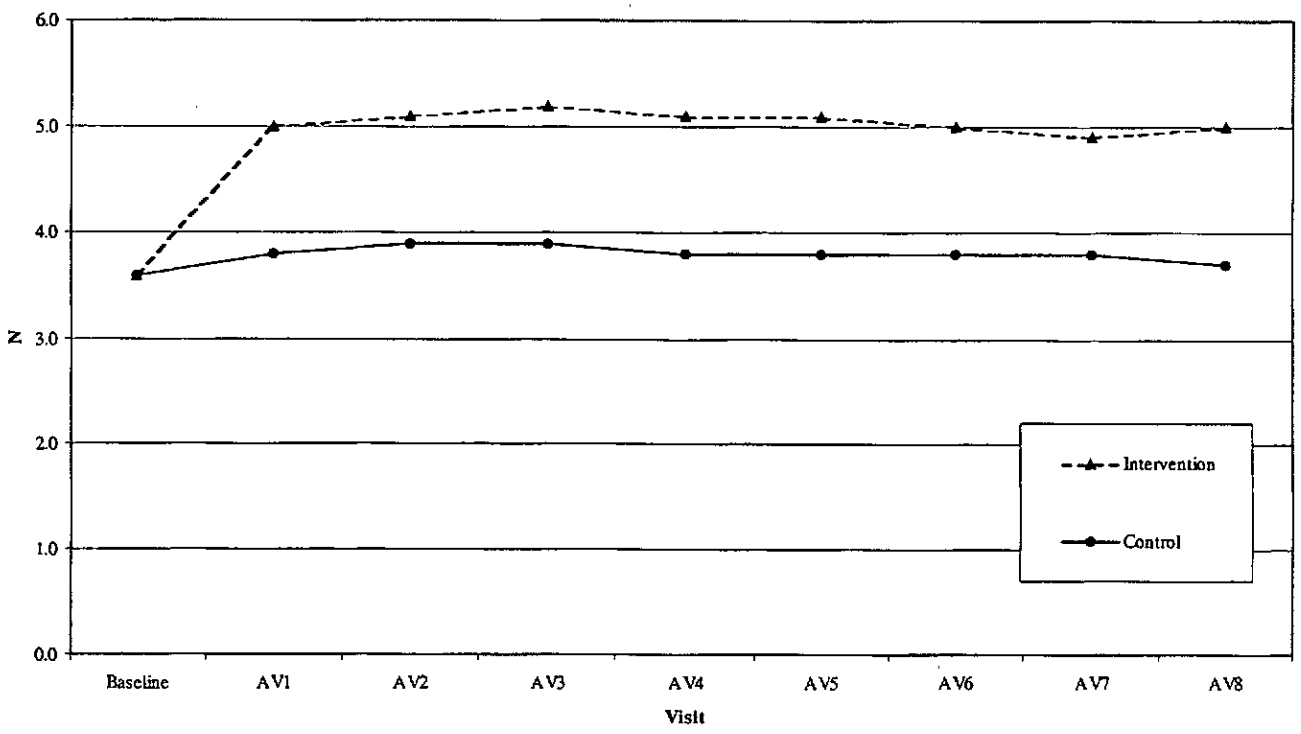
(continues)

[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: February 28, 2003

Fruit & Vegetable Servings per Day



Grain Servings per Day

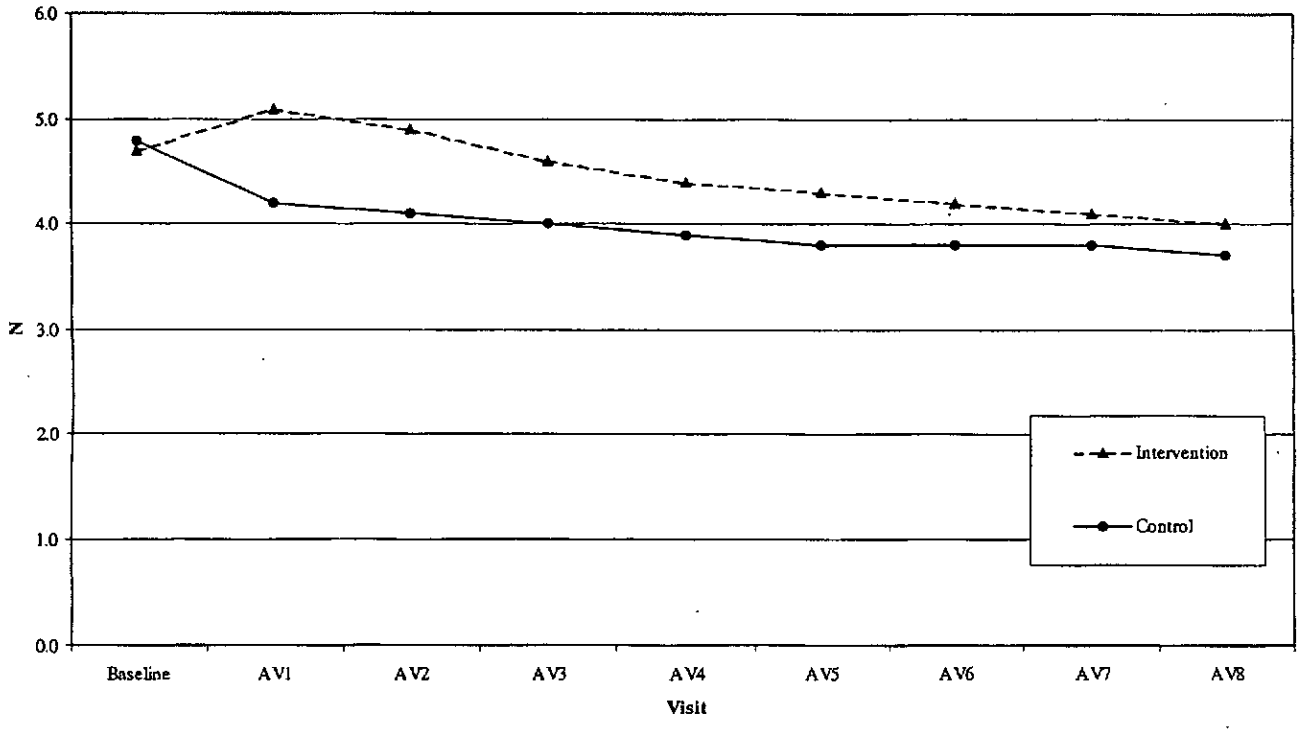


Table 3.3
Nutrient Intake Monitoring in American Indian/Alaskan Native Women

Data as of: February 28, 2003

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	88	39.5	5.7	114	40.0	5.2	0.5	0.8	0.49
FFQ Year 1[3]	73	27.5	8.9	96	38.0	8.0	10.5	1.3	<.01
FFQ Year 2[4]	28	26.9	8.8	32	38.2	6.8	11.3	2.0	<.01
FFQ Year 3[5]	18	31.3	8.9	41	38.0	7.0	6.7	2.1	<.01
FFQ Year 4[6]	23	30.3	9.3	28	39.9	7.6	9.6	2.4	<.01
FFQ Year 5[7]	19	27.6	7.6	16	39.9	7.8	12.3	2.6	<.01
FFQ Year 6[8]	21	32.9	7.5	24	42.1	8.2	9.2	2.4	<.01
FFQ Year 7[9]	11	26.9	7.5	7	37.7	10.3	10.8	4.2	0.04
FFQ Year 8[10]	2	31.9	1.5	5	37.6	5.6	5.7	4.3	0.09
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	21	1065.3	420.2	24	1831.3	840.9	765.9	202.7	<.01
FFQ Year 7	11	1508.4	487.2	7	2010.8	1379.7	502.4	449.0	0.44
FFQ Year 8	2	1406.8	452.2	5	1594.1	516.4	187.2	421.9	0.72
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	21	38.5	16.6	24	86.3	47.2	47.8	10.9	<.01
FFQ Year 7	11	44.5	19.0	7	80.6	49.2	36.1	16.3	0.05
FFQ Year 8	2	49.5	13.7	5	68.9	33.3	19.4	25.5	0.40
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] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 14 (19%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 1.
[4] 6 (21%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 2.
[5] 1 (6%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 3.
[6] 5 (22%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 4.
[7] 3 (16%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 5.
[8] 2 (10%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 6.
[9] 2 (18%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 7.
[10] 0 (0%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 8.

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

Data as of: February 28, 2003

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	88	26.9	14.2	114	27.9	14.1	1.0	2.0	0.42
FFQ Year 1[3]	73	17.4	11.0	96	23.7	18.0	6.2	2.4	<.01
FFQ Year 2[4]	28	15.5	9.9	32	23.3	14.9	7.8	3.3	<.01
FFQ Year 3[5]	18	19.8	13.9	41	22.9	11.9	3.0	3.5	0.27
FFQ Year 4[6]	23	17.2	8.4	28	28.3	16.6	11.2	3.8	<.01
FFQ Year 5[7]	19	18.3	11.6	16	22.0	17.0	3.7	4.8	0.50
FFQ Year 6[8]	21	13.2	6.5	24	29.3	15.6	16.1	3.7	<.01
FFQ Year 7[9]	11	15.1	6.7	7	29.3	22.5	14.2	7.1	0.09
FFQ Year 8[10]	2	15.6	4.7	5	24.6	12.7	9.0	9.7	0.28
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	21	7.4	3.7	24	17.5	12.0	10.1	2.7	<.01
FFQ Year 7	11	8.2	3.8	7	14.5	6.1	6.4	2.3	0.02
FFQ Year 8	2	10.0	1.4	5	14.6	7.3	4.6	5.5	0.32
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	21	4.5	3.0	24	3.6	2.2	0.9	0.8	0.31
FFQ Year 7	11	6.3	3.5	7	5.1	3.0	1.2	1.6	0.53
FFQ Year 8	2	3.9	1.3	5	4.4	2.5	0.5	1.9	0.95
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	21	3.0	1.9	24	4.9	3.1	1.9	0.8	0.03
FFQ Year 7	11	4.3	2.7	7	4.1	2.3	0.3	1.3	0.88
FFQ Year 8	2	4.5	1.5	5	2.8	1.9	1.7	1.6	0.19

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 14 (19%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 1.
[4] 6 (21%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 2.
[5] 1 (6%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 3.
[6] 5 (22%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 4.
[7] 3 (16%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 5.
[8] 2 (10%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 6.
[9] 2 (18%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 7.
[10] 0 (0%) American Indian/Alaskan Native 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: February 28, 2003

	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	189	37.4	6.6	7.8	0.9	<.01
FFQ Year 5[7]	129	28.9	8.2	210	37.0	7.2	8.1	0.8	<.01
FFQ Year 6[8]	92	28.7	7.5	178	37.8	6.3	9.0	0.9	<.01
FFQ Year 7[9]	21	26.2	7.7	39	37.0	7.6	10.7	2.1	<.01
FFQ Year 8[10]	3	34.4	7.5	9	39.1	7.7	4.7	5.1	0.41
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	189	1507.8	612.0	32.1	74.5	0.97
FFQ Year 5	129	1508.9	635.5	210	1504.0	813.5	4.9	84.0	0.33
FFQ Year 6	92	1439.7	524.7	178	1558.3	773.8	118.6	89.8	0.28
FFQ Year 7	21	1548.2	639.4	39	1462.6	529.5	85.5	154.2	0.62
FFQ Year 8	3	1221.9	644.6	9	1266.2	569.4	44.3	390.2	0.89
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	189	63.3	29.6	13.8	3.6	<.01
FFQ Year 5	129	49.9	29.5	210	62.8	39.0	12.9	4.0	<.01
FFQ Year 6	92	46.2	22.5	178	65.7	35.2	19.6	4.0	<.01
FFQ Year 7	21	47.1	29.8	39	61.4	29.8	14.2	8.1	0.03
FFQ Year 8	3	46.2	27.8	9	57.6	34.3	11.5	22.1	0.66
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] 17 (13%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 5.
[8] 10 (11%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 6.
[9] 5 (24%) 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: February 28, 2003

	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	189	19.9	9.6	4.5	1.2	<.01
FFQ Year 5[7]	129	15.8	10.2	210	19.7	13.3	3.8	1.4	<.01
FFQ Year 6[8]	92	14.4	8.2	178	20.9	12.4	6.5	1.4	<.01
FFQ Year 7[9]	21	16.0	12.2	39	19.6	10.7	3.7	3.0	0.07
FFQ Year 8[10]	3	13.8	8.6	9	18.5	11.6	4.7	7.4	0.56
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	189	13.4	6.5	2.6	0.8	<.01
FFQ Year 5	129	10.5	7.2	210	13.5	8.1	3.0	0.9	<.01
FFQ Year 6	92	9.9	5.1	178	13.9	7.0	4.0	0.8	<.01
FFQ Year 7	21	9.2	5.3	39	12.4	6.9	3.2	1.7	0.04
FFQ Year 8	3	9.1	5.7	9	10.8	7.4	1.7	4.7	0.81
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	189	3.2	1.9	1.5	0.3	<.01
FFQ Year 5	129	4.9	2.3	210	3.5	2.0	1.3	0.2	<.01
FFQ Year 6	92	4.8	2.4	178	3.5	1.9	1.3	0.3	<.01
FFQ Year 7	21	5.2	2.2	39	3.7	2.1	1.5	0.6	<.01
FFQ Year 8	3	5.0	3.5	9	2.7	1.1	2.3	1.2	0.62
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	189	4.4	2.1	0.6	0.3	0.01
FFQ Year 5	129	5.0	2.3	210	4.4	3.0	0.6	0.3	<.01
FFQ Year 6	92	4.9	2.2	178	4.5	2.8	0.4	0.3	0.05
FFQ Year 7	21	5.5	2.5	39	4.0	1.6	1.5	0.5	<.01
FFQ Year 8	3	4.0	2.7	9	3.6	1.5	0.3	1.2	0.89

(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] 17 (13%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 5.
[8] 10 (11%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 6.
[9] 5 (24%) 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: February 28, 2003

	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	2629	36.9	7.4	8.8	0.2	<.01
FFQ Year 2[4]	613	29.4	8.0	829	36.4	7.3	7.0	0.4	<.01
FFQ Year 3[5]	350	29.4	7.9	514	38.2	7.2	8.8	0.5	<.01
FFQ Year 4[6]	485	30.7	8.3	773	37.5	7.4	6.8	0.4	<.01
FFQ Year 5[7]	548	31.2	8.6	802	37.3	7.5	6.1	0.4	<.01
FFQ Year 6[8]	549	31.0	8.0	825	37.5	7.6	6.5	0.4	<.01
FFQ Year 7[9]	160	31.2	7.4	265	37.0	6.6	5.8	0.7	<.01
FFQ Year 8[10]	64	32.4	7.6	73	36.6	7.2	4.2	1.3	<.01
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	2629	1492.4	774.6	109.7	21.8	<.01
FFQ Year 2	613	1393.4	717.5	829	1449.0	724.7	55.6	38.4	0.36
FFQ Year 3	350	1386.7	631.4	514	1537.1	791.3	150.3	50.6	0.01
FFQ Year 4	485	1342.7	622.4	773	1435.9	744.8	93.2	40.6	0.10
FFQ Year 5	548	1356.9	638.4	802	1368.5	690.3	11.6	37.1	0.86
FFQ Year 6	549	1291.6	553.8	825	1387.1	753.9	95.5	37.5	0.16
FFQ Year 7	160	1320.5	573.7	265	1355.4	733.7	35.0	67.9	0.90
FFQ Year 8	64	1313.2	749.2	73	1360.0	905.8	46.9	143.2	0.88
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	2629	62.3	37.2	18.7	1.0	<.01
FFQ Year 2	613	46.4	32.5	829	60.1	36.0	13.6	1.8	<.01
FFQ Year 3	350	46.1	27.0	514	66.3	38.6	20.2	2.4	<.01
FFQ Year 4	485	46.2	26.7	773	60.9	35.8	14.7	1.9	<.01
FFQ Year 5	548	47.5	27.5	802	58.1	34.6	10.5	1.8	<.01
FFQ Year 6	549	45.1	25.1	825	59.0	37.5	13.9	1.8	<.01
FFQ Year 7	160	45.7	23.2	265	57.2	36.0	11.6	3.2	<.01
FFQ Year 8	64	48.3	33.8	73	56.5	43.6	8.2	6.7	0.27
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] 44 (8%) Black/African American Intervention women had <=20% energy from fat at year 5.
[8] 48 (9%) Black/African American Intervention women had <=20% energy from fat at year 6.
[9] 11 (7%) Black/African American Intervention women had <=20% energy from fat at year 7.
[10] 3 (5%) 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: February 28, 2003

	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	2629	20.5	12.8	6.2	0.3	<.01
FFQ Year 2[4]	613	15.3	11.8	829	19.8	12.3	4.5	0.6	<.01
FFQ Year 3[5]	350	15.0	9.5	514	21.8	13.4	6.8	0.8	<.01
FFQ Year 4[6]	485	14.9	9.3	773	20.0	12.5	5.2	0.7	<.01
FFQ Year 5[7]	548	15.4	9.3	802	19.0	12.2	3.6	0.6	<.01
FFQ Year 6[8]	549	14.5	8.4	825	19.2	13.0	4.7	0.6	<.01
FFQ Year 7[9]	160	14.8	8.4	265	18.8	12.3	4.0	1.1	<.01
FFQ Year 8[10]	64	15.7	11.5	73	18.5	14.9	2.9	2.3	0.28
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	2629	12.7	8.0	4.0	0.2	<.01
FFQ Year 2	613	9.2	6.2	829	12.1	7.5	2.9	0.4	<.01
FFQ Year 3	350	9.3	5.6	514	13.4	8.0	4.1	0.5	<.01
FFQ Year 4	485	9.5	5.7	773	12.4	7.6	2.9	0.4	<.01
FFQ Year 5	548	9.6	5.8	802	12.0	7.7	2.4	0.4	<.01
FFQ Year 6	549	9.3	5.6	825	12.1	7.8	2.9	0.4	<.01
FFQ Year 7	160	9.4	4.9	265	11.7	7.8	2.3	0.7	<.01
FFQ Year 8	64	9.9	7.1	73	11.7	9.9	1.8	1.5	0.25
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	2623	3.4	2.1	1.1	0.1	<.01
FFQ Year 2	612	4.5	2.6	824	3.5	2.2	1.0	0.1	<.01
FFQ Year 3	350	4.7	2.7	514	3.7	2.3	1.0	0.2	<.01
FFQ Year 4	485	4.8	2.7	773	3.4	2.1	1.3	0.1	<.01
FFQ Year 5	545	4.6	2.7	801	3.5	2.1	1.2	0.1	<.01
FFQ Year 6	549	4.5	2.6	823	3.5	2.2	1.0	0.1	<.01
FFQ Year 7	160	4.6	2.8	264	3.4	2.0	1.2	0.2	<.01
FFQ Year 8	64	4.4	2.5	72	3.1	1.7	1.3	0.4	<.01
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	2621	3.8	2.5	0.6	0.1	<.01
FFQ Year 2	612	4.2	2.6	823	3.7	2.4	0.5	0.1	<.01
FFQ Year 3	350	4.2	2.7	514	3.8	2.5	0.4	0.2	0.01
FFQ Year 4	485	4.0	2.5	771	3.6	2.4	0.4	0.1	<.01
FFQ Year 5	544	3.9	2.5	800	3.4	2.2	0.5	0.1	<.01
FFQ Year 6	549	3.6	2.2	820	3.4	2.1	0.3	0.1	<.01
FFQ Year 7	160	3.7	2.2	264	3.5	2.5	0.2	0.2	0.15
FFQ Year 8	64	3.7	2.7	72	3.6	2.7	0.1	0.5	0.32

(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] 44 (8%) Black/African American Intervention women had <=20% energy from fat at year 5.
[8] 48 (9%) Black/African American Intervention women had <=20% energy from fat at year 6.
[9] 11 (7%) Black/African American Intervention women had <=20% energy from fat at year 7.
[10] 3 (5%) 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: February 28, 2003

	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]	163	30.9	8.3	295	37.0	7.2	6.1	0.7	<.01
FFQ Year 5[7]	178	29.5	8.3	296	36.4	7.5	6.9	0.7	<.01
FFQ Year 6[8]	146	30.4	8.1	256	37.0	6.5	6.6	0.7	<.01
FFQ Year 7[9]	51	30.4	9.5	74	37.1	7.4	6.8	1.5	<.01
FFQ Year 8[10]	14	26.7	5.1	31	35.2	5.6	8.5	1.8	<.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	163	1385.3	651.8	295	1526.8	757.5	141.5	70.4	0.04
FFQ Year 5	178	1374.5	663.3	296	1572.6	910.2	198.1	78.4	0.03
FFQ Year 6	146	1313.3	684.3	256	1484.0	719.6	170.7	73.3	0.01
FFQ Year 7	51	1224.4	620.6	74	1467.3	727.4	243.0	124.8	0.05
FFQ Year 8	14	1407.9	633.7	31	1501.2	689.9	93.3	216.8	0.77
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	163	48.1	27.8	295	63.5	35.5	15.5	3.2	<.01
FFQ Year 5	178	46.1	29.9	296	65.8	44.6	19.7	3.8	<.01
FFQ Year 6	146	44.6	26.7	256	61.7	33.6	17.1	3.2	<.01
FFQ Year 7	51	41.3	29.0	74	60.7	34.4	19.4	5.9	<.01
FFQ Year 7	14	40.2	16.2	31	59.1	29.0	18.9	8.3	0.02
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] 24 (13%) Hispanic/Latino Intervention women had <=20% energy from fat at year 5.
[8] 15 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 6.
[9] 6 (12%) 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: February 28, 2003

	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]	163	15.7	9.9	295	21.2	12.3	5.4	1.1	<.01
FFQ Year 5[7]	178	15.3	10.5	296	22.3	15.8	7.0	1.3	<.01
FFQ Year 6[8]	146	14.6	9.6	256	21.0	12.4	6.4	1.2	<.01
FFQ Year 7[9]	51	13.6	11.8	74	20.5	13.0	6.9	2.3	<.01
FFQ Year 8[10]	14	13.6	6.7	31	20.9	10.8	7.3	3.1	0.01
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	163	9.4	5.7	295	12.4	7.1	3.1	0.6	<.01
FFQ Year 5	178	9.1	6.4	296	12.7	9.3	3.7	0.8	<.01
FFQ Year 6	146	8.9	5.6	256	11.8	6.6	3.0	0.7	<.01
FFQ Year 7	51	8.2	5.1	74	11.8	7.2	3.6	1.2	<.01
FFQ Year 8	14	7.5	3.4	31	10.6	6.5	3.2	1.8	0.09
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	163	4.7	2.7	295	3.2	2.1	1.5	0.2	<.01
FFQ Year 5	177	4.4	2.5	296	3.3	2.1	1.2	0.2	<.01
FFQ Year 6	144	4.4	2.5	256	3.1	2.1	1.3	0.2	<.01
FFQ Year 7	51	4.3	3.0	74	3.1	2.1	1.1	0.5	0.02
FFQ Year 8	14	5.3	2.8	31	3.0	1.4	2.3	0.6	0.01
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	163	4.3	2.9	295	4.6	2.9	0.3	0.3	0.19
FFQ Year 5	177	4.3	3.0	296	4.8	3.4	0.4	0.3	0.15
FFQ Year 6	144	4.3	3.2	256	4.4	3.1	0.1	0.3	0.47
FFQ Year 7	51	3.7	2.6	74	4.4	2.6	0.7	0.5	0.04
FFQ Year 8	14	4.9	2.8	31	4.8	3.2	0.1	1.0	0.67

(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] 24 (13%) Hispanic/Latino Intervention women had <=20% energy from fat at year 5.
[8] 15 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 6.
[9] 6 (12%) 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: February 28, 2003

	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	22153	36.0	6.8	11.3	0.1	<.01
FFQ Year 2[4]	4833	25.8	7.5	7167	36.2	7.0	10.4	0.1	<.01
FFQ Year 3[5]	2589	27.3	7.8	3929	37.2	7.1	9.9	0.2	<.01
FFQ Year 4[6]	4202	28.2	8.0	6478	37.6	7.0	9.5	0.1	<.01
FFQ Year 5[7]	4604	28.8	8.1	7117	37.9	7.3	9.2	0.1	<.01
FFQ Year 6[8]	3908	29.3	8.2	5935	37.7	7.0	8.5	0.2	<.01
FFQ Year 7[9]	1908	29.8	8.1	2869	37.7	7.2	7.9	0.2	<.01
FFQ Year 8[10]	643	30.1	7.9	1035	37.8	7.2	7.7	0.4	<.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	22153	1599.0	611.4	113.4	6.1	<.01
FFQ Year 2	4833	1492.8	497.0	7167	1590.8	597.6	98.0	10.4	<.01
FFQ Year 3	2589	1484.7	511.8	3929	1582.9	618.6	98.2	14.6	<.01
FFQ Year 4	4202	1457.5	516.0	6478	1580.2	611.1	122.7	11.4	<.01
FFQ Year 5	4604	1465.7	514.1	7117	1579.3	611.1	113.6	10.9	<.01
FFQ Year 6	3908	1456.5	533.8	5935	1553.5	591.5	97.0	11.7	<.01
FFQ Year 7	1908	1456.8	534.4	2869	1564.6	617.7	107.8	17.3	<.01
FFQ Year 8	643	1428.3	509.7	1035	1537.1	622.1	108.7	29.2	<.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	22153	64.8	30.5	23.9	0.3	<.01
FFQ Year 2	4833	42.9	20.2	7167	64.9	30.1	21.9	0.5	<.01
FFQ Year 3	2589	45.3	22.5	3929	66.3	31.5	21.0	0.7	<.01
FFQ Year 4	4202	46.0	23.2	6478	67.0	31.5	21.0	0.6	<.01
FFQ Year 5	4604	47.2	23.5	7117	67.5	31.8	20.3	0.5	<.01
FFQ Year 6	3908	47.6	23.7	5935	66.0	30.6	18.4	0.6	<.01
FFQ Year 7	1908	48.8	25.4	2869	66.7	32.0	17.9	0.9	<.01
FFQ Year 8	643	47.9	22.5	1035	65.4	32.0	17.5	1.4	<.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] 1098 (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] 657 (14%) White Intervention women had <=20% energy from fat at year 5.
[8] 444 (11%) White Intervention women had <=20% energy from fat at year 6.
[9] 199 (10%) White Intervention women had <=20% energy from fat at year 7.
[10] 66 (10%) White Intervention women had <=20% energy from fat at year 8.

Table 3.3 (continued)
Nutrient Intake Monitoring in White Women

Data as of: February 28, 2003

	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	22153	22.9	11.6	8.8	0.1	<.01
FFQ Year 2[4]	4833	14.7	7.5	7167	22.9	11.4	8.1	0.2	<.01
FFQ Year 3[5]	2589	15.5	8.6	3929	23.3	12.0	7.8	0.3	<.01
FFQ Year 4[6]	4202	15.8	8.8	6478	23.7	12.1	7.9	0.2	<.01
FFQ Year 5[7]	4604	16.3	8.9	7117	23.9	12.2	7.6	0.2	<.01
FFQ Year 6[8]	3908	16.3	8.8	5935	23.4	11.9	7.0	0.2	<.01
FFQ Year 7[9]	1908	16.9	9.5	2869	23.6	12.5	6.6	0.3	<.01
FFQ Year 8[10]	643	16.6	8.6	1035	23.3	13.0	6.7	0.6	<.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	22153	12.4	6.4	4.7	0.1	<.01
FFQ Year 2	4833	8.1	4.1	7167	12.3	6.2	4.2	0.1	<.01
FFQ Year 3	2589	8.6	4.4	3929	12.7	6.5	4.1	0.1	<.01
FFQ Year 4	4202	8.9	4.7	6478	12.8	6.5	4.0	0.1	<.01
FFQ Year 5	4604	9.0	4.7	7117	12.9	6.6	3.9	0.1	<.01
FFQ Year 6	3908	9.2	4.9	5935	12.6	6.2	3.4	0.1	<.01
FFQ Year 7	1908	9.3	5.2	2869	12.8	6.5	3.5	0.2	<.01
FFQ Year 8	643	9.2	4.5	1035	12.3	6.1	3.1	0.3	<.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	22078	3.9	2.0	1.2	0.0	<.01
FFQ Year 2	4815	5.2	2.3	7140	4.0	2.0	1.2	0.0	<.01
FFQ Year 3	2584	5.3	2.4	3915	4.0	2.0	1.3	0.1	<.01
FFQ Year 4	4194	5.2	2.4	6464	3.9	2.0	1.3	0.0	<.01
FFQ Year 5	4585	5.2	2.4	7092	3.9	2.1	1.2	0.0	<.01
FFQ Year 6	3888	5.1	2.4	5912	3.9	2.0	1.2	0.0	<.01
FFQ Year 7	1892	5.0	2.4	2857	3.8	1.9	1.1	0.1	<.01
FFQ Year 8	638	5.0	2.4	1032	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	22070	4.2	2.2	0.9	0.0	<.01
FFQ Year 2	4814	5.0	2.4	7135	4.1	2.1	0.8	0.0	<.01
FFQ Year 3	2583	4.6	2.5	3910	3.9	2.1	0.7	0.1	<.01
FFQ Year 4	4190	4.4	2.3	6454	3.9	2.1	0.6	0.0	<.01
FFQ Year 5	4582	4.3	2.2	7084	3.8	2.0	0.5	0.0	<.01
FFQ Year 6	3886	4.3	2.4	5907	3.7	2.0	0.5	0.0	<.01
FFQ Year 7	1891	4.1	2.2	2855	3.8	2.0	0.4	0.1	<.01
FFQ Year 8	638	4.0	2.1	1031	3.7	2.0	0.3	0.1	<.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] 1098 (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] 657 (14%) White Intervention women had <=20% energy from fat at year 5.
[8] 444 (11%) White Intervention women had <=20% energy from fat at year 6.
[9] 199 (10%) White Intervention women had <=20% energy from fat at year 7.
[10] 66 (10%) 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: February 28, 2003

	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]	73	29.1	8.2	93	38.4	7.5	9.3	1.2	<.01
FFQ Year 6[8]	47	31.0	8.2	91	39.0	6.4	8.1	1.3	<.01
FFQ Year 7[9]	17	33.7	8.8	23	38.5	7.4	4.8	2.6	0.08
FFQ Year 8[10]	3	35.1	8.5	12	35.5	7.7	0.5	5.1	0.94
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	73	1460.1	556.5	93	1448.0	637.8	12.1	94.4	0.53
FFQ Year 6	47	1594.4	524.1	91	1570.4	645.5	24.0	109.1	0.53
FFQ Year 7	17	1267.5	597.8	23	1702.5	888.2	434.9	249.2	0.09
FFQ Year 8	3	1601.8	714.3	12	1219.5	415.6	382.3	306.0	0.46
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	73	48.2	26.4	93	62.8	32.7	14.6	4.7	<.01
FFQ Year 6	47	54.7	23.6	91	69.0	34.8	14.3	5.7	<.01
FFQ Year 7	17	43.2	12.9	23	72.8	40.2	29.5	10.1	<.01
FFQ Year 8	3	58.4	16.3	12	50.0	23.0	8.4	14.3	0.34
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 (15%) Unknown Intervention women had <=20% energy from fat at year 5.
[8] 5 (11%) Unknown Intervention women had <=20% energy from fat at year 6.
[9] 1 (6%) 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: February 28, 2003

	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]	73	15.8	9.3	93	21.4	11.5	5.6	1.7	<.01
FFQ Year 6[8]	47	17.8	9.0	91	23.5	13.1	5.6	2.1	<.01
FFQ Year 7[9]	17	14.8	5.1	23	25.9	15.7	11.1	4.0	0.01
FFQ Year 8[10]	3	20.1	8.2	12	16.3	7.8	3.8	5.1	0.44
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	73	9.8	5.4	93	12.5	7.4	2.7	1.0	0.02
FFQ Year 6	47	11.4	5.4	91	13.6	6.6	2.2	1.1	0.04
FFQ Year 7	17	8.2	2.8	23	13.9	8.4	5.6	2.1	<.01
FFQ Year 8	3	10.3	2.1	12	10.0	5.3	0.3	3.2	0.42
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	73	4.9	2.6	93	3.4	2.2	1.5	0.4	<.01
FFQ Year 6	46	5.5	2.4	91	4.0	2.0	1.6	0.4	<.01
FFQ Year 7	17	3.8	2.6	23	5.5	3.6	1.6	1.0	0.13
FFQ Year 8	3	3.8	2.4	12	4.3	2.3	0.5	1.5	0.80
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	73	4.7	2.3	93	3.8	2.3	0.9	0.4	<.01
FFQ Year 6	46	4.9	2.5	91	3.7	2.0	1.2	0.4	<.01
FFQ Year 7	17	4.2	2.7	23	3.9	2.2	0.2	0.8	0.86
FFQ Year 8	3	5.3	3.2	12	2.4	1.3	2.8	1.1	0.08

(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 (15%) Unknown Intervention women had <=20% energy from fat at year 5.
[8] 5 (11%) Unknown Intervention women had <=20% energy from fat at year 6.
[9] 1 (6%) 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: February 28, 2003

	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			19.6%				19.6%				19.6%	
Age												
60-69	6445				6445				6445			
50-54 vs. 60-69	1959	0.55			1959	0.52			1959	0.73		
55-59 vs. 60-69	3180	0.14			3180	0.04			3180	0.13		
70-79 vs. 60-69	2162	-0.77 *			2162	-0.58			2162	-0.61		
Ethnicity												
White	11391				11391							
American Indian vs. White	33	3.70			33	3.64			33	4.01		
Asian/Pacific Islander vs. White	318	-0.44			318	-0.43			318	-0.52		
Black vs. White	1369	-1.93 **			1369	-1.86 **			1369	-1.54 **		
Hispanic vs. White	465	-0.66			465	-0.65			465	-0.73		
Unknown vs. White	170	0.33			170	0.28			170	0.60		
Education												
Post H.S.	10801				10801				10801			
0-8 Years vs. Post H.S.	149	-1.25			149	-0.72			149	-0.73		
Some H.S. or Diploma vs. Post H.S.	2796	0.35			2796	0.51			2796	0.31		
Family Income												
≥75K	2448				2448				2448			
<20K vs. ≥75K	2379	-0.51			2379	-0.35			2379	-0.24		
20-35K vs. ≥75K	3146	0.00			3146	0.18			3146	0.13		
35-50K vs. ≥75K	2926	-0.28			2926	-0.02			2926	-0.17		
50-75K vs. ≥75K	2847	-0.06			2847	0.05			2847	-0.09		
HRT Randomized												
No	11544				11544							
Yes vs. No	2202	0.33			2202	0.49			2202	0.41		
Visit			20.1%	(0.5%)			20.1%	(0.5%)			20.1%	(0.5%)
Visit Year												
AV-5	3560				3560				3560			
AV-4 vs. AV-5	817	-0.35			817	-0.18			817	0.09		
AV-6 vs. AV-5	4899	-0.13			4899	-0.06			4899	0.00		
AV-7 vs. AV-5	2732	-0.35			2732	-0.37			2732	-0.31		
AV-8 vs. AV-5	1726	-0.40			1726	-0.40			1726	-0.42		
Clinic Effect			24.6%	(4.5%)			24.6%	(4.5%)			24.6%	(4.5%)
Intervention Participation												
# Sessions Attended in Previous 12 Months			28.1%	(3.5%)								
None	10148											
1 vs. None	815	3.58 **										
2 vs. None	1101	4.84 **										
3 vs. None	1072	5.74 **										
4+ vs. None	610	6.74 **										
# Sessions Completed in Previous 12 Months							28.3%	(3.7%)				
None					9195							
1 vs. None					476	1.36 **						
2 vs. None					798	5.11 **						
3 vs. None					1331	6.09 **						
4+ vs. None					1946	7.19 **						
# Fat Scores Provided in Previous 12 Months											29.2%	(4.6%)
None									10320			
1 vs. None									622	3.06 **		
2 vs. None									757	5.07 **		
3 vs. None									930	6.37 **		
4+ vs. None									1117	7.23 **		

[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: February 28, 2003

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	18148	74.4	16.8	26678	76.3	16.8	1.9	0.2	<.01
Year 2	16710	75.4	17.2	25050	76.7	16.9	1.4	0.2	<.01
Year 3	16668	75.7	17.1	25384	76.8	16.8	1.1	0.2	<.01
Year 4	15780	76.0	17.1	24348	76.8	16.7	0.7	0.2	<.01
Year 5	14243	76.1	17.1	22057	76.7	16.8	0.6	0.2	<.01
Year 6	10218	76.0	16.8	15814	76.5	16.6	0.5	0.2	0.01
Year 7	5179	76.0	16.5	7979	76.2	16.1	0.2	0.3	0.50
Year 8	2022	75.3	15.9	3158	75.6	15.8	0.3	0.5	0.56
AV-1 – Baseline	18133	-2.2	8.5	26656	0.0	8.7	-2.2	0.1	<.01
AV-2 – Baseline	16986	-1.2	9.5	25455	0.5	9.3	-1.6	0.1	<.01
AV-3 – Baseline	16653	-0.7	9.2	25362	0.6	9.3	-1.3	0.1	<.01
AV-4 – Baseline	15765	-0.4	9.5	24328	0.7	9.1	-1.0	0.1	<.01
AV-5 – Baseline	14229	-0.1	9.5	22038	0.7	9.3	-0.9	0.1	<.01
AV-6 – Baseline	10205	0.0	8.7	15795	0.8	8.9	-0.8	0.1	<.01
AV-7 – Baseline	5166	0.3	8.4	7962	1.0	7.9	-0.6	0.1	<.01
AV-8 – Baseline	2022	0.1	7.7	3158	1.1	8.8	-1.0	0.2	<.01
Participants Aged 70-79									
Baseline	3247	73.0	14.7	4872	72.9	14.5	-0.1	0.3	0.80
Year 1	3011	70.7	15.2	4487	72.6	15.4	1.9	0.4	<.01
Year 2	2788	71.0	15.0	4174	72.6	15.3	1.5	0.4	<.01
Year 3	2755	71.1	15.4	4198	72.2	14.8	1.1	0.4	<.01
Year 4	2560	71.1	15.1	3923	71.7	14.4	0.6	0.4	0.09
Year 5	2191	70.7	15.1	3378	71.2	14.3	0.5	0.4	0.20
Year 6	1390	69.8	14.8	2177	70.5	14.0	0.6	0.5	0.20
Year 7	610	70.1	14.8	969	70.0	13.8	-0.1	0.7	0.90
Year 8	230	69.0	13.7	397	69.9	14.3	0.9	1.2	0.44

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

Table 3.5 (continued)
Body Weight by Race/Ethnicity

Data as of: February 28, 2003

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	60	76.7	15.4	72	85.3	17.1	8.5	2.9	<.01
Year 6	45	76.2	15.6	52	85.1	16.0	8.9	3.2	<.01
Year 7	22	78.7	14.6	23	81.7	12.4	3.0	4.0	0.47
Year 8	9	73.7	15.9	6	75.0	7.6	1.3	7.0	0.83
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	63.8	14.7	0.7	0.9	0.44
Year 4	366	63.2	12.6	608	63.8	13.8	0.5	0.9	0.54
Year 5	330	63.3	13.9	538	63.3	12.7	0.0	0.9	0.97
Year 6	205	61.7	12.1	359	63.2	13.4	1.5	1.1	0.17
Year 7	65	62.5	17.4	105	61.3	14.1	-1.2	2.4	0.63
Year 8	12	62.8	7.7	15	60.0	9.4	-2.8	3.4	0.40
Black/African American									
Baseline	2133	85.3	18.2	3126	85.1	18.5	-0.1	0.5	0.79
Year 1	1890	84.2	19.3	2661	84.9	18.9	0.6	0.6	0.26
Year 2	1716	84.9	18.8	2503	85.2	18.9	0.3	0.6	0.59
Year 3	1698	85.3	19.4	2509	85.2	18.8	-0.1	0.6	0.89
Year 4	1588	85.4	19.1	2376	85.5	18.4	0.2	0.6	0.78
Year 5	1397	85.8	19.6	2107	85.6	19.1	-0.2	0.7	0.78
Year 6	1022	84.6	18.2	1554	85.7	18.5	1.1	0.7	0.15
Year 7	492	83.8	18.6	739	84.6	18.3	0.8	1.1	0.46
Year 8	153	83.9	17.2	232	83.4	17.6	-0.5	1.8	0.79
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	936	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	865	74.3	16.5	-1.0	0.9	0.26
Year 4	517	75.5	16.8	831	73.9	15.2	-1.7	0.9	0.06
Year 5	475	74.8	16.0	749	74.1	14.7	-0.8	0.9	0.40
Year 6	314	75.4	17.4	498	74.6	14.3	-0.9	1.1	0.46
Year 7	143	76.0	18.2	220	73.6	15.7	-2.4	1.8	0.20
Year 8	44	72.8	13.4	67	68.9	13.7	-3.9	2.6	0.14

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

Table 3.5 (continued)
Body Weight by Race/Ethnicity

Data as of: February 28, 2003

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	22007	75.8	16.2	2.3	0.2	<.01
Year 2	13760	74.5	16.6	20653	76.2	16.3	1.6	0.2	<.01
Year 3	13760	74.9	16.5	20980	76.2	16.2	1.3	0.2	<.01
Year 4	13048	75.2	16.5	20127	76.2	16.2	1.0	0.2	<.01
Year 5	11814	75.3	16.5	18328	76.1	16.2	0.8	0.2	<.01
Year 6	8532	75.3	16.3	13174	75.9	16.0	0.5	0.2	0.01
Year 7	4414	75.3	15.9	6825	75.6	15.5	0.3	0.3	0.32
Year 8	1794	74.7	15.6	2812	75.2	15.5	0.5	0.5	0.33
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	196	76.3	18.3	318	76.6	16.2	0.3	1.5	0.83
Year 5	167	75.7	15.9	263	77.4	19.0	1.7	1.8	0.33
Year 6	100	76.9	17.8	177	76.5	18.2	-0.4	2.3	0.84
Year 7	43	79.9	17.6	67	76.4	16.9	-3.5	3.4	0.31
Year 8	10	79.9	18.9	26	76.3	17.2	-3.6	6.6	0.61

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

Figure 3.2
Mean Body Weight for DM Participants
Stratified by Treatment Arm

Data as of: February 28, 2003

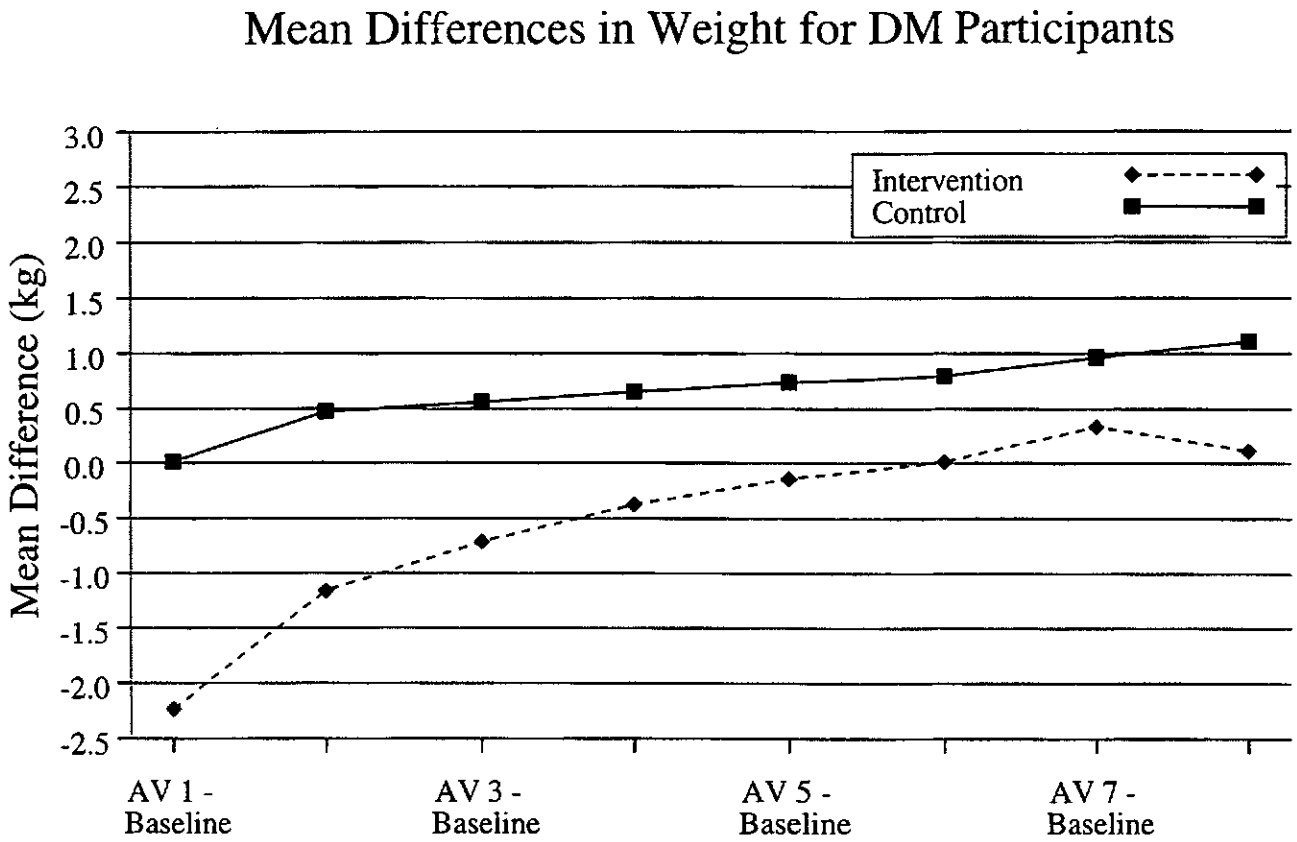


Table 3.6
Reasons for Stopping DM[1]

Data as of: February 28, 2003

Reasons[2]	(N = 2446)	
Personal/family		
Demands of work	233	9.5%
Family illness, emergency, or other family demands[3]	274	11.2%
Financial problems	9	0.4%
Lack of cooperation/support from family/friends[4]	42	1.7%
Living in nursing home	26	1.1%
Issues of interest in study[5]	241	9.9%
Travel		
Too far to CC	114	4.7%
Moved out of area or refuses to be followed at another CC	19	0.8%
Other Travel Issues[6]	61	2.5%
Visits & Procedures		
Doesn't like visits/calls	46	1.9%
Doesn't like required forms or safety procedures[7]	44	1.8%
Problems with other procedures[8]	10	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]	29	1.2%

(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: February 28, 2003

Reasons[2]	(N = 2446)	
Symptoms		
GI Problems[3]	3	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]	97	4.0%
Communication difficulties[7]	57	2.3%
Intervention		
Doesn't like randomized nature of intervention	11	0.4%
Expected some benefit from intervention	31	1.3%
Feels guilty/unhappy or like a failure for not meeting study goals	18	0.7%
Pill Issues[8]	5	0.2%
CaD Issues[9]	1	< 0.1%
HRT Issues[10]	2	< 0.1%
Problem with DM group nutritionist or group members	29	1.2%
Doesn't like attending DM intervention classes	65	2.7%
Doesn't like self-monitoring	46	1.9%
Doesn't like budgeting fat grams	6	0.2%
Health concerns regarding long-term risk/benefits of low fat diet	18	0.7%
Unhappy that not losing weight	19	0.8%
Not in control of meal preparation	12	0.5%
Too difficult to meet or maintain dietary goals	42	1.7%
Doesn't like eating low fat diet	32	1.3%
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	0.2%
Eating pattern conflicts with personal health beliefs	28	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]	30	1.2%
Other		
Other reasons not listed above	453	18.5%
Refuses to give a reason	90	3.7%

[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 February 28, 2003

	All (N = 19,541)		Age at Screening: 50 – 54 (N = 2,783)		55 – 59 (N = 4,424)		60 – 69 (N = 9,085)		70 – 79 (N = 3,249)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping Intervention	2446	12.5%	384	13.8%	546	12.3%	993	10.9%	523	16.1%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	274	11.2%	45	11.7%	69	12.6%	108	10.9%	52	9.9%
Demands of work	233	9.5%	71	18.5%	71	13.0%	75	7.6%	16	3.1%
Issues of interest in study[6]	241	9.9%	35	9.1%	57	10.4%	102	10.3%	47	9.0%
Too far to CC	114	4.7%	25	6.5%	33	6.0%	42	4.2%	14	2.7%
Other ("Other reasons not listed above")	453	18.5%	77	20.1%	127	23.3%	178	17.9%	71	13.6%

	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	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping Intervention	22	25.0%	61	14.2%	328	15.4%	167	22.2%	1821	11.5%	47	17.7%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Family illness, emergency, or other family demands[5]	2	9.1%	3	4.9%	32	9.8%	22	13.2%	209	11.5%	6	12.8%
Demands of work	1	4.5%	5	8.2%	45	13.7%	16	9.6%	162	8.9%	4	8.5%
Issues of interest in study[6]	3	13.6%	6	9.8%	35	10.7%	8	4.8%	186	10.2%	3	6.4%
Too far to CC	2	9.1%	2	3.3%	6	1.8%	6	3.6%	97	5.3%	1	2.1%
Other ("Other reasons not listed above")	5	22.7%	8	13.1%	49	14.9%	50	29.9%	333	18.3%	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 or race/ethnicity category.
[3] Multiple reasons may be reported for a woman.
[4] Percentages are of DM intervention participants in the same age or race/ethnicity 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".

Table 3.8
Bone Mineral Density[1] Analysis: DM Participants

Data as of: February 28, 2003

	N	Mean	S.D.
Whole Body Scan			
Baseline	3594	1.03	0.11
AV1	3261	1.03	0.11
AV3	3078	1.04	0.11
AV6	2597	1.05	0.12
AV1 % Change from baseline BMD[2]	3220	0.17	2.49
AV3 % Change from baseline BMD[3]	3039	1.26	3.58
AV6 % Change from baseline BMD[4]	2560	2.12	5.29
Spine Scan			
Baseline	3502	0.99	0.17
AV1	3168	1.00	0.17
AV3	3000	1.01	0.17
AV6	2532	1.02	0.18
AV1 % Change from baseline BMD[2]	3145	0.73	3.82
AV3 % Change from baseline BMD[3]	2974	2.12	5.20
AV6 % Change from baseline BMD[4]	2513	3.44	6.81
Hip Scan			
Baseline	3620	0.87	0.14
AV1	3275	0.87	0.14
AV3	3100	0.88	0.14
AV6	2642	0.88	0.14
AV1 % Change from baseline BMD[2]	3254	-0.04	2.76
AV3 % Change from baseline BMD[3]	3072	0.98	4.18
AV6 % Change from baseline BMD[4]	2613	0.44	5.23

[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 3.9
Bone Mineral Density[1] Analysis: DM Participants by Race/Ethnicicty

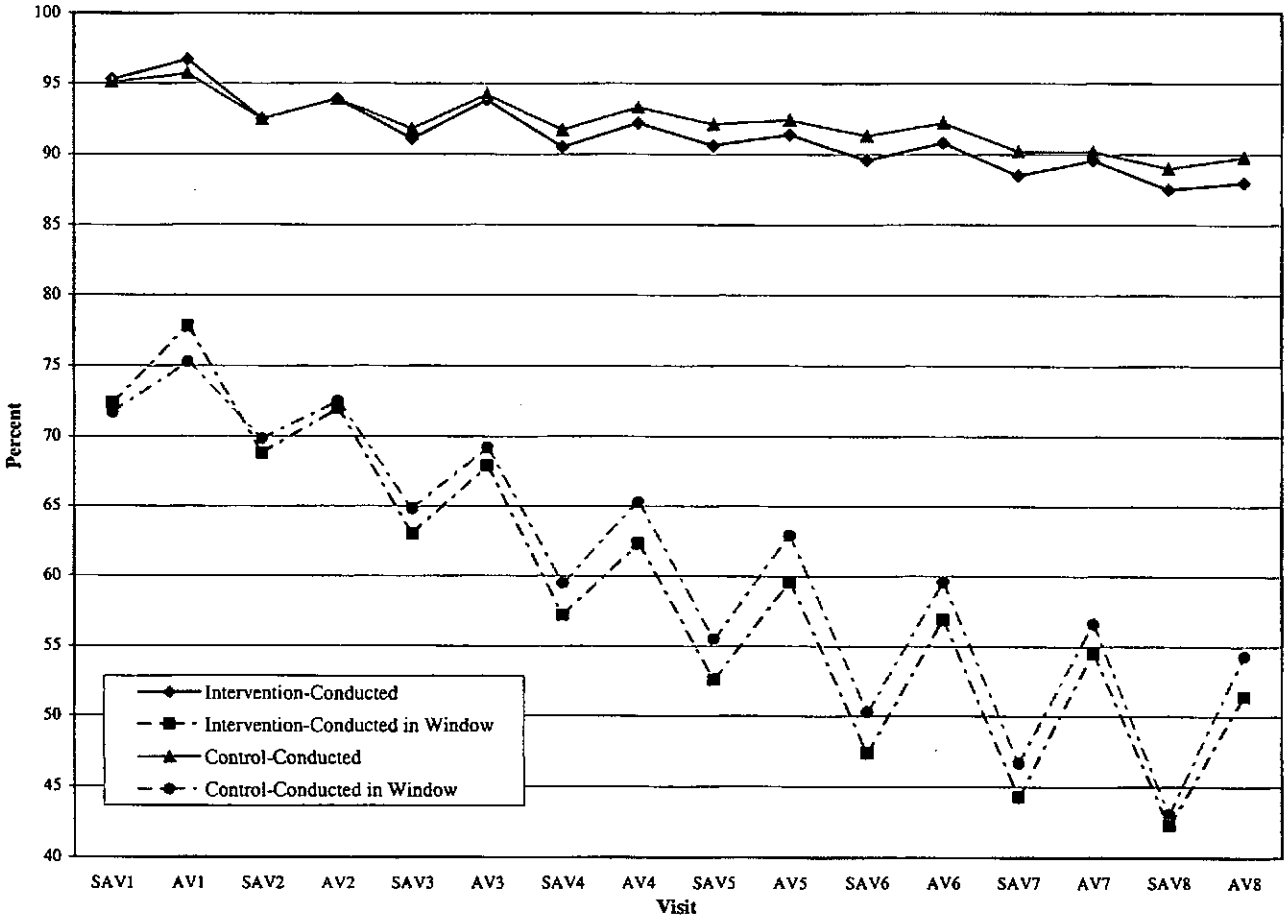
Data as of: February 28, 2003

	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	2389	1.02	0.11
AV6	399	1.08	0.12	145	1.10	0.14	2010	1.04	0.12
AV1 % Change from baseline BMD[2]	506	0.98	2.96	151	-0.33	2.24	2521	0.05	2.36
AV3 % Change from baseline BMD[3]	490	1.97	2.89	151	0.65	4.45	2357	1.16	3.63
AV6 % Change from baseline BMD[4]	394	0.33	3.48	145	4.59	7.49	1979	2.29	5.30
Spine Scan									
Baseline	574	1.07	0.18	188	0.97	0.15	2683	0.97	0.16
AV1	505	1.08	0.18	146	0.98	0.16	2474	0.98	0.16
AV3	490	1.09	0.19	147	0.96	0.15	2321	0.99	0.17
AV6	379	1.09	0.19	142	0.98	0.16	1968	1.01	0.17
AV1 % Change from baseline BMD[2]	499	0.79	4.31	145	0.15	4.38	2459	0.75	3.66
AV3 % Change from baseline BMD[3]	485	2.07	5.13	146	0.08	5.92	2302	2.28	5.14
AV6 % Change from baseline BMD[4]	374	2.37	6.80	142	1.08	6.84	1955	3.82	6.76
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	0.87	0.14	2566	0.85	0.13
AV3	497	0.99	0.15	152	0.88	0.14	2409	0.86	0.13
AV6	407	0.96	0.15	147	0.90	0.14	2045	0.86	0.13
AV1 % Change from baseline BMD[2]	510	0.85	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	2388	0.90	4.10
AV6 % Change from baseline BMD[4]	402	-1.31	4.85	145	2.08	5.98	2024	0.65	5.13

[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 3.10
Adherence to Follow-up Contacts

Data as of: February 28, 2003



Contact		Due N	Conducted N	Conducted %	Conducted in Window N	Conducted in Window %
Semi-Annual Contact 3	Intervention	19541	17802	91.1	12306	63.0
	Control	29294	26886	91.8	18993	64.8
Annual Visit 3	Intervention	19541	18324	93.8	13262	67.9
	Control	29294	27607	94.2	20262	69.2
Semi-Annual Contact 4	Intervention	19541	17677	90.5	11173	57.2
	Control	29294	26852	91.7	17434	59.5
Annual Visit 4	Intervention	19541	18011	92.2	12168	62.3
	Control	29294	27332	93.3	19117	65.3
Semi-Annual Contact 5	Intervention	19538	17692	90.6	10271	52.6
	Control	29289	26982	92.1	16267	55.5
Annual Visit 5	Intervention	18087	16536	91.4	10777	59.6
	Control	27134	25085	92.4	17056	62.9
Semi-Annual Visit 6	Intervention	15608	13986	89.6	7405	47.4
	Control	23421	21374	91.3	11789	50.3
Annual Visit 6	Intervention	12667	11504	90.8	7208	56.9
	Control	18979	17498	92.2	11316	59.6
Semi-Annual Visit 7	Intervention	9448	8361	88.5	4187	44.3
	Control	14187	12791	90.2	6623	46.7
Annual Visit 7	Intervention	6598	5912	89.6	3597	54.5
	Control	9863	8900	90.2	5582	56.6
Semi-Annual Visit 8	Intervention	4337	3796	87.5	1833	42.3
	Control	6472	5757	89.0	2789	43.1
Annual Visit 8	Intervention	2667	2348	88.0	1372	51.4
	Control	3977	3571	89.8	2159	54.3

Table 3.11
Lost-to-Follow-up and Vital Status: DM Participants

Data as of: February 28, 2003

	DM Participants (N = 48,835)	
	N	%
Vital Status/Participation		
Deceased	1458	3.0
Alive: Current Participation[1]	44684	91.5
Alive: Recent Participation[2]	772	1.6
Alive: Past/Unknown Participation[3]	28	0.1
Stopped Follow-Up[4]	1132	2.3
Lost to Follow-Up[5]	761	1.6

[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 3.12
Locally Verified Outcomes (Annualized Percentages) by Age for Dietary Modification

Data as of: February 28, 2003

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48835	6961	11041	22712	8121
Mean follow-up (months)	73.4	79.7	75.8	71.3	70.4
Cancer					
Breast cancer[1]	1554 (0.52%)	170 (0.37%)	353 (0.51%)	746 (0.55%)	285 (0.60%)
Invasive breast cancer	1233 (0.41%)	119 (0.26%)	287 (0.41%)	603 (0.45%)	224 (0.47%)
Non-invasive breast cancer	328 (0.11%)	51 (0.11%)	68 (0.10%)	147 (0.11%)	62 (0.13%)
Ovarian cancer	145 (0.05%)	18 (0.04%)	29 (0.04%)	62 (0.05%)	36 (0.08%)
Endometrial cancer[2]	203 (0.12%)	24 (0.09%)	45 (0.11%)	95 (0.13%)	39 (0.15%)
Colorectal cancer	376 (0.13%)	25 (0.05%)	60 (0.09%)	193 (0.14%)	98 (0.21%)
Other cancer[3]	1407 (0.47%)	129 (0.28%)	226 (0.32%)	697 (0.52%)	355 (0.75%)
Total cancer	3578 (1.20%)	358 (0.77%)	689 (0.99%)	1742 (1.29%)	789 (1.66%)
Cardiovascular					
CHD[4]	914 (0.31%)	50 (0.11%)	104 (0.15%)	433 (0.32%)	327 (0.69%)
CHD death[5]	192 (0.06%)	8 (0.02%)	18 (0.03%)	88 (0.07%)	78 (0.16%)
Total MI[6]	790 (0.26%)	43 (0.09%)	91 (0.13%)	377 (0.28%)	279 (0.59%)
Clinical MI	749 (0.25%)	36 (0.08%)	85 (0.12%)	361 (0.27%)	267 (0.56%)
Evolving Q-wave MI[7]	43 (0.01%)	7 (0.02%)	6 (0.01%)	18 (0.01%)	12 (0.03%)
Possible evolving Q-wave MI[7]	163 (0.05%)	20 (0.04%)	27 (0.04%)	73 (0.05%)	43 (0.09%)
Angina	1197 (0.40%)	66 (0.14%)	162 (0.23%)	631 (0.47%)	338 (0.71%)
CABG/PTCA	1233 (0.41%)	50 (0.11%)	154 (0.22%)	653 (0.48%)	376 (0.79%)
Carotid artery disease	191 (0.06%)	5 (0.01%)	23 (0.03%)	96 (0.07%)	67 (0.14%)
Congestive heart failure	718 (0.24%)	36 (0.08%)	79 (0.11%)	325 (0.24%)	278 (0.58%)
Stroke	703 (0.24%)	33 (0.07%)	63 (0.09%)	326 (0.24%)	281 (0.59%)
PVD	167 (0.06%)	6 (0.01%)	18 (0.03%)	78 (0.06%)	65 (0.14%)
CHD[4]/Possible evolving Q-wave MI	1071 (0.36%)	70 (0.15%)	130 (0.19%)	502 (0.37%)	369 (0.78%)
Coronary disease[8]	2699 (0.90%)	154 (0.33%)	345 (0.49%)	1351 (1.00%)	849 (1.78%)
Total cardiovascular disease	3539 (1.19%)	191 (0.41%)	426 (0.61%)	1771 (1.31%)	1151 (2.42%)
Fractures					
Hip fracture	291 (0.10%)	9 (0.02%)	24 (0.03%)	122 (0.09%)	136 (0.29%)
Vertebral fracture	341 (0.11%)	14 (0.03%)	42 (0.06%)	143 (0.11%)	142 (0.30%)
Other fracture[3]	3881 (1.30%)	490 (1.06%)	789 (1.13%)	1805 (1.34%)	797 (1.67%)
Total fracture	4359 (1.46%)	509 (1.10%)	845 (1.21%)	2002 (1.48%)	1003 (2.11%)
Deaths					
Cardiovascular deaths	411 (0.14%)	16 (0.03%)	31 (0.04%)	184 (0.14%)	180 (0.38%)
Cancer deaths	661 (0.22%)	39 (0.08%)	86 (0.12%)	329 (0.24%)	207 (0.43%)
Other known cause	220 (0.07%)	14 (0.03%)	24 (0.03%)	94 (0.07%)	88 (0.18%)
Unknown cause	71 (0.02%)	6 (0.01%)	7 (0.01%)	40 (0.03%)	18 (0.04%)
Not yet adjudicated	95 (0.03%)	6 (0.01%)	16 (0.02%)	30 (0.02%)	43 (0.09%)
Total death	1458 (0.49%)	81 (0.18%)	164 (0.24%)	677 (0.50%)	536 (1.13%)

[1] Excludes six 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 3.12 (continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Dietary Modification

Data as of: February 28, 2003

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)	71.6	69.7	71.7	68.9	74.0	69.0
Cancer						
Breast cancer[1]	4 (0.33%)	32 (0.50%)	108 (0.34%)	39 (0.37%)	1355 (0.55%)	16 (0.42%)
Invasive breast cancer	4 (0.33%)	23 (0.36%)	80 (0.25%)	31 (0.29%)	1083 (0.44%)	12 (0.32%)
Non-invasive breast cancer	0 (0.00%)	9 (0.14%)	29 (0.09%)	8 (0.08%)	278 (0.11%)	4 (0.11%)
Ovarian cancer	1 (0.08%)	2 (0.03%)	13 (0.04%)	2 (0.02%)	124 (0.05%)	3 (0.08%)
Endometrial cancer[2]	0 (0.00%)	2 (0.05%)	12 (0.09%)	8 (0.14%)	177 (0.12%)	4 (0.19%)
Colorectal cancer	4 (0.33%)	7 (0.11%)	41 (0.13%)	15 (0.14%)	302 (0.12%)	7 (0.18%)
Other cancer[3]	5 (0.41%)	19 (0.30%)	105 (0.33%)	29 (0.27%)	1232 (0.50%)	17 (0.45%)
Total cancer	14 (1.16%)	61 (0.95%)	270 (0.86%)	89 (0.84%)	3101 (1.26%)	43 (1.13%)
Cardiovascular						
CHD[4]	2 (0.17%)	9 (0.14%)	92 (0.29%)	14 (0.13%)	790 (0.32%)	7 (0.18%)
CHD death[5]	0 (0.00%)	1 (0.02%)	25 (0.08%)	1 (0.01%)	163 (0.07%)	2 (0.05%)
Total MI[6]	2 (0.17%)	9 (0.14%)	78 (0.25%)	14 (0.13%)	680 (0.28%)	7 (0.18%)
Clinical MI	2 (0.17%)	8 (0.12%)	74 (0.24%)	14 (0.13%)	645 (0.26%)	6 (0.16%)
Evolving Q-wave MI[7]	0 (0.00%)	1 (0.02%)	4 (0.01%)	0 (0.00%)	37 (0.02%)	1 (0.03%)
Possible evolving Q-wave MI[7]	2 (0.17%)	6 (0.09%)	22 (0.07%)	3 (0.03%)	128 (0.05%)	2 (0.05%)
Angina	2 (0.17%)	14 (0.22%)	166 (0.53%)	34 (0.32%)	961 (0.39%)	20 (0.53%)
CABG/PTCA	1 (0.08%)	10 (0.16%)	122 (0.39%)	22 (0.21%)	1066 (0.43%)	12 (0.32%)
Carotid artery disease	2 (0.17%)	1 (0.02%)	18 (0.06%)	1 (0.01%)	167 (0.07%)	2 (0.05%)
Congestive heart failure	0 (0.00%)	3 (0.05%)	129 (0.41%)	19 (0.18%)	556 (0.23%)	11 (0.29%)
Stroke	4 (0.33%)	16 (0.25%)	88 (0.28%)	15 (0.14%)	570 (0.23%)	10 (0.26%)
PVD	1 (0.08%)	1 (0.02%)	30 (0.10%)	2 (0.02%)	130 (0.05%)	3 (0.08%)
CHD[4]/Possible evolving Q-wave MI	4 (0.33%)	15 (0.23%)	114 (0.36%)	17 (0.16%)	912 (0.37%)	9 (0.24%)
Coronary disease[8]	6 (0.50%)	30 (0.47%)	361 (1.15%)	65 (0.61%)	2200 (0.90%)	37 (0.98%)
Total cardiovascular disease	12 (1.00%)	47 (0.73%)	462 (1.47%)	81 (0.76%)	2888 (1.18%)	49 (1.29%)
Fractures						
Hip fracture	0 (0.00%)	1 (0.02%)	9 (0.03%)	5 (0.05%)	273 (0.11%)	3 (0.08%)
Vertebral fracture	1 (0.08%)	8 (0.12%)	4 (0.01%)	6 (0.06%)	318 (0.13%)	4 (0.11%)
Other fracture[3]	15 (1.24%)	57 (0.89%)	225 (0.72%)	94 (0.89%)	3445 (1.41%)	45 (1.19%)
Total fracture	15 (1.24%)	65 (1.01%)	236 (0.75%)	103 (0.97%)	3888 (1.59%)	52 (1.37%)
Deaths						
Cardiovascular deaths	1 (0.08%)	6 (0.09%)	58 (0.18%)	5 (0.05%)	337 (0.14%)	4 (0.11%)
Cancer deaths	4 (0.33%)	9 (0.14%)	63 (0.20%)	16 (0.15%)	560 (0.23%)	9 (0.24%)
Other known cause	5 (0.41%)	1 (0.02%)	33 (0.10%)	4 (0.04%)	175 (0.07%)	2 (0.05%)
Unknown cause	0 (0.00%)	1 (0.02%)	8 (0.03%)	4 (0.04%)	58 (0.02%)	0 (0.00%)
Not yet adjudicated	1 (0.08%)	1 (0.02%)	7 (0.02%)	6 (0.06%)	79 (0.03%)	1 (0.03%)
Total death	11 (0.91%)	18 (0.28%)	169 (0.54%)	35 (0.33%)	1209 (0.49%)	16 (0.42%)

[1] Excludes six 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 3.13
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: February 28, 2003

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48835	6961	11041	22712	8121
Mean follow-up (months)	73.4	79.7	75.8	71.3	70.4
Hospitalizations					
Ever	20010 (6.70%)	2128 (4.60%)	3775 (5.41%)	9715 (7.20%)	4392 (9.22%)
Two or more	9631 (3.23%)	860 (1.86%)	1617 (2.32%)	4692 (3.48%)	2462 (5.17%)
Other					
DVT[1]	401 (0.14%)	25 (0.06%)	61 (0.09%)	187 (0.14%)	128 (0.28%)
Pulmonary embolism	250 (0.08%)	13 (0.03%)	40 (0.06%)	129 (0.10%)	68 (0.14%)
Diabetes (treated)	2661 (0.93%)	363 (0.81%)	598 (0.89%)	1228 (0.96%)	472 (1.05%)
Gallbladder disease[2]	2980 (1.19%)	462 (1.12%)	700 (1.17%)	1400 (1.26%)	418 (1.09%)
Hysterectomy	1223 (0.72%)	180 (0.69%)	278 (0.66%)	578 (0.77%)	187 (0.72%)
Glaucoma	3898 (1.36%)	385 (0.85%)	788 (1.15%)	1920 (1.48%)	805 (1.83%)
Osteoporosis	7957 (2.83%)	819 (1.81%)	1463 (2.17%)	3962 (3.14%)	1713 (4.03%)
Osteoarthritis[3]	7469 (4.08%)	1080 (3.17%)	1716 (3.64%)	3455 (4.42%)	1218 (5.14%)
Rheumatoid arthritis	2177 (0.76%)	300 (0.67%)	493 (0.73%)	1006 (0.78%)	378 (0.84%)
Intestinal polyps	5657 (2.04%)	694 (1.55%)	1230 (1.86%)	2833 (2.28%)	900 (2.12%)
Lupus	359 (0.12%)	56 (0.12%)	86 (0.12%)	169 (0.13%)	48 (0.10%)
Kidney stones[3]	902 (0.38%)	119 (0.34%)	203 (0.37%)	435 (0.40%)	145 (0.38%)
Cataracts[3]	11629 (5.36%)	713 (1.99%)	1926 (3.53%)	6494 (6.54%)	2496 (9.16%)
Pills for hypertension	9446 (4.53%)	1267 (3.40%)	2086 (3.97%)	4426 (4.89%)	1667 (5.91%)

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)	71.6	69.7	71.7	68.9	74.0	69.0
Hospitalizations						
Ever	79 (6.55%)	295 (4.60%)	2143 (6.82%)	627 (5.92%)	16618 (6.78%)	248 (6.54%)
Two or more	46 (3.82%)	106 (1.65%)	1061 (3.38%)	276 (2.60%)	8018 (3.27%)	124 (3.27%)
Other						
DVT[1]	0 (0.00%)	0 (0.00%)	36 (0.12%)	6 (0.06%)	353 (0.15%)	6 (0.16%)
Pulmonary embolism	2 (0.17%)	1 (0.02%)	24 (0.08%)	2 (0.02%)	217 (0.09%)	4 (0.11%)
Diabetes (treated)	15 (1.34%)	74 (1.22%)	496 (1.78%)	147 (1.48%)	1890 (0.80%)	39 (1.09%)
Gallbladder disease[2]	11 (1.28%)	43 (0.74%)	236 (0.84%)	127 (1.59%)	2524 (1.24%)	39 (1.20%)
Hysterectomy	4 (0.70%)	25 (0.62%)	74 (0.53%)	38 (0.67%)	1074 (0.75%)	8 (0.38%)
Glaucoma	19 (1.65%)	74 (1.20%)	566 (1.93%)	144 (1.40%)	3050 (1.29%)	45 (1.26%)
Osteoporosis	37 (3.23%)	191 (3.15%)	472 (1.56%)	291 (2.95%)	6861 (2.97%)	105 (2.99%)
Osteoarthritis[3]	36 (5.21%)	171 (3.70%)	756 (4.04%)	313 (4.38%)	6081 (4.07%)	112 (4.85%)
Rheumatoid arthritis	17 (1.57%)	40 (0.65%)	399 (1.36%)	174 (1.72%)	1510 (0.64%)	37 (1.03%)
Intestinal polyps	30 (2.69%)	124 (2.11%)	621 (2.12%)	180 (1.78%)	4618 (2.03%)	84 (2.41%)
Lupus	3 (0.25%)	3 (0.05%)	53 (0.17%)	12 (0.11%)	283 (0.12%)	5 (0.13%)
Kidney stones[3]	6 (0.65%)	15 (0.29%)	91 (0.36%)	40 (0.46%)	736 (0.38%)	14 (0.46%)
Cataracts[3]	47 (5.57%)	226 (4.75%)	1123 (4.88%)	391 (4.76%)	9681 (5.46%)	161 (5.80%)
Pills for hypertension	34 (4.37%)	200 (4.66%)	1021 (6.49%)	394 (5.00%)	7679 (4.33%)	118 (4.62%)

[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 – Calcium and Vitamin D Component Age – and Race/Ethnicity – Specific Recruitment 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 – CaD Adherence Summary 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 – CaD Adherence Summary*) at 56%-64%. At AV-5, which is nearly complete, 95% of visits due have been conducted, and of those women who have completed visits, 4% have stopped taking the CaD study medication, and 85% completed the pill collection procedure. The AV-5 through AV-6 adherence summary percentages have improved over the most recent time interval (*Figure 4.1*). Over the most recent time interval, the adherence summary at AV-5 rose from 63% to 69%. About 20-37% of women on study medication take less than 80% of their CaD pills, but nonetheless remain partially adherent.

Table 4.3 – CaD Drop-Out Rates by Follow-Up Time 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 3.0-5.5%, which compares favorably to the 5.9% design assumption. At AV-5, the cumulative drop-out rate was 20.8% (design assumption was 24.0%). From AV-6 through AV-8, observed rates are below the design assumption by > 4-6%.

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. 931 women (9.9%) reported health problems or diseases, 2,235 women (23.8%) reported symptoms not known to be related to the intervention, and 515 women (5.5%) reported that the study conflicts with other health issues. "Other pill issues" was the most frequently reported intervention-related reason (10.8%) followed by not liking the randomized nature of the intervention (3.9%). Miscellaneous reasons grouped together as "other reasons not listed above" were reported by 21.5% of women. Four common reasons for stopping CaD are shown first by age, and then by

race/ethnicity, in *Table 4.5 – Reasons for Stopping CaD*. 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 February 28, 2003, 2360 (6.5%) of women were taking alendronate, 221 (0.6%) were taking risendronate, 268 (0.7%) were taking calcitonin, and 714 (2.0%) were taking raloxifene.

4.3 Bone Mineral Density

Table 4.6 – Bone Mineral Density Analysis: CaD Participants 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 two times as large as those observed at AV-3 for the spine and whole body. At the hip, BMD change from AV-6 to AV-1 was 0.77%, less than the 1.27% increase observed at AV-3. *Table 4.7 – Bone Mineral Density Analysis: CaD Participants* 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. At AV-6, white and Hispanic/Latino women experienced BMD gains of approximately 1-6% at the various skeletal sites, whereas African American women had small negative percent changes in BMD at the hip and whole body.

4.4 Vital Status

Table 4.8 – Lost-to-Follow-up and Vital Status 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, 2.1% of the participants are lost-to-follow-up or have stopped follow-up, and 2.5% 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 5.0 years, suggesting that approximately 14.2% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

4.5 Outcomes

Table 4.9 – Locally Verified Outcomes (Annualized Percentages) by Age and Race/Ethnicity for Calcium and Vitamin D 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 3% 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 203 cases of hip fracture locally verified, we have observed only about 40% of the number of hip fractures that were projected by the assumptions underlying the power calculations. The number of observed colorectal cancer cases (233 cases) is approximately 80%, the number of invasive breast cancer cases (760 cases) is approximately 120%, and the number of CHD cases is about 70% of what was expected (605 cases).

Table 4.10 (by age and race/ethnicity) 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

There are no issues to report related to the CaD trial at this time. During this period of follow-up, our focus remains primarily on maximizing adherence and retention.

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

Data as of: February 28, 2003

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**36,282**			
50-54	5,157	118%	14%	10
55-59	8,265	94%	23%	20
60-69	16,518	84%	46%	45
70-79	6,342	58%	17%	25
Race/Ethnicity	**36,282**			
American Indian	149		<1%	
Asian	721		2%	
Black	3,315		9%	
Hispanic	1,502		4%	
White	30,155		83%	
Unknown	440		1%	

Table 4.2
CaD Adherence Summary
All CaD Participants

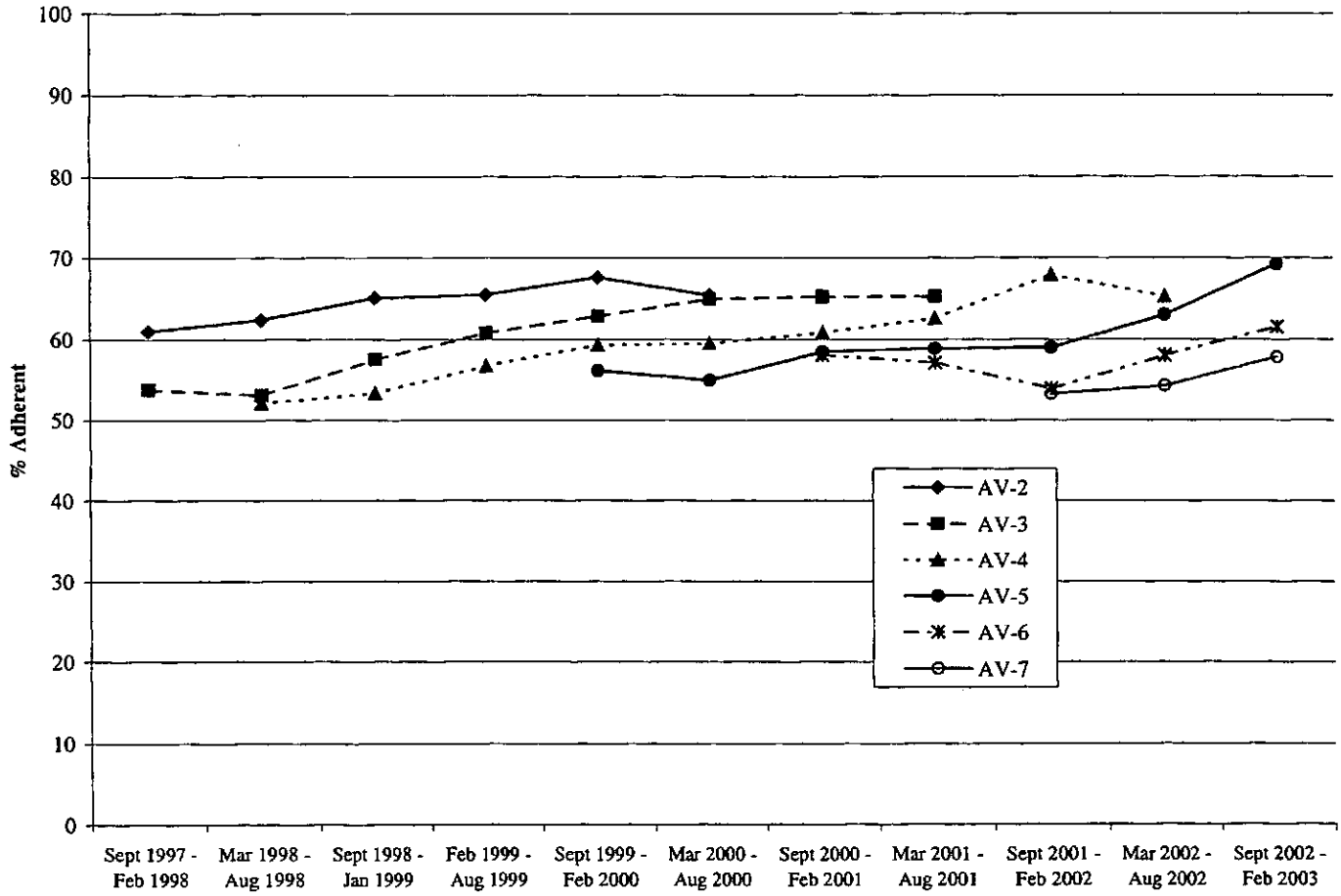
Data as of: February 28, 2003

	Due	Conducted[1]		Conducted in Window		Stopped CaD		Missed Pill Collection		Total with Collections		Medication Rate[2,3] <50%		Medication Rate[2,3] 50%-80%		Medication Rate[2,3] 80% +		Adherence Summary[4]
	N	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	%
Annual Visit - 2	33070	32259	98	25859	78	2468	7	169	1	32630	99	6093	19	7404	23	20999	64	64
Annual Visit - 3	36282	35240	97	26515	74	1994	6	450	1	33225	99	5186	15	5728	17	22347	66	62
Annual Visit - 4	36282	34766	96	24601	69	1634	5	527	2	31144	98	4014	13	4796	15	22356	71	62
Annual Visit - 5	33476	31750	95	21576	66	1327	4	575	2	27140	98	3104	11	3796	14	20252	73	61
Annual Visit - 6	22593	21221	94	13757	62	765	3	393	2	17319	98	1891	11	2367	13	13070	74	59
Annual Visit - 7	11342	10529	93	6681	60	348	3	235	3	8310	97	869	10	1108	13	6333	74	57
Annual Visit - 8	4326	3992	92	2427	58	124	3	119	4	3050	96	300	9	399	13	2351	74	56

[1] Based on Form 33 collection.
[2] Medication rate calculated as the number of pills taken divided by the number of days since bottle(s) were dispensed.
[3] Percentage calculated based on denominator of total dispensation which is the sum of missed pill collection and total with collection.
[4] 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: February 28, 2003



[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: February 28, 2003

	Design		Observed			
	Int	Cum	Stopped[1]	Dead/ Lost[2]	Int[3]	Cum[4]
Drop-Outs[5]						
AV-2	8.8	8.8	7.5	0.2	7.5	7.4
AV-3	5.9	14.2	5.5	0.4	5.5	12.5
AV-4	5.9	19.2	4.6	0.6	4.6	16.9
AV-5	5.9	24.0	4.0	0.6	4.0	20.8
AV-6	5.9	28.5	3.5	0.7	3.5	24.3
AV-7	5.9	32.7	3.2	0.7	3.2	27.4
AV-8	5.9	36.7	3.0	0.9	3.0	30.3

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

Table 4.4
Reasons for Stopping CaD[1]

Data as of: February 28, 2003

Reasons[2]	(N = 9396)	
Personal/family		
Demands of work	199	2.1%
Family illness, emergency or other family demands[3]	348	3.7%
Financial problems	15	0.2%
Lack of cooperation/support from family/friends[4]	69	0.7%
Living in nursing home	45	0.5%
Issues of interest in study[5]	331	3.5%
Travel		
Too far to CC	235	2.5%
Moved out of area or refuses to be followed at another CC	89	0.9%
Other travel issues[6]	94	1.0%
Visits & Procedures		
Doesn't like visits, calls	90	1.0%
Doesn't like required forms or safety procedures[7]	80	0.9%
Problems with other procedures[8]	34	0.4%
Worried about health effects of medical tests/procedures	33	0.4%
Wants results of blood analyses	4	<0.1%
Wants results of bone mineral density	2	<0.1%
Problems with CC[9]	55	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: February 28, 2003

Reasons[2]	(N = 9396)	
Symptoms		
Bloating/gas	182	1.9%
Constipation	200	2.1%
Other gastrointestinal problems	240	2.6%
HRT Related Symptoms[3]	38	0.4%
Other[4]	2235	23.8%
Health Conditions		
Hypercalcemia	197	2.1%
Renal calculi	182	1.9%
Osteoporosis	80	0.9%
Other Diseases/Health Conditions[5]	931	9.9%
Communication difficulties[6]	110	1.2%
Intervention		
Doesn't like randomized nature of intervention	364	3.9%
Expected some benefit from intervention	58	0.6%
Feels guilty, unhappy, or like a failure for not meeting study goals of intervention	19	0.2%
Takes too many pills	290	3.1%
Other pill issues[7]	1014	10.8%
HRT Issues[8]	141	1.5%
DM Issues[9]	16	0.2%
Wants to take her own calcium	356	3.8%
Feels diet is already sufficient in calcium/Vit D	37	0.4%
Taking more than the max allowable IU of Vit D	38	0.4%
Taking Calcitrol	21	0.2%
Other Health Issues		
Worried about cost if adverse effects occur	8	0.1%
Expected more health care	24	0.3%
Advised not to participate by health care provider[10]	745	7.9%
Study conflicts with other health issues[11]	515	5.5%
Other		
Other reasons not listed above	2016	21.5%
Refuses to give a reason	148	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 February 28, 2003

	All (N = 36,282)		Age at Screening: 50 – 54 (N = 5,157)		55 – 59 (N = 8,265)		60 – 69 (N = 16,518)		70 – 79 (N = 6,342)	
	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping CaD	9396	25.9%	1472	28.5%	2069	25.0%	4004	24.2%	1851	29.2%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Doesn't like randomized nature of intervention	364	3.9%	59	4.0%	82	4.0%	161	4.0%	62	3.3%
Other pill issues[5]	1014	10.8%	157	10.7%	230	11.1%	441	11.0%	186	10.0%
Advised not to participate by health care provider[6]	745	7.9%	80	5.4%	159	7.7%	344	8.6%	162	8.8%
Study conflicts with other health issues[7]	515	5.5%	63	4.3%	100	4.8%	227	5.7%	125	6.8%

	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	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]	N	%[2]
Women Stopping CaD	45	30.2%	183	25.4%	983	29.7%	459	30.6%	7603	25.2%	123	28.0%
REASONS FOR STOPPING[3]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]	N	%[4]
Doesn't like randomized nature of intervention	0	0.0%	3	1.6%	32	3.3%	9	2.0%	316	4.2%	4	3.3%
Other pill issues[5]	6	13.3%	22	12.0%	93	9.5%	53	11.5%	830	10.9%	10	8.1%
Advised not to participate by health care provider[6]	2	4.4%	7	3.8%	61	6.2%	34	7.4%	632	8.3%	9	7.3%
Study conflicts with other health issues[7]	1	2.2%	6	3.3%	41	4.2%	19	4.1%	441	5.8%	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 or race/ethnicity category.
[3] Multiple reasons may be reported for a woman.
[4] Percentages are of CaD participants in the same age or race/ethnicity 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".

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

Data as of: February 28, 2003

	N	Mean	S.D.
Whole Body Scan			
AV1	2426	1.02	0.10
AV3	2264	1.03	0.11
AV6	1703	1.05	0.12
AV3 % Change from AV1 BMD[2]	2191	1.42	3.36
AV6 % Change from AV1 BMD[3]	1641	2.39	5.19
Spine Scan			
AV1	2346	0.99	0.16
AV3	2210	1.01	0.17
AV6	1666	1.02	0.17
AV3 % Change from AV1 BMD[2]	2141	1.59	4.21
AV6 % Change from AV1 BMD[3]	1607	2.98	5.93
Hip Scan			
AV1	2431	0.86	0.14
AV3	2286	0.87	0.14
AV6	1735	0.87	0.14
AV3 % Change from AV1 BMD[2]	2212	1.27	3.55
AV6 % Change from AV1 BMD[3]	1666	0.77	4.95

[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: February 28, 2003

	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	1847	1.02	0.11
AV6	194	1.08	0.12	96	1.10	0.16	1383	1.04	0.12
AV3 % Change from AV1 BMD[2]	261	1.21	3.02	104	2.20	4.36	1792	1.41	3.34
AV6 % Change from AV1 BMD[3]	190	-0.10	3.73	79	5.71	8.10	1345	2.56	4.99
Spine Scan									
AV1	274	1.07	0.18	119	0.98	0.16	1915	0.98	0.16
AV3	261	1.08	0.19	113	0.97	0.15	1800	1.00	0.17
AV6	182	1.08	0.18	95	0.99	0.16	1359	1.02	0.17
AV3 % Change from AV1 BMD[2]	257	1.17	4.40	101	0.39	3.99	1749	1.75	4.17
AV6 % Change from AV1 BMD[3]	178	1.49	6.21	78	1.76	5.67	1324	3.25	5.88
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	1869	0.86	0.13
AV6	198	0.97	0.14	98	0.90	0.14	1409	0.86	0.13
AV3 % Change from AV1 BMD[2]	261	0.83	3.18	103	1.68	4.67	1814	1.31	3.52
AV6 % Change from AV1 BMD[3]	193	-1.58	4.41	80	3.37	5.21	1366	0.99	4.85

[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: February 28, 2003

	CaD Participants (N=36,282)	
	N	%
Vital Status/Participation		
Deceased	922	2.5
Alive: Current Participation[1]	34182	94.2
Alive: Recent Participation[2]	397	1.1
Alive: Past/Unknown Participation[3]	18	0.0
Stopped Follow-Up[4]	450	1.2
Lost to Follow-Up[5]	313	0.9

[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: February 28, 2003

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number of participants	36282	5157	8265	16518	6342
Mean follow-up (months)	60.5	66.2	62.8	58.8	57.6
Fractures					
Hip fracture	203 (0.11%)	5 (0.02%)	18 (0.04%)	81 (0.10%)	99 (0.33%)
Vertebral fracture	221 (0.12%)	5 (0.02%)	26 (0.06%)	95 (0.12%)	95 (0.31%)
Other fracture[1]	2559 (1.40%)	330 (1.16%)	516 (1.19%)	1154 (1.43%)	559 (1.84%)
Total fracture	2881 (1.57%)	337 (1.18%)	554 (1.28%)	1282 (1.58%)	708 (2.33%)
Cancer					
Colorectal cancer	233 (0.13%)	17 (0.06%)	34 (0.08%)	114 (0.14%)	68 (0.22%)
Breast cancer[2]	966 (0.53%)	107 (0.38%)	229 (0.53%)	465 (0.57%)	165 (0.54%)
Invasive breast cancer	760 (0.42%)	78 (0.27%)	182 (0.42%)	368 (0.45%)	132 (0.43%)
Non-invasive breast cancer	208 (0.11%)	29 (0.10%)	47 (0.11%)	99 (0.12%)	33 (0.11%)
Ovarian cancer	93 (0.05%)	10 (0.04%)	24 (0.06%)	38 (0.05%)	21 (0.07%)
Endometrial cancer[3]	126 (0.12%)	16 (0.10%)	29 (0.11%)	57 (0.12%)	24 (0.14%)
Other cancer[1]	912 (0.50%)	86 (0.30%)	149 (0.34%)	434 (0.54%)	243 (0.80%)
Total cancer	2275 (1.24%)	234 (0.82%)	455 (1.05%)	1080 (1.33%)	506 (1.66%)
Cardiovascular					
CHD[4]	605 (0.33%)	36 (0.13%)	59 (0.14%)	285 (0.35%)	225 (0.74%)
CHD death[5]	135 (0.07%)	8 (0.03%)	13 (0.03%)	54 (0.07%)	60 (0.20%)
Total MI[6]	512 (0.28%)	30 (0.11%)	48 (0.11%)	251 (0.31%)	183 (0.60%)
Clinical MI	472 (0.26%)	26 (0.09%)	43 (0.10%)	236 (0.29%)	167 (0.55%)
Evolving Q-wave MI[7]	42 (0.02%)	4 (0.01%)	5 (0.01%)	17 (0.02%)	16 (0.05%)
Possible evolving Q-wave MI[7]	129 (0.07%)	17 (0.06%)	21 (0.05%)	52 (0.06%)	39 (0.13%)
Angina	787 (0.43%)	34 (0.12%)	108 (0.25%)	405 (0.50%)	240 (0.79%)
CABG/PTCA	828 (0.45%)	35 (0.12%)	98 (0.23%)	430 (0.53%)	265 (0.87%)
Carotid artery disease	130 (0.07%)	5 (0.02%)	13 (0.03%)	72 (0.09%)	40 (0.13%)
Congestive heart failure	475 (0.26%)	19 (0.07%)	51 (0.12%)	225 (0.28%)	180 (0.59%)
Stroke	465 (0.25%)	20 (0.07%)	42 (0.10%)	210 (0.26%)	193 (0.63%)
PVD	121 (0.07%)	5 (0.02%)	13 (0.03%)	56 (0.07%)	47 (0.15%)
CHD[4]/Possible evolving Q-wave MI	728 (0.40%)	53 (0.19%)	79 (0.18%)	334 (0.41%)	262 (0.86%)
Coronary disease[8]	1814 (0.99%)	98 (0.34%)	230 (0.53%)	881 (1.09%)	605 (1.99%)
Total cardiovascular disease	2383 (1.30%)	124 (0.44%)	284 (0.66%)	1170 (1.45%)	805 (2.65%)
Deaths					
Cardiovascular deaths	258 (0.14%)	13 (0.05%)	20 (0.05%)	106 (0.13%)	119 (0.39%)
Cancer deaths	423 (0.23%)	30 (0.11%)	53 (0.12%)	205 (0.25%)	135 (0.44%)
Other known cause	129 (0.07%)	7 (0.02%)	16 (0.04%)	61 (0.08%)	45 (0.15%)
Unknown cause	51 (0.03%)	4 (0.01%)	5 (0.01%)	27 (0.03%)	15 (0.05%)
Not yet adjudicated	61 (0.03%)	5 (0.02%)	13 (0.03%)	25 (0.03%)	18 (0.06%)
Total death	922 (0.50%)	59 (0.21%)	107 (0.25%)	424 (0.52%)	332 (1.09%)

[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 six 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: February 28, 2003

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)	60.3	56.6	59.3	58.6	60.9	57.0
Fractures						
Hip fracture	0 (0.00%)	3 (0.09%)	4 (0.02%)	2 (0.03%)	194 (0.13%)	0 (0.00%)
Vertebral fracture	0 (0.00%)	3 (0.09%)	3 (0.02%)	5 (0.07%)	205 (0.13%)	5 (0.24%)
Other fracture[1]	13 (1.74%)	31 (0.91%)	126 (0.77%)	63 (0.86%)	2301 (1.50%)	25 (1.20%)
Total fracture	13 (1.74%)	35 (1.03%)	132 (0.81%)	70 (0.95%)	2602 (1.70%)	29 (1.39%)
Cancer						
Colorectal cancer	2 (0.27%)	5 (0.15%)	21 (0.13%)	9 (0.12%)	193 (0.13%)	3 (0.14%)
Breast cancer[2]	3 (0.40%)	19 (0.56%)	56 (0.34%)	30 (0.41%)	850 (0.56%)	8 (0.38%)
Invasive breast cancer	3 (0.40%)	12 (0.35%)	40 (0.24%)	25 (0.34%)	672 (0.44%)	8 (0.38%)
Non-invasive breast cancer	0 (0.00%)	7 (0.21%)	16 (0.10%)	5 (0.07%)	180 (0.12%)	0 (0.00%)
Ovarian cancer	0 (0.00%)	2 (0.06%)	8 (0.05%)	0 (0.00%)	82 (0.05%)	1 (0.05%)
Endometrial cancer[3]	1 (0.32%)	0 (0.00%)	2 (0.03%)	3 (0.07%)	118 (0.13%)	2 (0.17%)
Other cancer[1]	3 (0.40%)	16 (0.47%)	55 (0.34%)	18 (0.25%)	811 (0.53%)	9 (0.43%)
Total cancer	9 (1.20%)	42 (1.24%)	141 (0.86%)	57 (0.78%)	2003 (1.31%)	23 (1.10%)
Cardiovascular						
CHD[4]	2 (0.27%)	3 (0.09%)	52 (0.32%)	10 (0.14%)	530 (0.35%)	8 (0.38%)
CHD death[5]	1 (0.13%)	1 (0.03%)	19 (0.12%)	1 (0.01%)	111 (0.07%)	2 (0.10%)
Total MI[6]	2 (0.27%)	3 (0.09%)	37 (0.23%)	10 (0.14%)	453 (0.30%)	7 (0.34%)
Clinical MI	2 (0.27%)	3 (0.09%)	34 (0.21%)	10 (0.14%)	417 (0.27%)	6 (0.29%)
Evolving Q-wave MI[7]	0 (0.00%)	0 (0.00%)	3 (0.02%)	0 (0.00%)	38 (0.02%)	1 (0.05%)
Possible evolving Q-wave MI[7]	0 (0.00%)	3 (0.09%)	19 (0.12%)	3 (0.04%)	104 (0.07%)	0 (0.00%)
Angina	1 (0.13%)	9 (0.26%)	83 (0.51%)	30 (0.41%)	654 (0.43%)	10 (0.48%)
CABG/PTCA	1 (0.13%)	7 (0.21%)	71 (0.43%)	25 (0.34%)	713 (0.47%)	11 (0.53%)
Carotid artery disease	1 (0.13%)	1 (0.03%)	6 (0.04%)	1 (0.01%)	121 (0.08%)	0 (0.00%)
Congestive heart failure	1 (0.13%)	3 (0.09%)	69 (0.42%)	17 (0.23%)	380 (0.25%)	5 (0.24%)
Stroke	5 (0.67%)	13 (0.38%)	48 (0.29%)	11 (0.15%)	382 (0.25%)	6 (0.29%)
PVD	1 (0.13%)	1 (0.03%)	16 (0.10%)	1 (0.01%)	101 (0.07%)	1 (0.05%)
CHD[4]/Possible evolving Q-wave MI	2 (0.27%)	6 (0.18%)	70 (0.43%)	13 (0.18%)	629 (0.41%)	8 (0.38%)
Coronary disease[8]	3 (0.40%)	17 (0.50%)	198 (1.21%)	54 (0.74%)	1520 (0.99%)	22 (1.05%)
Total cardiovascular disease	8 (1.07%)	30 (0.88%)	254 (1.55%)	67 (0.91%)	1995 (1.30%)	29 (1.39%)
Deaths						
Cardiovascular deaths	1 (0.13%)	5 (0.15%)	37 (0.23%)	3 (0.04%)	210 (0.14%)	2 (0.10%)
Cancer deaths	0 (0.00%)	11 (0.32%)	34 (0.21%)	9 (0.12%)	365 (0.24%)	4 (0.19%)
Other known cause	2 (0.27%)	0 (0.00%)	16 (0.10%)	1 (0.01%)	109 (0.07%)	1 (0.05%)
Unknown cause	1 (0.13%)	0 (0.00%)	6 (0.04%)	0 (0.00%)	44 (0.03%)	0 (0.00%)
Not yet adjudicated	1 (0.13%)	0 (0.00%)	7 (0.04%)	2 (0.03%)	50 (0.03%)	1 (0.05%)
Total death	5 (0.67%)	16 (0.47%)	100 (0.61%)	15 (0.20%)	778 (0.51%)	8 (0.38%)

[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 six 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: February 28, 2003

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	36282	5157	8265	16518	6342
Mean follow-up (months)	60.5	66.2	62.8	58.8	57.6
Hospitalizations					
Ever	13100 (7.16%)	1353 (4.76%)	2486 (5.75%)	6236 (7.71%)	3025 (9.94%)
Two or more	5796 (3.17%)	512 (1.80%)	989 (2.29%)	2765 (3.42%)	1530 (5.03%)
Other					
DVT[1]	282 (0.16%)	16 (0.06%)	47 (0.11%)	127 (0.16%)	92 (0.31%)
Pulmonary embolism	161 (0.09%)	9 (0.03%)	30 (0.07%)	84 (0.10%)	38 (0.13%)
Diabetes (treated)	1891 (1.08%)	278 (1.00%)	433 (1.04%)	847 (1.10%)	333 (1.15%)
Gallbladder disease[2]	1836 (1.19%)	288 (1.15%)	465 (1.25%)	833 (1.24%)	250 (1.01%)
Hysterectomy	716 (0.67%)	101 (0.62%)	172 (0.65%)	330 (0.70%)	113 (0.66%)
Glaucoma	2587 (1.47%)	262 (0.93%)	515 (1.22%)	1252 (1.61%)	558 (1.97%)
Osteoporosis	5233 (3.00%)	499 (1.78%)	946 (2.25%)	2555 (3.33%)	1233 (4.46%)
Osteoarthritis[3]	4970 (4.36%)	724 (3.44%)	1155 (3.92%)	2258 (4.72%)	833 (5.36%)
Rheumatoid arthritis	1319 (0.75%)	199 (0.72%)	319 (0.76%)	568 (0.73%)	233 (0.81%)
Intestinal polyps	3588 (2.10%)	437 (1.59%)	777 (1.88%)	1762 (2.35%)	612 (2.25%)
Lupus	233 (0.13%)	40 (0.14%)	54 (0.13%)	96 (0.12%)	43 (0.14%)
Kidney stones[3]	505 (0.33%)	70 (0.31%)	119 (0.34%)	222 (0.33%)	94 (0.37%)
Cataracts[3]	8259 (6.18%)	525 (2.38%)	1393 (4.09%)	4491 (7.50%)	1850 (10.52%)
Pills for hypertension	6929 (5.30%)	916 (3.94%)	1538 (4.62%)	3166 (5.70%)	1309 (7.00%)

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)	60.3	56.6	59.3	58.6	60.9	57.0
Hospitalizations						
Ever	58 (7.75%)	178 (5.23%)	1232 (7.53%)	449 (6.12%)	11025 (7.20%)	158 (7.56%)
Two or more	32 (4.28%)	64 (1.88%)	563 (3.44%)	179 (2.44%)	4888 (3.19%)	70 (3.35%)
Other						
DVT[1]	2 (0.27%)	0 (0.00%)	22 (0.14%)	5 (0.07%)	251 (0.17%)	2 (0.10%)
Pulmonary embolism	3 (0.40%)	0 (0.00%)	13 (0.08%)	2 (0.03%)	140 (0.09%)	3 (0.14%)
Diabetes (treated)	9 (1.30%)	51 (1.60%)	299 (2.05%)	129 (1.87%)	1374 (0.93%)	29 (1.48%)
Gallbladder disease[2]	8 (1.41%)	28 (0.91%)	125 (0.84%)	92 (1.63%)	1560 (1.21%)	23 (1.31%)
Hysterectomy	2 (0.64%)	12 (0.54%)	31 (0.44%)	24 (0.59%)	642 (0.70%)	5 (0.43%)
Glaucoma	14 (1.97%)	41 (1.25%)	338 (2.20%)	125 (1.76%)	2048 (1.38%)	21 (1.06%)
Osteoporosis	18 (2.53%)	105 (3.19%)	274 (1.73%)	212 (3.08%)	4561 (3.13%)	63 (3.23%)
Osteoarthritis[3]	30 (6.33%)	97 (3.94%)	435 (4.38%)	243 (4.85%)	4091 (4.32%)	74 (5.45%)
Rheumatoid arthritis	12 (1.81%)	20 (0.61%)	225 (1.49%)	112 (1.60%)	932 (0.63%)	18 (0.92%)
Intestinal polyps	22 (3.19%)	64 (2.04%)	345 (2.25%)	119 (1.69%)	2999 (2.10%)	39 (2.03%)
Lupus	4 (0.54%)	1 (0.03%)	27 (0.17%)	6 (0.08%)	193 (0.13%)	2 (0.10%)
Kidney stones[3]	3 (0.50%)	10 (0.35%)	41 (0.31%)	23 (0.38%)	421 (0.33%)	7 (0.40%)
Cataracts[3]	40 (7.18%)	134 (5.33%)	678 (5.64%)	332 (5.85%)	6987 (6.28%)	88 (5.62%)
Pills for hypertension	28 (5.96%)	127 (5.44%)	674 (7.92%)	322 (5.70%)	5704 (5.07%)	74 (5.58%)

[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 – Observation Study Age and Race/Ethnicity Specific Recruitment* 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 CCs in Fall 1997. Year 6 visits at bone density sites started in Fall 2000.

5.3 Completeness of Annual Mail Follow-up

Table 5.2 – Response Rates to OS Follow-up Procedures 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 is 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, 6, and 7 the rates of 94.2% (Y2), 93.7% (Y4), 94.7% (Y5), 94.1% (Y6), and 94.5% (Y7) exceed the 94% (Y2), 92% (Y4), 91% (Y5), 90% (Y6), and 90% (Y7) goals for the *Exposure Update*. These rates fall slightly short of the optimal goals (98% at Y1 with a ½% annual decline to 95% by Y7) for the *Medical History Update*.

5.4 Completeness of Year 3 Clinic Visit

Table 5.3 – OS Annual Visit 3 Task Completeness 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 2/28/03, 96.01 overall completed *Form 33 - Medical History Updates* and 82.7% provided *Form 100 – Blood Samples*. Of those participants due for the year 6 visit, 86.6% completed *Form 33 – Medical History Updates* and 78.1% 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 - Bone Mineral Density Analysis (OS participants) and *Table 5.5* (by race and ethnicity) show the OS component-specific BMD means and standard deviations for baseline, AV-3, and AV-6, along with % change from baseline for the three types of scans available: whole body, spine, and hip. Baseline and % change at AV-3 is given using only those women who have an AV-3 bone scan; baseline and % change at AV-6 is given only for those who have an AV-6 scan. The current data suggest overall a small increase in bone density over three and six 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 – Lost-to-Follow-up and Vital Status: OS Participants 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 1.6% of the participants have stopped follow-up. 3.6% of the OS participants are deceased.

5.7 Outcomes

Table 5.7 – Locally Verified Outcomes (Annualized Percentages) by Age for OS Participants contains counts of the number of locally verified major WHI outcomes for OS participants by age and race/ethnicity. As approximately 4% 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 35% of the expected number hip fractures.

Table 5.8 – Locally Verified Outcomes (Annualized Percentages) of Participants with Self Reported Outcomes by Age and Race/Ethnicity for OS Participants 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 – First Reported Locally Verified Outcomes and *5.10 – Counts of Participants with Self-Reported Outcomes,* contain counts of outcomes relative to AV-3. These tables count the *first* event of a particular type, thus a participant who reports, say, a myocardial infarction 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: February 28, 2003

	Total Enrolled	Distribution
Age	**93,676**	
50-54	12,385	13%
55-59	17,321	18%
60-69	41,195	44%
70-79	22,775	24%
Race/Ethnicity	**93,676**	
American Indian	421	<1%
Asian	2,671	3%
Black	7,635	8%
Hispanic	3,609	4%
White	78,016	83%
Unknown	1,324	1%

Table 5.2
Response Rates to OS Follow-up Procedures

Data as of: February 28, 2003

	# Due[1]	Mailings Initiated[2]		Response to Mailings		Response to CC follow-up		Total Responses	
		N	%	N	%[3]	N	%[4]	N	%[5]
Year 1	93,466	93,280	99.8%	86,656	92.9%	2,829	42.7%	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	93.3%	1,140	33.1%	49,375	95.3%
Year 2	93,030	91,392	98.2%	86,316	94.4%	N/A		87,615	94.2%
VCC	41,453	40,707	98.2%	38,478	94.5%	N/A		39,099	94.3%
NCC	51,577	50,685	98.3%	47,838	94.4%	N/A		48,516	94.1%
Year 4	74,642	73,198	98.1%	68,373	93.4%	N/A		69,909	93.7%
VCC	33,728	33,049	98.0%	30,716	92.9%	N/A		31,351	93.0%
NCC	40,914	40,149	98.1%	37,657	93.8%	N/A		38,558	94.2%
Year 5	53,707	52,716	98.2%	49,632	94.1%	1,216	39.4%	50,848	94.7%
VCC	25,379	24,994	98.5%	23,350	93.4%	575	35.0%	23,925	94.3%
NCC	28,328	27,722	97.9%	26,282	94.8%	641	44.5%	26,923	95.0%
Year 6[6]	22,809	22,278	97.7%	20,984	94.2%	N/A		21,461	94.1%
VCC	9,973	9,767	97.9%	9,127	93.4%	N/A		9,279	93.0%
NCC	12,836	12,511	97.5%	11,857	94.8%	N/A		12,182	94.9%
Year 7	2,549	2,497	98.0%	2,365	94.7%	43	32.6%	2,408	94.5%
VCC	2,518	2,467	98.0%	2,337	94.7%	43	33.1%	2,380	94.5%
NCC	31	30	96.8%	28	93.3%	0	0.0%	28	90.3%

[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: February 28, 2003

	Task	# Due[1]	# Done[2]	% Done
Year 3	Form 33 - Medical History Update	92,498	88,853	96.1%
	Form 38 - Daily Life	92,498	82,339	89.0%
	Form 44 - Current Medications	92,498	79,263	85.7%
	Form 45 - Current Supplements	92,498	79,162	85.6%
	Form 60 - Food Frequency Quest	92,498	82,497	89.2%
	Form 80 - Physical Measures	92,498	77,385	83.7%
	Form 100 - Blood Collection	92,498	76,495	82.7%
	Form 143 - Follow-up	92,498	81,973	88.6%
Year 6[3]	Form 33 - Medical History Update	3,625	3,141	86.6%
	Form 80 - Physical Measures	3,625	2,854	78.7%
	Form 87 - Bone Densitometry	3,625	2,830	78.1%
	Form 146 - Follow-up	3,625	3,028	83.5%

[1] Includes all Year 3/6 contacts due through 4/30/02. 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: February 28, 2003

	N	Mean	S.D.
Whole Body Scan			
Baseline	6390	1.01	0.11
Baseline (for ppts. with an AV3 scan)	5076	1.01	0.11
Baseline (for ppts. with an AV6 scan)	3747	1.01	0.11
AV3	5135	1.02	0.11
AV6	3775	1.03	0.12
AV3 % Change from baseline BMD[2]	5069	0.92	3.63
AV6 % Change from baseline BMD[3]	3739	1.98	5.56
Spine Scan			
Baseline	6235	0.98	0.17
Baseline (for ppts. with an AV3 scan)	4989	0.97	0.17
Baseline (for ppts. with an AV6 scan)	3631	0.98	0.17
AV3	5028	0.99	0.17
AV6	3647	1.01	0.18
AV3 % Change from baseline BMD[2]	4981	1.67	5.14
AV6 % Change from baseline BMD[3]	3623	3.60	6.88
Hip Scan			
Baseline	6418	0.84	0.14
Baseline (for ppts. with an AV3 scan)	5146	0.84	0.14
Baseline (for ppts. with an AV6 scan)	3807	0.84	0.14
AV3	5186	0.85	0.14
AV6	3822	0.84	0.14
AV3 % Change from baseline BMD[2]	5114	0.48	4.34
AV6 % Change from baseline BMD[3]	3771	0.17	5.43

[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: February 28, 2003

	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	569	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)	37	1.04	0.13	13	1.02	0.07	414	1.05	0.11	192	1.03	0.10	3071	1.01	0.10	20	1.00	0.13
AV3	81	1.03	0.13	22	1.03	0.11	577	1.06	0.12	338	1.03	0.11	4080	1.01	0.11	37	1.01	0.10
AV6	37	1.05	0.14	13	1.02	0.11	417	1.05	0.12	193	1.07	0.13	3095	1.03	0.12	20	0.99	0.14
AV3 % Change from baseline BMD[2]	77	0.70	4.45	22	-0.03	5.44	569	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]	37	0.61	4.64	13	0.21	5.38	414	0.16	3.81	191	3.60	6.44	3064	2.17	5.65	20	-0.69	5.42
Spine Scan																		
Baseline	109	0.99	0.17	24	0.95	0.12	814	1.04	0.18	450	0.95	0.16	4793	0.97	0.17	45	0.99	0.19
Baseline (for ppts. with an AV3 scan)	77	0.99	0.15	21	0.96	0.12	572	1.04	0.17	314	0.95	0.16	3971	0.97	0.17	34	0.95	0.18
Baseline (for ppts. with an AV6 scan)	37	1.02	0.17	12	0.95	0.11	397	1.04	0.18	190	0.97	0.17	2975	0.97	0.16	20	0.97	0.25
AV3	81	1.00	0.16	21	0.96	0.12	575	1.05	0.19	327	0.95	0.16	3989	0.98	0.17	35	0.95	0.17
AV6	37	1.04	0.17	12	0.96	0.10	397	1.06	0.19	192	0.98	0.18	2989	1.01	0.18	20	1.00	0.26
AV3 % Change from baseline BMD[2]	77	0.19	5.80	21	0.45	4.60	572	1.19	5.56	313	0.26	5.41	3964	1.90	5.01	34	0.84	5.17
AV6 % Change from baseline BMD[3]	37	1.61	7.36	12	1.69	4.15	397	1.95	6.13	189	1.25	7.04	2968	4.00	6.90	20	3.73	7.57
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	582	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)	37	0.91	0.17	13	0.79	0.08	422	0.93	0.15	195	0.85	0.12	3119	0.83	0.13	21	0.83	0.16
AV3	82	0.88	0.15	22	0.82	0.09	588	0.94	0.15	338	0.85	0.13	4119	0.83	0.13	37	0.82	0.13
AV6	37	0.90	0.16	13	0.81	0.09	424	0.91	0.15	196	0.86	0.13	3131	0.83	0.13	21	0.82	0.16
AV3 % Change from baseline BMD[2]	77	-0.41	4.86	22	0.90	4.48	582	0.36	4.00	322	1.69	5.00	4075	0.43	4.30	36	-0.81	4.76
AV6 % Change from baseline BMD[3]	37	-1.11	6.56	13	2.19	6.12	420	-2.06	4.92	193	1.64	6.22	3087	0.40	5.34	21	-0.91	6.81

[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: February 28, 2003

	OS Participants (N=93,676)	
	N	%
Vital Status/Participation		
Deceased	3401	3.6
Alive: Current Participation[1]	84259	89.9
Alive: Recent Participation[2]	2265	2.4
Alive: Past/Unknown Participation[3]	194	0.2
Stopped Follow-Up[4]	1462	1.6
Lost to Follow-Up[5]	2095	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: February 28, 2003

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number enrolled	93676	12385	17321	41195	22775
Mean follow-up (months)	65.7	69.6	68.2	64.7	63.4
Cardiovascular					
CHD[1]	1482 (0.29%)	48 (0.07%)	116 (0.12%)	614 (0.28%)	704 (0.58%)
CHD death[2]	405 (0.08%)	8 (0.01%)	20 (0.02%)	143 (0.06%)	234 (0.19%)
Clinical MI	1201 (0.23%)	42 (0.06%)	102 (0.10%)	510 (0.23%)	547 (0.45%)
Angina	2186 (0.43%)	94 (0.13%)	220 (0.22%)	1014 (0.46%)	858 (0.71%)
CABG/PTCA	2080 (0.41%)	72 (0.10%)	206 (0.21%)	978 (0.44%)	824 (0.68%)
Carotid artery disease	450 (0.09%)	24 (0.03%)	32 (0.03%)	174 (0.08%)	220 (0.18%)
Congestive heart failure	1419 (0.28%)	47 (0.07%)	109 (0.11%)	558 (0.25%)	705 (0.59%)
Stroke	1197 (0.23%)	31 (0.04%)	92 (0.09%)	457 (0.21%)	617 (0.51%)
PVD	327 (0.06%)	11 (0.02%)	30 (0.03%)	130 (0.06%)	156 (0.13%)
Coronary disease[3]	4509 (0.88%)	176 (0.24%)	419 (0.43%)	1958 (0.88%)	1956 (1.63%)
Total cardiovascular disease	6088 (1.19%)	235 (0.33%)	544 (0.55%)	2557 (1.15%)	2752 (2.29%)
Cancer					
Breast cancer[4]	2868 (0.56%)	289 (0.40%)	511 (0.52%)	1320 (0.59%)	748 (0.62%)
Invasive breast cancer	2376 (0.46%)	242 (0.34%)	416 (0.42%)	1082 (0.49%)	636 (0.53%)
Non-invasive breast cancer	518 (0.10%)	51 (0.07%)	101 (0.10%)	250 (0.11%)	116 (0.10%)
Ovarian cancer	252 (0.05%)	24 (0.03%)	41 (0.04%)	115 (0.05%)	72 (0.06%)
Endometrial cancer[5]	369 (0.12%)	32 (0.07%)	52 (0.08%)	170 (0.13%)	115 (0.17%)
Colorectal cancer	607 (0.12%)	35 (0.05%)	70 (0.07%)	273 (0.12%)	229 (0.19%)
Other cancer[6]	2660 (0.52%)	185 (0.26%)	325 (0.33%)	1213 (0.55%)	937 (0.78%)
Total cancer	6544 (1.28%)	553 (0.77%)	971 (0.99%)	2994 (1.35%)	2026 (1.68%)
Fractures					
Hip fracture	614 (0.12%)	15 (0.02%)	51 (0.05%)	190 (0.09%)	358 (0.30%)
Vertebral fracture[7]	75 (0.19%)	4 (0.07%)	6 (0.08%)	28 (0.17%)	37 (0.39%)
Other fracture[6,7]	531 (1.35%)	67 (1.16%)	88 (1.20%)	213 (1.26%)	163 (1.73%)
Total fracture[8]	1184 N/A	85 N/A	141 N/A	419 N/A	539 N/A
Deaths					
Cardiovascular deaths	879 (0.17%)	22 (0.03%)	51 (0.05%)	302 (0.14%)	504 (0.42%)
Cancer deaths	1460 (0.28%)	82 (0.11%)	164 (0.17%)	619 (0.28%)	595 (0.49%)
Other known cause	590 (0.12%)	30 (0.04%)	67 (0.07%)	219 (0.10%)	274 (0.23%)
Unknown cause	217 (0.04%)	9 (0.01%)	20 (0.02%)	78 (0.04%)	110 (0.09%)
Not yet adjudicated	255 (0.05%)	10 (0.01%)	31 (0.03%)	93 (0.04%)	121 (0.10%)
Total death	3401 (0.66%)	153 (0.21%)	333 (0.34%)	1311 (0.59%)	1604 (1.33%)

[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: February 28, 2003

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)	61.4	63.8	61.7	58.2	66.6	63.1
Cardiovascular						
CHD[1]	8 (0.37%)	31 (0.22%)	134 (0.34%)	25 (0.14%)	1260 (0.29%)	24 (0.34%)
CHD death[2]	3 (0.14%)	9 (0.06%)	59 (0.15%)	3 (0.02%)	324 (0.07%)	7 (0.10%)
Clinical MI	6 (0.28%)	25 (0.18%)	91 (0.23%)	23 (0.13%)	1037 (0.24%)	19 (0.27%)
Angina	14 (0.65%)	43 (0.30%)	191 (0.49%)	55 (0.31%)	1860 (0.43%)	23 (0.33%)
CABG/PTCA	11 (0.51%)	42 (0.30%)	130 (0.33%)	52 (0.30%)	1814 (0.42%)	31 (0.45%)
Carotid artery disease	4 (0.19%)	6 (0.04%)	27 (0.07%)	10 (0.06%)	396 (0.09%)	7 (0.10%)
Congestive heart failure	10 (0.46%)	19 (0.13%)	151 (0.38%)	30 (0.17%)	1185 (0.27%)	24 (0.34%)
Stroke	8 (0.37%)	33 (0.23%)	125 (0.32%)	23 (0.13%)	991 (0.23%)	17 (0.24%)
PVD	2 (0.09%)	4 (0.03%)	33 (0.08%)	4 (0.02%)	278 (0.06%)	6 (0.09%)
Coronary disease[3]	26 (1.21%)	82 (0.58%)	415 (1.06%)	104 (0.59%)	3826 (0.88%)	56 (0.80%)
Total cardiovascular disease	33 (1.53%)	120 (0.84%)	574 (1.46%)	135 (0.77%)	5144 (1.19%)	82 (1.18%)
Cancer						
Breast cancer[4]	6 (0.28%)	55 (0.39%)	172 (0.44%)	74 (0.42%)	2534 (0.59%)	27 (0.39%)
Invasive breast cancer	4 (0.19%)	43 (0.30%)	135 (0.34%)	59 (0.34%)	2111 (0.49%)	24 (0.34%)
Non-invasive breast cancer	2 (0.09%)	12 (0.08%)	38 (0.10%)	16 (0.09%)	446 (0.10%)	4 (0.06%)
Ovarian cancer	0 (0.00%)	4 (0.03%)	11 (0.03%)	7 (0.04%)	229 (0.05%)	1 (0.01%)
Endometrial cancer[5]	0 (0.00%)	6 (0.06%)	11 (0.06%)	7 (0.07%)	339 (0.13%)	6 (0.15%)
Colorectal cancer	1 (0.05%)	9 (0.06%)	69 (0.18%)	14 (0.08%)	506 (0.12%)	8 (0.11%)
Other cancer[6]	11 (0.51%)	47 (0.33%)	172 (0.44%)	52 (0.30%)	2335 (0.54%)	43 (0.62%)
Total cancer	18 (0.84%)	117 (0.82%)	420 (1.07%)	152 (0.87%)	5755 (1.33%)	82 (1.18%)
Fractures						
Hip fracture	4 (0.19%)	7 (0.05%)	14 (0.04%)	7 (0.04%)	573 (0.13%)	9 (0.13%)
Vertebral fracture[7]	1 (0.19%)	0 (0.00%)	1 (0.02%)	2 (0.08%)	71 (0.23%)	0 (0.00%)
Other fracture[6,7]	7 (1.35%)	2 (1.29%)	32 (0.63%)	28 (1.07%)	457 (1.48%)	5 (1.99%)
Total fracture[8]	11 N/A	9 N/A	46 N/A	36 N/A	1068 N/A	14 N/A
Deaths						
Cardiovascular deaths	7 (0.33%)	23 (0.16%)	115 (0.29%)	13 (0.07%)	707 (0.16%)	14 (0.20%)
Cancer deaths	7 (0.33%)	26 (0.18%)	117 (0.30%)	35 (0.20%)	1255 (0.29%)	20 (0.29%)
Other known cause	11 (0.51%)	11 (0.08%)	56 (0.14%)	30 (0.17%)	475 (0.11%)	7 (0.10%)
Unknown cause	0 (0.00%)	3 (0.02%)	38 (0.10%)	7 (0.04%)	167 (0.04%)	2 (0.03%)
Not yet adjudicated	2 (0.09%)	2 (0.01%)	29 (0.07%)	9 (0.05%)	208 (0.05%)	5 (0.07%)
Total death	27 (1.25%)	65 (0.46%)	355 (0.90%)	94 (0.54%)	2812 (0.65%)	48 (0.69%)

[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: February 28, 2003

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	93676	12385	17321	41195	22775
Mean follow-up (months)	65.7	69.6	68.2	64.7	63.4
Hospitalizations					
Ever	34292 (6.69%)	3177 (4.42%)	4937 (5.02%)	15374 (6.92%)	10804 (8.98%)
Two or more	15208 (2.97%)	1176 (1.64%)	1834 (1.86%)	6780 (3.05%)	5418 (4.50%)
Other					
DVT[1]	523 (0.11%)	44 (0.06%)	59 (0.06%)	241 (0.11%)	179 (0.16%)
Pulmonary embolism	322 (0.06%)	31 (0.04%)	43 (0.04%)	139 (0.06%)	109 (0.09%)
Diabetes (treated)	3472 (0.70%)	422 (0.60%)	641 (0.67%)	1576 (0.74%)	833 (0.73%)
Gallbladder disease[2]	4158 (0.96%)	642 (1.01%)	822 (0.97%)	1858 (1.00%)	836 (0.85%)
Hysterectomy	2299 (0.77%)	322 (0.75%)	445 (0.73%)	1074 (0.84%)	458 (0.68%)
Glaucoma	5644 (1.16%)	550 (0.78%)	838 (0.87%)	2615 (1.23%)	1641 (1.49%)
Osteoporosis	16121 (3.43%)	1550 (2.24%)	2467 (2.63%)	7465 (3.69%)	4639 (4.46%)
Osteoarthritis[3]	11688 (3.91%)	1449 (2.79%)	2071 (3.21%)	5251 (4.23%)	2917 (5.02%)
Rheumatoid arthritis	3350 (0.69%)	461 (0.67%)	648 (0.69%)	1364 (0.65%)	877 (0.78%)
Intestinal polyps	9232 (1.99%)	1052 (1.54%)	1712 (1.86%)	4314 (2.16%)	2154 (2.07%)
Lupus	737 (0.14%)	114 (0.16%)	148 (0.15%)	320 (0.14%)	155 (0.13%)
Kidney stones[3]	1572 (0.38%)	209 (0.38%)	284 (0.37%)	666 (0.37%)	413 (0.42%)
Cataracts[3]	19526 (5.58%)	1043 (1.87%)	2583 (3.41%)	10207 (6.55%)	5693 (9.14%)
Pills for hypertension	15709 (4.29%)	1759 (2.95%)	2740 (3.57%)	6865 (4.44%)	4345 (5.76%)

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)	61.4	63.8	61.7	58.2	66.6	63.1
Hospitalizations						
Ever	174 (8.08%)	613 (4.32%)	2685 (6.84%)	973 (5.56%)	29404 (6.80%)	443 (6.36%)
Two or more	87 (4.04%)	221 (1.56%)	1194 (3.04%)	348 (1.99%)	13154 (3.04%)	204 (2.93%)
Other						
DVT[1]	3 (0.15%)	4 (0.03%)	46 (0.12%)	9 (0.05%)	457 (0.11%)	4 (0.06%)
Pulmonary embolism	1 (0.05%)	3 (0.02%)	25 (0.06%)	2 (0.01%)	288 (0.07%)	3 (0.04%)
Diabetes (treated)	38 (2.07%)	130 (0.96%)	554 (1.60%)	226 (1.39%)	2475 (0.59%)	49 (0.74%)
Gallbladder disease[2]	25 (1.48%)	58 (0.45%)	270 (0.78%)	168 (1.23%)	3580 (0.98%)	57 (0.98%)
Hysterectomy	4 (0.38%)	37 (0.40%)	98 (0.55%)	79 (0.83%)	2041 (0.79%)	40 (0.99%)
Glaucoma	35 (1.77%)	183 (1.35%)	680 (1.89%)	201 (1.21%)	4465 (1.08%)	80 (1.20%)
Osteoporosis	72 (3.66%)	487 (3.75%)	734 (1.97%)	547 (3.40%)	14032 (3.55%)	249 (3.90%)
Osteoarthritis[3]	48 (3.97%)	351 (3.52%)	964 (4.24%)	541 (4.71%)	9603 (3.86%)	181 (4.29%)
Rheumatoid arthritis	25 (1.27%)	70 (0.52%)	503 (1.41%)	289 (1.78%)	2399 (0.58%)	64 (0.98%)
Intestinal polyps	30 (1.52%)	234 (1.84%)	727 (2.02%)	280 (1.71%)	7839 (2.01%)	122 (1.94%)
Lupus	7 (0.33%)	12 (0.08%)	73 (0.19%)	41 (0.24%)	593 (0.14%)	11 (0.16%)
Kidney stones[3]	13 (0.76%)	27 (0.23%)	188 (0.58%)	94 (0.65%)	1221 (0.35%)	29 (0.51%)
Cataracts[3]	69 (4.70%)	510 (5.32%)	1408 (5.08%)	629 (4.75%)	16617 (5.67%)	293 (6.16%)
Pills for hypertension	71 (5.21%)	433 (4.33%)	1288 (6.70%)	668 (5.09%)	13013 (4.09%)	236 (4.85%)

[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: February 28, 2003

Outcome	Number of Events	
	Before AV-3	After AV-3
Cardiovascular		
CHD[2]	754	728
CHD death[3]	174	231
Clinical MI	637	564
Angina	1348	838
CABG/PTCA	1160	920
Carotid artery disease	254	196
Congestive heart failure	712	707
Stroke	571	626
PVD	197	130
Coronary disease[4]	2569	1940
Total cardiovascular disease	3429	2659
Cancer		
Breast cancer[5]	1596	1272
Invasive breast cancer	1301	1075
Non-invasive breast cancer	311	207
Ovarian cancer	150	102
Endometrial cancer	203	166
Colorectal cancer	342	265
Other cancer[6]	1437	1223
Total cancer	3663	2881
Fractures		
Hip fracture[7]	292	322
Vertebral fracture[7]	35	40
Other fracture[6, 7]	275	256
Total fracture[7]	592	592
Deaths		
Cardiovascular deaths	367	512
Cancer deaths	606	854
Deaths: other known cause	218	372
Deaths: unknown cause	59	158
Deaths: not yet adjudicated	13	242
Total death	1263	2138

[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 been enrolled for at least 3 years.
[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: February 28, 2003

Outcome	Number of Events	
	Before AV-3	After AV-3
Ever hospitalized	19158	15134
DVT[2]	226	297
Pulmonary embolism	130	192
Diabetes (treated)	1740	1732
Gallbladder disease[3]	2137	2021
Hysterectomy	1245	1054
Glaucoma	2755	2889
Osteoporosis	8702	7419
Osteoarthritis[4]	6337	5351
Rheumatoid arthritis	1724	1626
Intestinal polyps	4396	4836
Lupus	348	389
Kidney stones[4]	646	926
Cataracts[4]	9146	10380
Pills for hypertension	8140	7569

[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 been enrolled for at least 3 years.
[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 – Medical History Update - Detail*) 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 97% of self-reported outcomes in the CT and 96% of the self-reported outcomes in the OS requiring adjudication have been closed. In particular, 58% of the outcomes in the CT and 59% of the outcomes in the OS have been closed within 90 days of self-report and 77% (CT) and 79% (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 0.2%. Currently, 32 of the 40 clinics have 25 or fewer outstanding *Forms 33D* that are more than six months old for the CT and OS combined.

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, PE, and DVT 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 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 97% of the cardiovascular outcomes has been adjudicated (was 85%), for stroke 79% has been centrally adjudicated (was 19%), and about 92% of the cancer outcomes has been centrally adjudicated (was 90%).

Tables 6.5 and *6.6* show how many outcomes were identified by local adjudicators, but denied centrally. *Tables 6.7* and *6.8 – Source of Outcomes Identified by Central Adjudications* shows outcomes that were identified by the central adjudicators, but not by the local adjudicators. Approximately 12 %(CT)-19 %(OS) of the MIs that were identified by central adjudicators were not found by local adjudicators. Most of these MIs were identified on cases that were called forward for "related" events, such as angina, CHF, and CABG/PTCA. 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; and most of the cases of stroke that were identified because of a locally confirmed other outcome were identified because of a locally confirmed case of TIA. Cancer of the uterus, upper leg fractures, and TIA 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 Race/Ethnicity for CT Participants contains the number of locally verified outcomes for the major WHI outcomes categories. Since about 4% 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 105% 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 Race/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 (Ron Prineas, 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 February 28, 2003, the CCC had received serial analysis on 59,075 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 Incident 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 47 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 29 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 (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 – Results of NDI Search.* The NDI search identified 26 women as dead, whose death had not otherwise been ascertained by WHI. A second NDI search is planned for the second half of 2003.

As of the February 28 database, there were 2,189 deaths in the CT and 3,401 in the OS. Of the 2,189 CT deaths, there were 1,911 (87%) for which a final adjudication (or NDI report) was available, and an additional 143 (7%) for which a temporary adjudication was available. For the OS there is cause of death information on 92% 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 3.2% of the CT participants are deceased, we do not know the vital status of about 1.5% of the CT participants, and 2.3% 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 6.2 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 0.1 to 9.8% per clinic. The percentage of participants who stopped follow-up ranges from less than 0.1 to 7.1%.

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 3.8% 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: February 28, 2003

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	3964	269	7%	778	20%	3957	100%	7	<1%
1996 July-December	1383	307	22%	714	52%	1383	100%	0	0%
1997 January-June	2180	764	35%	1329	61%	2177	100%	3	<1%
1997 July-December	2549	980	38%	1517	60%	2548	100%	1	<1%
1998 January-June	3576	1664	47%	2779	78%	3576	100%	0	0%
1998 July-December	4160	2360	57%	3333	80%	4158	100%	2	<1%
1999 January-June	4604	2830	61%	3805	83%	4602	100%	2	<1%
1999 July-December	4476	2869	64%	3692	82%	4476	100%	0	0%
2000 January-June	4716	3102	66%	3961	84%	4713	100%	3	<1%
2000 July-December	4410	2986	68%	3813	86%	4408	100%	2	<1%
2001 January- June	5211	3653	70%	4550	87%	5200	100%	11	<1%
2001 July-December	4766	3238	68%	4297	90%	4732	99%	34	1%
2002 January	941	705	75%	862	92%	924	98%	17	2%
2002 February	838	644	77%	748	89%	821	98%	17	2%
2002 March	892	684	77%	821	92%	870	98%	22	2%
2002 April	940	706	75%	836	89%	916	97%	24	3%
2002 May	902	701	78%	832	92%	881	98%	21	2%
2002 June	766	539	70%	695	91%	734	96%	32	4%
2002 July	1065	830	78%	1000	94%	1034	97%	31	3%
2002 August	965	751	78%	910	94%	924	96%	41	4%
2002 September	810	606	75%	743	92%	743	92%	67	8%
2002 October	968	742	77%	860	89%	860	89%	108	11%
2002 November	747	584	78%	617	83%	617	83%	130	17%
2002 December	702	513	73%	513	73%	513	73%	189	27%
2003 January	942	452	48%	452	48%	452	48%	490	52%
2003 February	627	78	12%	78	12%	78	12%	549	88%
Total	58100	33557	58%	44535	77%	56297	97%	1803	3%

[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: February 28, 2003

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	83	35%	126	53%	238	100%	0	0%
1996 July-December	1311	307	23%	701	53%	1310	100%	1	<1%
1997 January-June	2155	844	39%	1401	65%	2154	100%	1	<1%
1997 July-December	2296	709	31%	1357	59%	2296	100%	0	0%
1998 January-June	2835	1268	45%	2036	72%	2835	100%	0	0%
1998 July-December	3806	2004	53%	2900	76%	3805	100%	1	<1%
1999 January-June	4753	2843	60%	3924	83%	4753	100%	0	0%
1999 July-December	4222	2526	60%	3413	81%	4222	100%	0	0%
2000 January-June	5929	3779	64%	4888	82%	5925	100%	4	<1%
2000 July-December	4317	2833	66%	3635	84%	4311	100%	6	<1%
2001 January- June	5379	3577	66%	4600	86%	5359	100%	20	<1%
2001 July-December	4705	3135	67%	4145	88%	4664	99%	41	1%
2002 January	886	650	73%	808	91%	872	98%	14	2%
2002 February	817	614	75%	740	91%	799	98%	18	2%
2002 March	822	587	71%	720	88%	786	96%	36	4%
2002 April	1120	772	69%	996	89%	1073	96%	47	4%
2002 May	1134	831	73%	1038	92%	1099	97%	35	3%
2002 June	983	687	70%	887	90%	929	95%	54	5%
2002 July	966	715	74%	875	91%	908	94%	58	6%
2002 August	997	712	71%	891	89%	906	91%	91	9%
2002 September	786	582	74%	707	90%	707	90%	79	10%
2002 October	824	605	73%	710	86%	710	86%	114	14%
2002 November	657	484	74%	535	81%	535	81%	122	19%
2002 December	671	475	71%	475	71%	475	71%	196	29%
2003 January	898	452	50%	452	50%	452	50%	446	50%
2003 February	708	99	14%	99	14%	99	14%	609	86%
Total	54215	32173	59%	43059	79%	52222	96%	1993	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.

Figure 6.1 Clinical Trial Timeliness per Period of Self-Report

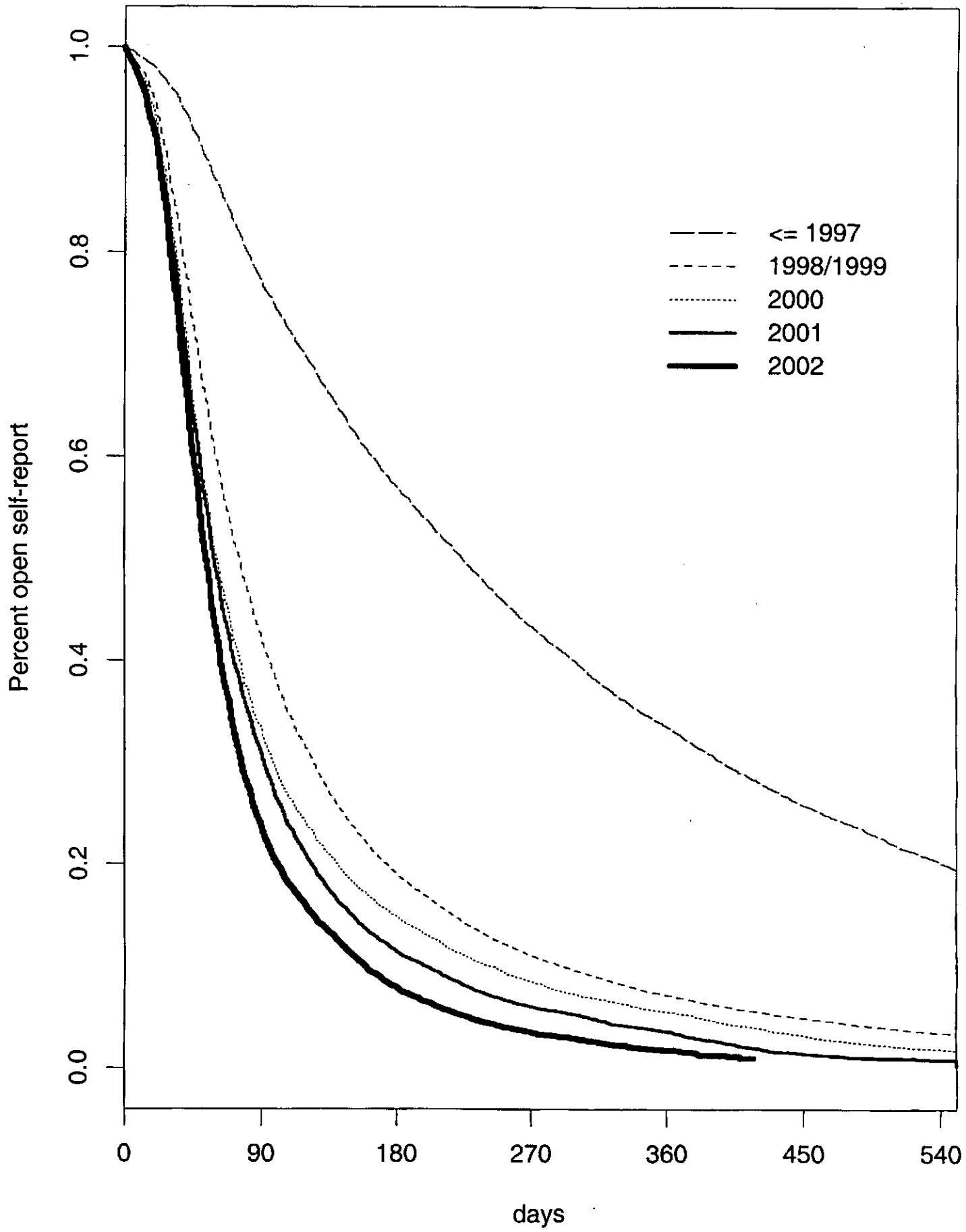


Figure 6.2 Observational Study Timeliness per Period of Self-Report

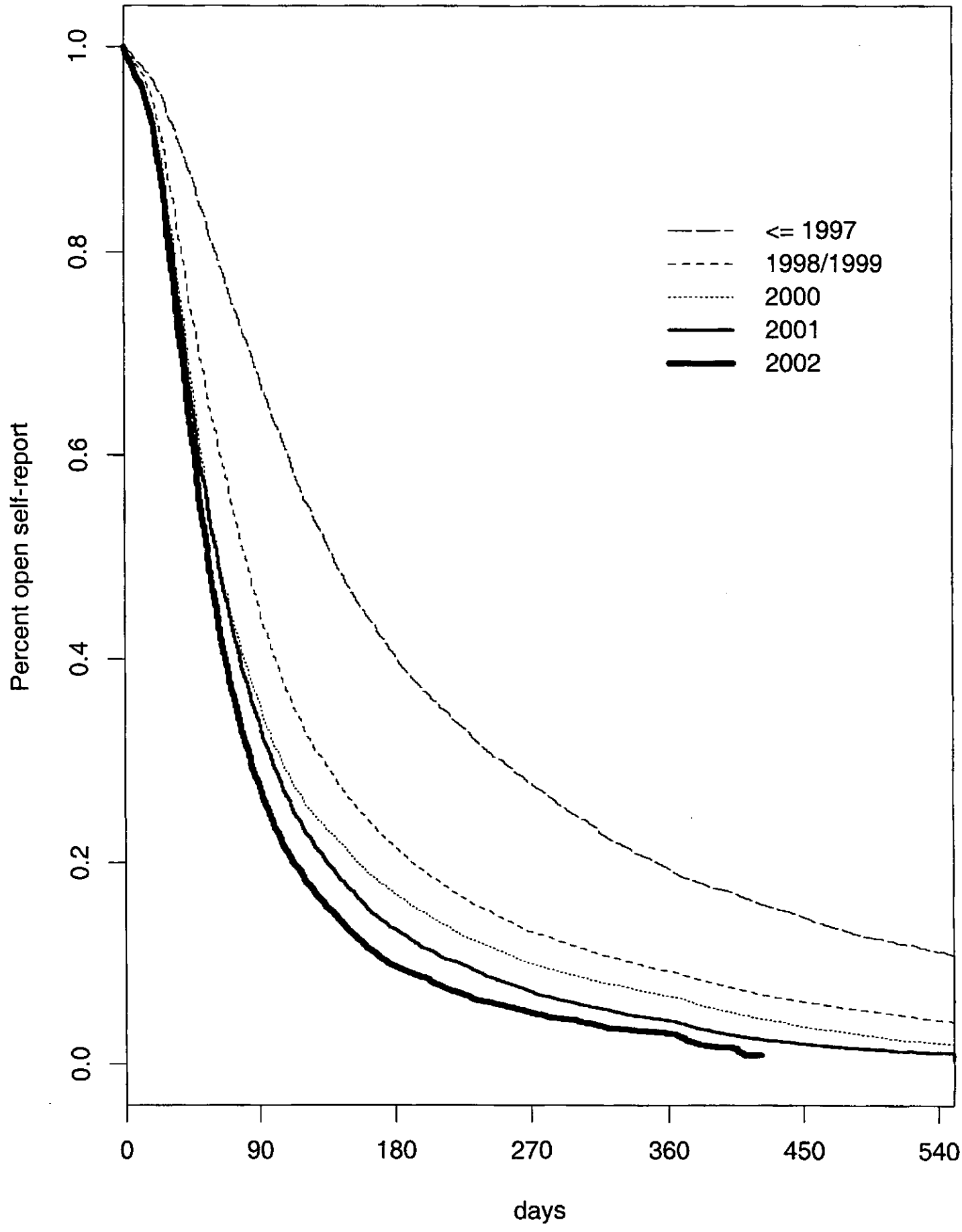


Table 6.3
Agreement of the Local Adjudications with Self-Reports — CT Participants

Data as of: February 28, 2003

	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	1040	979	94%	695	(71%)	154	(16%)	119	(12%)	11	(1%)
Angina[2]	2026	1944	96%	935	(48%)	87	(4%)	888	(46%)	34	(2%)
Congestive heart failure	696	661	95%	490	(74%)	40	(6%)	121	(18%)	10	(2%)
CABG/PTCA	2276	2174	96%	1724	(79%)	179	(8%)	245	(11%)	26	(1%)
Carotid artery disease[3]	301	289	96%	243	(84%)	23	(8%)	19	(7%)	4	(1%)
Stroke/TIA[4]	1713	1632	95%	1248	(76%)	76	(5%)	281	(17%)	27	(2%)
PVD	229	216	94%	126	(58%)	27	(13%)	58	(27%)	5	(2%)
DVT[5]	337	317	94%	220	(69%)	42	(13%)	48	(15%)	7	(2%)
Pulmonary embolism[5]	162	148	91%	127	(86%)	8	(5%)	13	(9%)	0	(0%)
Cancers											
Breast cancer	2159	2058	95%	1988	(97%)	1	(<1%)	61	(3%)	8	(<1%)
Ovarian cancer	203	197	97%	143	(73%)	40	(20%)	9	(5%)	5	(3%)
Endometrial cancer	256	245	96%	189	(77%)	30	(12%)	23	(9%)	3	(1%)
Colorectal cancer	560	545	97%	477	(88%)	32	(6%)	35	(6%)	1	(<1%)
Other cancer[6]	2352	2246	95%	1711	(76%)	123	(5%)	373	(17%)	39	(2%)
Fractures											
Hip fracture	487	460	94%	373	(81%)	37	(8%)	45	(10%)	5	(1%)
Vertebral fracture	812	768	95%	412	(54%)	31	(4%)	301	(39%)	24	(3%)
Other fracture	6807	6585	97%	5383	(82%)	65	(1%)	961	(15%)	176	(3%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI is not adjudicated. In particular, 233 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, 6 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 386 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: February 28, 2003

	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	990	931	94%	630	(68%)	163	(18%)	119	(13%)	19	(2%)
Angina[2]	2323	2214	95%	1012	(46%)	132	(6%)	1023	(46%)	47	(2%)
Congestive heart failure	851	797	94%	597	(75%)	49	(6%)	134	(17%)	17	(2%)
CABG/PTCA	2559	2439	95%	1876	(77%)	230	(9%)	287	(12%)	46	(2%)
Carotid artery disease[3]	365	352	96%	287	(82%)	33	(9%)	27	(8%)	5	(1%)
Stroke/TIA[4]	2029	1908	94%	1400	(73%)	81	(4%)	376	(20%)	51	(3%)
PVD	316	296	94%	171	(58%)	38	(13%)	81	(27%)	6	(2%)
Cancers											
Breast cancer	3088	2911	94%	2669	(92%)	18	(1%)	181	(6%)	43	(1%)
Ovarian cancer	278	259	93%	180	(69%)	42	(16%)	35	(14%)	2	(1%)
Endometrial cancer	338	325	96%	250	(77%)	47	(14%)	21	(6%)	7	(2%)
Colorectal	647	616	95%	517	(84%)	37	(6%)	51	(8%)	11	(2%)
Other cancer[5]	3178	3001	94%	2105	(70%)	203	(7%)	611	(20%)	82	(3%)
Fractures											
Hip fracture	671	637	95%	498	(78%)	5	(1%)	118	(19%)	16	(3%)
Vertebral fracture	104	99	95%	62	(63%)	6	(6%)	25	(25%)	6	(6%)
Other fracture	759	739	97%	538	(73%)	14	(2%)	153	(21%)	34	(5%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI, is not adjudicated. In particular, 225 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, 6 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 458 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: February 28, 2003

	Locally confirmed N	Called forward for central adjudication N	Called forward for central adjudication %[1]	Centrally adjudicated N	Centrally adjudicated %[2]	In agreement N	In agreement %[3]
Cardiovascular							
Clinical MI	1119	862	77%	829	96%	744	90%
Angina[4]	1907	1532	80%	1485	97%	1108	75%
Congestive heart failure	1075	810	75%	773	95%	589	76%
CABG/PTCA	1855	1438	78%	1385	96%	1340	97%
DVT[5]	285	285	100%	281	99%	271	96%
Pulmonary embolism[5]	177	177	100%	173	98%	171	99%
Stroke	1016	493	100%	388	79%	362	93%
Cancers							
Breast cancer	2010	2010	100%	1856	92%	1850	100%
Invasive	1584	1584	100%	1464	92%	1429	98%
Non-invasive	426	426	100%	392	92%	339	86%
Ovarian cancer	173	173	100%	156	90%	126	81%
Endometrial cancer	246	246	100%	230	93%	220	96%
Colorectal cancer	530	530	100%	504	95%	492	98%
Fractures							
Hip fracture	459	458	100%	395	86%	373	94%

[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: February 28, 2003

	Locally confirmed N	Called forward for central adjudication N	%[1]	Centrally adjudicated N	%[2]	In agreement N	%[3]
Cardiovascular							
Clinical MI	1201	709	59%	685	97%	560	82%
Angina[4]	2186	1447	66%	1404	97%	1075	77%
Congestive heart failure	1419	790	56%	765	97%	610	80%
CABG/PTCA	2080	1271	61%	1235	97%	1182	96%
Cancers							
Breast cancer	2747	2747	100%	2559	93%	2509	98%
Invasive	2254	2254	100%	2101	93%	2004	95%
Non-Invasive	493	493	100%	458	93%	367	80%
Ovarian cancer	225	225	100%	191	85%	156	82%
Endometrial cancer	354	354	100%	315	89%	291	92%
Colorectal cancer	578	578	100%	539	93%	509	94%
Fractures							
Hip fracture	614	614	100%	477	78%	463	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: February 28, 2003

	Centrally confirmed	Reason for central investigation						Denied self-reports reviewed by CCC
		Locally confirmed same outcome		Locally confirmed other outcome		Self-report but no outcome found		
	N	N	%	N	%	N	%	N
Cardiovascular								
Clinical MI	836	731	87%	103	12%	2	0%	95
Angina	1345	1069	79%	258	19%	18	1%	N/A
Congestive heart failure	683	574	84%	104	15%	5	1%	N/A
CABG/PTCA	1381	1323	96%	55	4%	3	0%	N/A
DVT	279	269	96%	7	3%	3	1%	59
Pulmonary embolism	178	171	96%	3	2%	4	2%	12
Stroke	391	355	91%	0	0%	36	9%	257
Cancers								
Breast cancer	1863	1855	100%	4	0%	4	0%	69
Ovarian cancer	136	126	93%	7	5%	3	2%	27
Endometrial cancer	242	219	90%	21	9%	2	1%	28
Colorectal cancer	499	491	98%	3	1%	5	1%	50
Fractures								
Hip fracture	386	373	97%	7	2%	6	2%	43

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

Data as of: February 28, 2003

	Centrally confirmed	Reason for central investigation						Denied self-reports reviewed by CCC
		Locally confirmed same outcome		Locally confirmed other outcome		Self-report but no outcome found		
	N	N	%	N	%	N	%	N
Cardiovascular								
Clinical MI	674	546	81%	126	19%	2	0%	52
Angina	1057	1057	100%	236	22%	8	1%	N/A
Congestive heart failure	684	602	88%	79	12%	3	0%	N/A
CABG/PTCA	1217	1164	96%	50	4%	3	0%	N/A
Cancers								
Breast cancer	2524	2513	100%	1	0%	10	0%	129
Ovarian cancer	166	156	94%	8	5%	2	1%	46
Endometrial cancer	327	290	89%	33	10%	4	1%	30
Colorectal cancer	517	509	98%	4	1%	4	1%	74
Fractures								
Hip fracture	468	463	99%	1	0%	4	1%	61

Table 6.9
Agreement of Locally and Centrally Adjudicated Cause of Death for All CT Participants

Data as of: February 28, 2003

	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	1910	1596	84%	1475	(92%)	79	(5%)	42	(3%)
Cardiovascular									
Atherosclerotic cardiac[3]	302	253	84%	246	(97%)	6	(2%)	1	(0%)
Cerebrovascular	145	113	78%	111	(98%)	1	(1%)	1	(1%)
Pulmonary embolism	11	9	82%	9	(100%)	0	(0%)	0	(0%)
Other cardiovascular	112	69	62%	52	(75%)	13	(19%)	4	(6%)
Unknown cardiovascular	30	15	50%	2	(13%)	9	(60%)	4	(27%)
Total cardiovascular deaths	600	459	77%	420	(92%)	29	(6%)	10	(2%)
Cancer									
Breast cancer	36	31	86%	31	(100%)	0	(0%)	0	(0%)
Ovarian cancer	72	61	85%	57	(93%)	3	(5%)	1	(2%)
Endometrial cancer	9	7	78%	6	(86%)	1	(14%)	0	(0%)
Colorectal cancer	94	84	89%	84	(100%)	0	(0%)	0	(0%)
Other cancer	669	610	91%	590	(97%)	16	(3%)	4	(1%)
Unknown cancer site	42	37	88%	26	(70%)	11	(30%)	0	(0%)
Total cancer deaths	922	830	90%	794	(96%)	31	(4%)	5	(1%)
Accident/injury									
Homicide	5	5	100%	4	(80%)	1	(20%)	0	(0%)
Accident	49	45	92%	41	(91%)	4	(9%)	0	(0%)
Suicide	7	7	100%	7	(100%)	0	(0%)	0	(0%)
Other injury	4	2	50%	0	(0%)	2	(100%)	0	(0%)
Total accidental deaths	65	59	91%	52	(88%)	7	(12%)	0	(0%)
Other									
Other known cause	263	205	78%	183	(89%)	5	(2%)	17	(8%)
Unknown cause	60	43	72%	26	(60%)	7	(16%)	10	(23%)
Total deaths - other causes	323	248	77%	209	(84%)	12	(5%)	27	(11%)

[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: February 28, 2003

	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	2899	1830	63%	1466	(80%)	163	(9%)	201	(11%)
Cardiovascular									
Atherosclerotic cardiac[3]	387	256	66%	201	(79%)	20	(8%)	35	(14%)
Cerebrovascular	208	121	58%	105	(87%)	6	(5%)	10	(8%)
Pulmonary embolism	24	13	54%	9	(69%)	0	(0%)	4	(31%)
Other cardiovascular	179	126	70%	53	(42%)	54	(43%)	19	(15%)
Unknown cardiovascular	36	26	72%	1	(4%)	17	(65%)	8	(31%)
Total cardiovascular deaths	834	542	65%	369	(68%)	97	(18%)	76	(14%)
Cancer									
Breast cancer	184	102	55%	96	(94%)	3	(3%)	3	(3%)
Ovarian cancer	92	60	65%	55	(92%)	3	(5%)	2	(3%)
Endometrial cancer	30	15	50%	10	(67%)	5	(33%)	0	(0%)
Colorectal cancer	114	79	69%	74	(94%)	2	(3%)	3	(4%)
Other cancer	901	581	64%	535	(92%)	21	(4%)	25	(4%)
Unknown cancer site	75	50	67%	35	(70%)	14	(28%)	1	(2%)
Total cancer deaths	1396	887	64%	805	(91%)	48	(5%)	34	(4%)
Accident/injury									
Homicide	6	4	67%	4	(100%)	0	(0%)	0	(0%)
Accident	63	47	75%	39	(83%)	2	(4%)	6	(13%)
Suicide	19	16	84%	13	(81%)	1	(6%)	2	(13%)
Other injury	3	2	67%	2	(100%)	0	(0%)	0	(0%)
Total accidental deaths	91	69	76%	58	(84%)	3	(4%)	8	(12%)
Other									
Other known cause	462	259	56%	206	(80%)	4	(2%)	49	(19%)
Unknown cause	116	73	63%	28	(38%)	11	(15%)	34	(47%)
Total deaths - other causes	578	332	57%	234	(70%)	15	(5%)	83	(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: February 28, 2003

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68132	9190	14662	31390	12890
Mean follow-up (months)	72.5	78.8	75.0	70.8	69.4
Cardiovascular					
CHD[1]	1388 (0.34%)	78 (0.13%)	141 (0.15%)	627 (0.34%)	542 (0.73%)
CHD death[2]	314 (0.08%)	14 (0.02%)	27 (0.03%)	132 (0.07%)	141 (0.19%)
Total MI[3]	1178 (0.29%)	67 (0.11%)	120 (0.13%)	536 (0.29%)	455 (0.61%)
Clinical MI	1119 (0.27%)	60 (0.10%)	114 (0.12%)	512 (0.28%)	433 (0.58%)
Evolving Q-wave MI[4]	61 (0.01%)	7 (0.01%)	6 (0.01%)	26 (0.01%)	22 (0.03%)
Possible evolving Q-wave MI[4]	245 (0.06%)	29 (0.05%)	37 (0.04%)	101 (0.05%)	78 (0.10%)
Angina	1814 (0.44%)	88 (0.15%)	239 (0.26%)	907 (0.49%)	580 (0.78%)
CABG/PTCA	1855 (0.45%)	76 (0.13%)	217 (0.24%)	939 (0.51%)	623 (0.84%)
Carotid artery disease	306 (0.07%)	8 (0.01%)	37 (0.04%)	156 (0.08%)	105 (0.14%)
Congestive heart failure	1075 (0.26%)	54 (0.09%)	117 (0.13%)	458 (0.25%)	446 (0.60%)
Stroke	1050 (0.25%)	41 (0.07%)	95 (0.10%)	476 (0.26%)	438 (0.59%)
PVD	272 (0.07%)	12 (0.02%)	27 (0.03%)	131 (0.07%)	102 (0.14%)
CHD[1]/Possible evolving Q-wave MI	1623 (0.39%)	107 (0.18%)	177 (0.19%)	724 (0.39%)	615 (0.82%)
Coronary disease[5]	4066 (0.99%)	226 (0.37%)	496 (0.54%)	1937 (1.05%)	1407 (1.89%)
Total cardiovascular disease	5339 (1.30%)	275 (0.46%)	616 (0.67%)	2565 (1.38%)	1883 (2.52%)
Cancer					
Breast cancer[6]	2014 (0.49%)	206 (0.34%)	428 (0.47%)	971 (0.52%)	409 (0.55%)
Invasive breast cancer	1590 (0.39%)	149 (0.25%)	346 (0.38%)	770 (0.42%)	325 (0.44%)
Non-invasive breast cancer	432 (0.10%)	57 (0.09%)	84 (0.09%)	206 (0.11%)	85 (0.11%)
Ovary cancer	192 (0.05%)	19 (0.03%)	39 (0.04%)	89 (0.05%)	45 (0.06%)
Endometrial cancer[7]	246 (0.10%)	25 (0.07%)	52 (0.09%)	118 (0.11%)	51 (0.12%)
Colorectal cancer	533 (0.13%)	31 (0.05%)	75 (0.08%)	275 (0.15%)	152 (0.20%)
Other cancer[8]	2017 (0.49%)	167 (0.28%)	312 (0.34%)	974 (0.53%)	564 (0.76%)
Total cancer	4856 (1.18%)	439 (0.73%)	879 (0.96%)	2353 (1.27%)	1185 (1.59%)
Fractures					
Hip fracture	459 (0.11%)	12 (0.02%)	28 (0.03%)	178 (0.10%)	241 (0.32%)
Vertebral fracture	501 (0.12%)	18 (0.03%)	60 (0.07%)	208 (0.11%)	215 (0.29%)
Other fracture[8]	5619 (1.36%)	672 (1.11%)	1040 (1.13%)	2612 (1.41%)	1295 (1.74%)
Total fracture	6347 (1.54%)	695 (1.15%)	1112 (1.21%)	2898 (1.56%)	1642 (2.20%)
Deaths					
Cardiovascular deaths	630 (0.15%)	23 (0.04%)	48 (0.05%)	266 (0.14%)	293 (0.39%)
Cancer deaths	967 (0.23%)	53 (0.09%)	118 (0.13%)	478 (0.26%)	318 (0.43%)
Other known cause	338 (0.08%)	21 (0.03%)	36 (0.04%)	139 (0.08%)	142 (0.19%)
Unknown cause	119 (0.03%)	9 (0.01%)	10 (0.01%)	59 (0.03%)	41 (0.05%)
Not yet adjudicated	135 (0.03%)	8 (0.01%)	22 (0.02%)	48 (0.03%)	57 (0.08%)
Total death	2189 (0.53%)	114 (0.19%)	234 (0.26%)	990 (0.53%)	851 (1.14%)

[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 ten 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: February 28, 2003

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)	70.1	69.0	71.2	68.5	73.1	68.4
Cardiovascular						
CHD[1]	4 (0.23%)	16 (0.18%)	133 (0.32%)	25 (0.15%)	1191 (0.35%)	19 (0.36%)
CHD death[2]	2 (0.12%)	4 (0.05%)	46 (0.11%)	3 (0.02%)	255 (0.08%)	4 (0.07%)
Total MI[3]	3 (0.18%)	15 (0.17%)	103 (0.25%)	23 (0.14%)	1017 (0.30%)	17 (0.32%)
Clinical MI	3 (0.18%)	14 (0.16%)	99 (0.24%)	23 (0.14%)	965 (0.29%)	15 (0.28%)
Evolving Q-wave MI[4]	0 (0.00%)	1 (0.01%)	4 (0.01%)	0 (0.00%)	54 (0.02%)	2 (0.04%)
Possible evolving Q-wave MI[4]	2 (0.12%)	7 (0.08%)	31 (0.07%)	6 (0.04%)	196 (0.06%)	3 (0.06%)
Angina	5 (0.29%)	25 (0.29%)	225 (0.54%)	58 (0.35%)	1475 (0.44%)	26 (0.49%)
CABG/PTCA	5 (0.29%)	17 (0.19%)	178 (0.43%)	46 (0.28%)	1589 (0.47%)	20 (0.37%)
Carotid artery disease	3 (0.18%)	2 (0.02%)	23 (0.06%)	2 (0.01%)	274 (0.08%)	2 (0.04%)
Congestive heart failure	3 (0.18%)	9 (0.10%)	175 (0.42%)	29 (0.18%)	843 (0.25%)	16 (0.30%)
Stroke	7 (0.41%)	23 (0.26%)	129 (0.31%)	29 (0.18%)	849 (0.25%)	13 (0.24%)
PVD	3 (0.18%)	1 (0.01%)	39 (0.09%)	4 (0.02%)	222 (0.07%)	3 (0.06%)
CHD[1]/Possible evolving Q-wave MI	6 (0.35%)	23 (0.26%)	163 (0.39%)	31 (0.19%)	1378 (0.41%)	22 (0.41%)
Coronary disease[5]	13 (0.76%)	52 (0.60%)	495 (1.19%)	112 (0.68%)	3337 (0.99%)	57 (1.07%)
Total cardiovascular disease	22 (1.29%)	76 (0.87%)	642 (1.55%)	142 (0.87%)	4386 (1.30%)	71 (1.33%)
Cancer						
Breast cancer[6]	6 (0.35%)	46 (0.53%)	149 (0.36%)	52 (0.32%)	1743 (0.52%)	18 (0.34%)
Invasive breast cancer	6 (0.35%)	33 (0.38%)	111 (0.27%)	42 (0.26%)	1384 (0.41%)	14 (0.26%)
Non-invasive breast cancer	0 (0.00%)	13 (0.15%)	39 (0.09%)	10 (0.06%)	366 (0.11%)	4 (0.07%)
Ovary cancer	1 (0.06%)	2 (0.02%)	16 (0.04%)	2 (0.01%)	167 (0.05%)	4 (0.07%)
Endometrial cancer[7]	1 (0.13%)	2 (0.04%)	12 (0.07%)	9 (0.10%)	218 (0.11%)	4 (0.13%)
Colorectal cancer	4 (0.23%)	12 (0.14%)	55 (0.13%)	22 (0.13%)	431 (0.13%)	9 (0.17%)
Other cancer[8]	9 (0.53%)	30 (0.34%)	147 (0.35%)	47 (0.29%)	1761 (0.52%)	23 (0.43%)
Total cancer	21 (1.23%)	91 (1.04%)	367 (0.89%)	127 (0.77%)	4196 (1.24%)	54 (1.01%)
Fractures						
Hip fracture	0 (0.00%)	3 (0.03%)	15 (0.04%)	7 (0.04%)	430 (0.13%)	4 (0.07%)
Vertebral fracture	1 (0.06%)	10 (0.11%)	6 (0.01%)	6 (0.04%)	473 (0.14%)	5 (0.09%)
Other fracture[8]	22 (1.29%)	85 (0.97%)	302 (0.73%)	148 (0.90%)	5004 (1.48%)	58 (1.08%)
Total fracture	22 (1.29%)	96 (1.10%)	320 (0.77%)	158 (0.96%)	5686 (1.68%)	65 (1.21%)
Deaths						
Cardiovascular deaths	3 (0.18%)	10 (0.11%)	92 (0.22%)	7 (0.04%)	512 (0.15%)	6 (0.11%)
Cancer deaths	5 (0.29%)	19 (0.22%)	90 (0.22%)	25 (0.15%)	816 (0.24%)	12 (0.22%)
Other known cause	5 (0.29%)	2 (0.02%)	46 (0.11%)	5 (0.03%)	278 (0.08%)	2 (0.04%)
Unknown cause	2 (0.12%)	1 (0.01%)	12 (0.03%)	5 (0.03%)	98 (0.03%)	1 (0.02%)
Not yet adjudicated	1 (0.06%)	2 (0.02%)	12 (0.03%)	6 (0.04%)	113 (0.03%)	1 (0.02%)
Total death	16 (0.94%)	34 (0.39%)	252 (0.61%)	48 (0.29%)	1817 (0.54%)	22 (0.41%)

[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 ten 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: February 28, 2003

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68132	9190	14662	31390	12890
Mean follow-up (months)	72.5	78.8	75.0	70.8	69.4
Hospitalizations					
Ever	28047 (6.81%)	2780 (4.61%)	4979 (5.43%)	13356 (7.21%)	6932 (9.29%)
Two or more	13636 (3.31%)	1161 (1.92%)	2148 (2.34%)	6472 (3.49%)	3855 (5.17%)
Other					
DVT[1]	606 (0.15%)	37 (0.06%)	87 (0.10%)	276 (0.15%)	206 (0.29%)
Pulmonary embolism	354 (0.09%)	18 (0.03%)	53 (0.06%)	176 (0.10%)	107 (0.14%)
Diabetes (treated)	3725 (0.95%)	509 (0.87%)	785 (0.89%)	1703 (0.97%)	728 (1.03%)
Gallbladder disease[2]	4082 (1.18%)	599 (1.12%)	931 (1.19%)	1910 (1.25%)	642 (1.07%)
Hysterectomy	1615 (0.67%)	212 (0.61%)	348 (0.61%)	772 (0.72%)	283 (0.68%)
Glaucoma	5522 (1.40%)	507 (0.85%)	1038 (1.16%)	2702 (1.52%)	1275 (1.85%)
Osteoporosis	11338 (2.92%)	1045 (1.77%)	1931 (2.18%)	5563 (3.20%)	2799 (4.20%)
Osteoarthritis[3]	10059 (5.50%)	1373 (3.08%)	2204 (3.53%)	4627 (4.29%)	1855 (4.96%)
Rheumatoid arthritis	3031 (0.77%)	411 (0.70%)	680 (0.77%)	1357 (0.76%)	583 (0.83%)
Intestinal polyps	7643 (2.00%)	868 (1.48%)	1554 (1.78%)	3845 (2.25%)	1376 (2.08%)
Lupus	522 (0.13%)	80 (0.13%)	121 (0.13%)	242 (0.13%)	79 (0.11%)
Kidney stones[3]	1271 (0.53%)	164 (0.35%)	265 (0.37%)	596 (0.39%)	246 (0.40%)
Cataracts[3]	16309 (7.51%)	922 (1.97%)	2501 (3.47%)	8979 (6.59%)	3907 (9.19%)
Pills for hypertension	13480 (4.65%)	1671 (3.43%)	2794 (4.00%)	6243 (4.96%)	2772 (6.12%)

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)	70.1	69.0	71.2	68.5	73.1	68.4
Hospitalizations						
Ever	127 (7.44%)	416 (4.77%)	2912 (7.03%)	945 (5.76%)	23291 (6.89%)	356 (6.65%)
Two or more	68 (3.98%)	161 (1.84%)	1457 (3.52%)	412 (2.51%)	11368 (3.36%)	170 (3.18%)
Other						
DVT[1]	2 (0.12%)	1 (0.01%)	56 (0.14%)	10 (0.06%)	531 (0.16%)	6 (0.11%)
Pulmonary embolism	4 (0.24%)	2 (0.02%)	32 (0.08%)	3 (0.02%)	308 (0.09%)	5 (0.09%)
Diabetes (treated)	21 (1.37%)	102 (1.25%)	668 (1.82%)	247 (1.61%)	2630 (0.81%)	57 (1.14%)
Gallbladder disease[2]	17 (1.36%)	63 (0.80%)	328 (0.89%)	189 (1.51%)	3425 (1.22%)	60 (1.32%)
Hysterectomy	5 (0.65%)	29 (0.51%)	95 (0.53%)	55 (0.60%)	1419 (0.70%)	12 (0.39%)
Glaucoma	27 (1.67%)	111 (1.32%)	739 (1.92%)	242 (1.52%)	4333 (1.33%)	70 (1.40%)
Osteoporosis	51 (3.15%)	276 (3.33%)	628 (1.57%)	448 (2.93%)	9777 (3.07%)	158 (3.17%)
Osteoarthritis[3]	54 (0.12%)	234 (0.37%)	991 (0.92%)	498 (1.33%)	8119 (5.43%)	163 (7.05%)
Rheumatoid arthritis	23 (1.50%)	60 (0.72%)	534 (1.39%)	281 (1.80%)	2080 (0.64%)	53 (1.04%)
Intestinal polyps	39 (2.49%)	158 (1.97%)	799 (2.07%)	270 (1.72%)	6276 (2.00%)	101 (2.05%)
Lupus	5 (0.30%)	7 (0.08%)	70 (0.17%)	21 (0.13%)	413 (0.12%)	6 (0.11%)
Kidney stones[3]	9 (0.02%)	29 (0.04%)	125 (0.08%)	59 (0.10%)	1029 (0.53%)	20 (0.66%)
Cataracts[3]	68 (0.15%)	317 (0.44%)	1502 (1.10%)	613 (1.44%)	13593 (7.66%)	216 (7.78%)
Pills for hypertension	60 (5.41%)	289 (4.87%)	1351 (6.53%)	616 (5.02%)	10997 (4.47%)	167 (4.72%)

[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: February 28, 2003

	CT		OS	
Number of participants	68132		93676	
Mean follow-up time (months)	72.5		65.7	
Ppts with other cancer	2017	(0.49%)	2660	(0.52%)
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)	28	(0.01%)	19	(<0.01%)
Bladder	116	(0.03%)	147	(0.03%)
Bones/joints/articular cartilage (limbs)	4	(<0.01%)	5	(<0.01%)
Bones/joints/articular cartilage (other)	1	(<0.01%)	2	(<0.01%)
Brain	55	(0.01%)	61	(0.01%)
Cervix	40	(0.01%)	34	(0.01%)
Connective/subcutaneous/soft tissues	9	(<0.01%)	14	(<0.01%)
Endocrine glands, related structures	2	(<0.01%)	1	(<0.01%)
Esophagus	21	(0.01%)	24	(<0.01%)
Eye and adnexa	3	(<0.01%)	3	(<0.01%)
Genital organs	17	(<0.01%)	10	(<0.01%)
Kidney	92	(0.02%)	116	(0.02%)
Larynx	9	(<0.01%)	8	(<0.01%)
Leukemia	88	(0.02%)	105	(0.02%)
Liver	23	(0.01%)	25	(<0.01%)
Lung	388	(0.09%)	478	(0.09%)
Lymph nodes	8	(<0.01%)	6	(<0.01%)
Lymphoma,Hodgkins	11	(<0.01%)	11	(<0.01%)
Lymphoma,Non-Hodgkins	164	(0.04%)	235	(0.05%)
Melanoma of the skin	260	(0.06%)	352	(0.07%)
Multiple myeloma	78	(0.02%)	63	(0.01%)
Oral (mouth)	14	(<0.01%)	13	(<0.01%)
Palate	3	(<0.01%)	5	(<0.01%)
Pancreas	103	(0.03%)	119	(0.02%)
Parotid gland (Stensen's duct)	5	(<0.01%)	15	(<0.01%)
Peripheral nerves and autonomic nervous system	0	(0.00%)	3	(<0.01%)
Pyriform sinus	0	(0.00%)	2	(<0.01%)
Respiratory system, intrathoracic, other	7	(<0.01%)	8	(<0.01%)
Salivary glands, major (other/unspecified)	2	(<0.01%)	5	(<0.01%)
Stomach	22	(0.01%)	34	(0.01%)
Thyroid	63	(0.02%)	71	(0.01%)
Tongue, part of (other/unspecified)	15	(<0.01%)	15	(<0.01%)
Urinary organs (other/unspecified)	6	(<0.01%)	12	(<0.01%)
Uterus, not otherwise specified	28	(0.01%)	54	(0.01%)
Other/unknown site of cancer	234	(0.06%)	307	(0.06%)
Other/unknown cancers reported on death form	123	(0.03%)	293	(0.06%)

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

Data as of: February 28, 2003

	CT		OS[1]	
Locally confirmed				
Number of participants	68132		6365	
Mean follow-up time (months)	72.5		74.2	
Ppts with other fractures	5619	(1.36%)	531	(1.35%)
Ankle	990	(0.24%)	89	(0.23%)
Carpal bone(s) in wrist	143	(0.03%)	9	(0.02%)
Clavicle or collar bone	100	(0.02%)	10	(0.03%)
Elbow, not otherwise specified	16	(<0.01%)	1	(<0.01%)
Humerus, shaft/unspecified	61	(0.01%)	5	(0.01%)
Humerus, upper end	593	(0.14%)	47	(0.12%)
Humerus, lower end	71	(0.02%)	7	(0.02%)
Metacarpal bone(s)	199	(0.05%)	18	(0.05%)
Patella	254	(0.06%)	24	(0.06%)
Pelvis	219	(0.05%)	31	(0.08%)
Radius or ulna	1564	(0.38%)	162	(0.41%)
Sacrum and coccyx	66	(0.02%)	8	(0.02%)
Scapula	25	(0.01%)	4	(0.01%)
Shaft of femur	79	(0.02%)	6	(0.02%)
Tarsal/metatarsal bones	958	(0.23%)	104	(0.26%)
Tibia and fibula	469	(0.11%)	27	(0.07%)
Tibial plateau	115	(0.03%)	7	(0.02%)
Upper radius/ulna	294	(0.07%)	28	(0.07%)
Unknown other fracture	1	(<0.01%)	0	(0.00%)
Self-Reports				
Number of participants			93676	
Mean follow-up time (months)			65.7	
Elbow			470	(0.09%)
Foot			1686	(0.33%)
Hand			313	(0.06%)
Knee			553	(0.11%)
Lower Arm			2415	(0.47%)
Lower Leg			1895	(0.37%)
Pelvis			428	(0.08%)
Tailbone			125	(0.02%)
Upper Arm			1000	(0.20%)
Upper Leg			253	(0.05%)
Vertebra			1066	(0.21%)
Other Fracture			2037	(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: February 28, 2003

	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]	56115	300	56415
Borderline Q-wave change[3]	1732	41	1773
Ischemic ST-T evolution[4]	1056	38	1094
Possible evolving Q-wave MI[5]	143[6]	19	162
Evolving Q-wave MI[7]	29[8]	18	47
Total	59075	416	59491
HRT Participants			
No significant Q or ST-T evolution[2]	22380	141	22521
Borderline Q-wave change[3]	742	18	760
Ischemic ST-T evolution[4]	488	16	504
Possible evolving Q-wave MI[5]	66[6]	8	74
Evolving Q-wave MI[7]	10[8]	11	21
Total	23686	194	23880
DM Participants			
No significant Q or ST-T evolution[2]	40324	200	40524
Borderline Q-wave change[3]	1204	27	1231
Ischemic ST-T evolution[4]	716	25	741
Possible evolving Q-wave MI[5]	88[6]	16	104
Evolving Q-wave MI[7]	22[8]	9	31
Total	42354	277	42631
CaD Participants			
No significant Q or ST-T evolution[2]	31739	102	31841
Borderline Q-wave change[3]	1004	17	1021
Ischemic ST-T evolution[4]	557	13	570
Possible evolving Q-wave MI[5]	83[6]	7	90
Evolving Q-wave MI[7]	19[8]	8	27
Total	33402	147	33549

[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: February 28, 2003

	CT		OS	
Number Randomized	68132		93676	
Mean Follow-up Time (months)	72.5		65.7	
Total death	2189	(0.53%)	3401	(0.66%)
Adjudicated death	2054	(0.50%)	3146	(0.61%)
Final adjudicated death	1904	(0.46%)	2883	(0.56%)
Temporary adjudicated death	143	(0.03%)	246	(0.05%)
Identified by NDI search	7	(<0.01%)	17	(<0.01%)
Cardiovascular				
Atherosclerotic cardiac	314	(0.08%)	405	(0.08%)
CHD deaths adjudicated before 10/99	86	(0.02%)	82	(0.02%)
Definite CHD deaths adjudicated after 10/99	122	(0.03%)	159	(0.03%)
Possible CHD deaths adjudicated after 10/99	106	(0.03%)	164	(0.03%)
Cerebrovascular	152	(0.04%)	219	(0.04%)
Pulmonary embolism	13	(<0.01%)	25	(<0.01%)
Other cardiovascular	116	(0.03%)	188	(0.04%)
Unknown cardiovascular	35	(0.01%)	42	(0.01%)
Total cardiovascular deaths	630	(0.15%)	879	(0.17%)
Cancer				
Breast cancer	39	(0.01%)	198	(0.04%)
Ovarian cancer	78	(0.02%)	96	(0.02%)
Endometrial cancer	9	(<0.01%)	30	(0.01%)
Colorectal cancer	97	(0.02%)	119	(0.02%)
Other cancer	701	(0.17%)	938	(0.18%)
Unknown cancer site	43	(0.01%)	79	(0.02%)
Total cancer deaths	967	(0.23%)	1460	(0.28%)
Accident/injury				
Homicide	5	(<0.01%)	6	(<0.01%)
Accident	51	(0.01%)	68	(0.01%)
Suicide	7	(<0.01%)	19	(<0.01%)
Other injury	5	(<0.01%)	5	(<0.01%)
Total accidental deaths	68	(0.02%)	98	(0.02%)
Other				
Other known cause	270	(0.07%)	492	(0.10%)
Unknown cause	119	(0.03%)	217	(0.04%)
Total deaths – other causes	389	(0.09%)	709	(0.14%)

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: February 28, 2003

	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	62	3.6	1608	93.6	10	0.6	0	0.0	25	1.5	13	0.8	1718
Birmingham	70	3.8	1687	92.1	28	1.5	0	0.0	33	1.8	14	0.8	1832
Bowman	48	3.1	1358	88.8	27	1.8	0	0.0	52	3.4	45	2.9	1530
Brigham	65	2.8	2181	94.7	20	0.9	3	0.1	1	0.0	32	1.4	2302
Buffalo	60	3.7	1512	94.4	6	0.4	0	0.0	23	1.4	1	0.1	1602
Chapel Hill	50	3.3	1453	94.5	0	0.0	0	0.0	27	1.8	7	0.5	1537
Chicago	58	3.6	1485	91.5	11	0.7	0	0.0	45	2.8	24	1.5	1623
Chi-Rush	49	3.7	1194	90.1	11	0.8	4	0.3	31	2.3	36	2.7	1325
Cincinnati	30	2.2	1290	92.8	13	0.9	0	0.0	53	3.8	4	0.3	1390
Columbus	53	3.4	1451	93.7	3	0.2	0	0.0	30	1.9	11	0.7	1548
Detroit	22	1.6	1132	82.2	93	6.8	0	0.0	94	6.8	36	2.6	1377
GWU-DC	39	2.6	1437	94.9	20	1.3	0	0.0	15	1.0	4	0.3	1515
Gainesville	63	3.0	1919	92.4	26	1.3	1	0.0	56	2.7	12	0.6	2077
Honolulu	33	2.3	1241	88.3	51	3.6	0	0.0	52	3.7	28	2.0	1405
Houston	30	2.4	1125	88.5	39	3.1	3	0.2	61	4.8	13	1.0	1271
Iowa City	87	3.6	2290	94.2	10	0.4	0	0.0	23	0.9	20	0.8	2430
Irvine	40	2.5	1477	91.1	11	0.7	1	0.1	49	3.0	43	2.7	1621
L.A.	50	3.0	1553	92.6	18	1.1	0	0.0	41	2.4	16	1.0	1678
La Jolla	81	3.7	1878	86.9	42	1.9	3	0.1	32	1.5	125	5.8	2161
Madison	33	2.1	1502	96.4	3	0.2	0	0.0	19	1.2	1	0.1	1558
Medlantic	61	4.1	1336	89.4	26	1.7	0	0.0	43	2.9	28	1.9	1494
Memphis	80	4.6	1536	88.2	43	2.5	0	0.0	57	3.3	25	1.4	1741
Miami	37	2.5	1226	82.7	19	1.3	0	0.0	55	3.7	145	9.8	1482
Milwaukee	46	2.8	1547	93.8	4	0.2	0	0.0	48	2.9	5	0.3	1650
Minneapolis	63	3.2	1884	94.7	19	1.0	0	0.0	21	1.1	2	0.1	1989
NY-City	59	3.1	1736	92.2	25	1.3	2	0.1	24	1.3	36	1.9	1882
Nevada	63	4.3	1390	93.9	6	0.4	0	0.0	18	1.2	4	0.3	1481
Newark	70	2.9	2204	89.9	46	1.9	16	0.7	91	3.7	24	1.0	2451
Oakland	41	2.6	1467	94.0	29	1.9	0	0.0	16	1.0	8	0.5	1561
Pawtucket	82	3.1	2456	92.9	27	1.0	0	0.0	59	2.2	21	0.8	2645
Pittsburgh	65	3.9	1559	94.0	11	0.7	0	0.0	22	1.3	1	0.1	1658
Portland	56	3.4	1479	90.4	36	2.2	2	0.1	37	2.3	26	1.6	1636
San Antonio	26	1.9	1229	88.5	14	1.0	0	0.0	99	7.1	21	1.5	1389
Seattle	65	3.6	1642	90.9	30	1.7	5	0.3	32	1.8	33	1.8	1807
Stanford	48	2.7	1640	93.6	11	0.6	2	0.1	42	2.4	10	0.6	1753
Stonybrook	42	3.1	1266	93.5	19	1.4	0	0.0	25	1.8	2	0.1	1354
Torrance	26	2.6	858	85.5	39	3.9	1	0.1	42	4.2	38	3.8	1004
Tucson	101	4.8	1838	87.6	16	0.8	1	0.0	55	2.6	88	4.2	2099
U.C. Davis	84	4.4	1729	89.8	51	2.6	3	0.2	44	2.3	14	0.7	1925
Worcester	51	3.1	1551	95.1	13	0.8	0	0.0	6	0.4	10	0.6	1631
Total	2189	3.2	62346	91.5	926	1.4	47	0.1	1598	2.3	1026	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: February 28, 2003

	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	80	3.2	2323	94.3	40	1.6	0	0.0	11	0.4	9	0.4	2463
Birmingham	114	4.5	2245	88.8	70	2.8	0	0.0	66	2.6	34	1.3	2529
Bowman	70	3.1	1876	84.2	109	4.9	0	0.0	32	1.4	140	6.3	2227
Brigham	54	1.8	2772	94.1	80	2.7	0	0.0	1	0.0	39	1.3	2946
Buffalo	122	5.4	2081	92.6	24	1.1	0	0.0	17	0.8	4	0.2	2248
Chapel Hill	60	2.9	1991	95.6	13	0.6	0	0.0	15	0.7	4	0.2	2083
Chicago	67	3.5	1724	91.3	31	1.6	1	0.1	30	1.6	36	1.9	1889
Chi-Rush	91	4.4	1778	86.8	48	2.3	23	1.1	45	2.2	64	3.1	2049
Cincinnati	81	3.6	1979	88.0	65	2.9	11	0.5	57	2.5	56	2.5	2249
Columbus	60	2.7	2118	95.4	23	1.0	0	0.0	15	0.7	3	0.1	2219
Detroit	54	2.6	1834	86.8	59	2.8	3	0.1	68	3.2	94	4.5	2112
GWU-DC	81	3.6	2117	94.2	36	1.6	3	0.1	5	0.2	5	0.2	2247
Gainesville	103	3.7	2510	89.9	94	3.4	2	0.1	60	2.1	23	0.8	2792
Honolulu	52	2.5	1810	85.7	115	5.4	1	0.0	73	3.5	62	2.9	2113
Houston	97	4.6	1926	90.4	13	0.6	4	0.2	78	3.7	12	0.6	2130
Iowa City	85	2.7	2917	93.5	45	1.4	0	0.0	32	1.0	41	1.3	3120
Irvine	74	3.3	2059	92.3	8	0.4	0	0.0	43	1.9	46	2.1	2230
L.A.	69	3.1	2076	94.6	8	0.4	0	0.0	24	1.1	18	0.8	2195
La Jolla	158	4.6	2987	86.3	71	2.1	6	0.2	32	0.9	209	6.0	3463
Madison	77	3.9	1867	94.2	26	1.3	0	0.0	10	0.5	1	0.1	1981
Medlantic	78	3.6	1977	90.2	68	3.1	6	0.3	36	1.6	28	1.3	2193
Memphis	87	3.5	2069	82.2	159	6.3	1	0.0	78	3.1	122	4.8	2516
Miami	50	3.6	1036	75.4	62	4.5	0	0.0	34	2.5	192	14.0	1374
Milwaukee	68	3.0	2044	91.0	47	2.1	2	0.1	34	1.5	51	2.3	2246
Minneapolis	79	2.9	2527	92.7	58	2.1	0	0.0	31	1.1	32	1.2	2727
NY-City	112	3.9	2492	85.8	168	5.8	1	0.0	17	0.6	113	3.9	2903
Nevada	139	6.4	1987	91.4	28	1.3	0	0.0	16	0.7	4	0.2	2174
Newark	87	2.6	2961	87.8	132	3.9	12	0.4	48	1.4	133	3.9	3373
Oakland	93	4.5	1897	92.4	33	1.6	0	0.0	22	1.1	8	0.4	2053
Pawtucket	118	3.3	3231	90.1	90	2.5	81	2.3	38	1.1	30	0.8	3588
Pittsburgh	95	5.0	1689	88.1	47	2.5	0	0.0	59	3.1	27	1.4	1917
Portland	69	3.1	1997	89.5	82	3.7	2	0.1	35	1.6	47	2.1	2232
San Antonio	59	3.0	1693	87.2	62	3.2	0	0.0	110	5.7	18	0.9	1942
Seattle	82	4.9	1437	86.4	63	3.8	23	1.4	20	1.2	38	2.3	1663
Stanford	103	3.9	2465	92.4	34	1.3	2	0.1	58	2.2	7	0.3	2669
Stonybrook	57	2.8	1904	93.9	31	1.5	0	0.0	15	0.7	21	1.0	2028
Torrance	58	3.9	1284	85.4	35	2.3	0	0.0	25	1.7	101	6.7	1503
Tucson	149	5.4	2394	86.1	10	0.4	1	0.0	40	1.4	188	6.8	2782
U.C. Davis	97	4.3	2059	90.7	60	2.6	8	0.4	23	1.0	22	1.0	2269
Worcester	72	3.2	2126	95.0	18	0.8	1	0.0	9	0.4	13	0.6	2239
Total	3401	3.6	84259	89.9	2265	2.4	194	0.2	1462	1.6	2095	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 for up to one hour until plasma or serum is separated from cells. In addition, urine samples are collected on both CT and OS participants at the three Bone Density Clinical Centers at baseline, year 1 and year 9 for CT, and baseline and year 3 for OS participants. Barcoded 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 began in September 2002. See *Sections 2* and *3* in this report for presentation of the laboratory results for HRT and DM.

MRL completed the analysis of the 1% OS Measurement Precision Study (OS-MPS). 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 HT Clinical Trial and for AS83, (Paul Ridker, PI: Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study). Extraction for AS132, (Simin Liu, PI: A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus) began in January 2003.

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, and MRL performed the lipid analyses. Results from all polymorphisims (Factor V Leiden, prothrombin, PAI-1, FV-HR2, FXIII, MTHFR) and lipid assays (IL-6, MMP-9, E-selectin, homocysteine, cholesterol, triglyceride, HDL, LDL, LDL particle size, Lp(a)) have been received. The University of Vermont was contracted to perform the assays for thrombosis for the study. The phase I and phase II samples were sent to Vermont in October 2001; and results from 10 of the 13 first priority assays (CRP,

Factor VIII activity, PAI-1 antigen, Fibrinogen, Protein C, Protein S free and total, Factor XI, TAFI, and prothrombin antigen) and 2 of the 7 second priority assays (F1+2, PAP) have been completed. Completion of the remaining assays (TGF-B, IL-1B, APC resistance, vWF, Factor VII Ag, antithrombin III, D-dimers, Factor XI) is expected is expected in mid-2003.

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". Results from the remaining 180 participants are expected in March 2003.

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 0.1 ml of serum. At the same time, aliquots of serum from the same samples were sent to two other labs (Herbert Yu at Yale University and Michael Pollak at Lady Davis Institute for Medical Research in Montreal) for an IGF validation study. Based on the results of this pilot study, the Lab Working Group agreed that AS129 (Howard Strickler, PI: Association of Diabetes and Insulin-like Growth Factor-I with Risks of Colorectal, Breast, and Endometrial Cancers) could use Esoterix's Vitros estradiol assay, but only to adjust for potential confounding without reporting the estradiol-breast cancer relationship.

The Laboratory Working Group also recommended that the CCC identify a hormone laboratory with an estradiol assay that uses 0.5 ml sample or less. Frank Stancyzk has agreed to assist in the design of a validation study and to prepare spiked samples for the CCC to send out competing labs as part of the selection process.

Ancillary Studies

Analyses of AS110 (Kathryn Rexrode, PI: Sex Steroid Hormones and Risk of Coronary Heart Disease: A nested Case Control Study) were completed in February 2003. Analyses of blood samples for ancillary studies is scheduled to greatly increase over the next year. Analyses for AS105 (Julie Mares-Perlman, PI: Carotenoids in Age-Related Eye Disease) began in December 2002, and analyses for seven other ancillary studies are scheduled to start before the end of 2003.

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 February 28, 2003, WHI has approved 21 ancillary studies using WHI blood specimens, with 12 funded and 9 pending funding. Six proposals were reviewed for the Fall 2002 OS blood competition, and review of three additional proposals requesting blood specimens is underway as part of the Spring 2003 OS blood competition. *Table 7.1 – OS Blood Committed to Ancillary Studies* gives a summary of the volume of OS blood samples committed to OS ancillary studies by disease type as of February 28, 2003. To date, no more baseline serum is available for additional ancillary studies for current CHD and hip fracture cases, and very limited baseline citrate and EDTA plasma is available for stroke cases (see volumes indicated in *Table 7.1*).

Table 7.1
OS Blood Committed to Ancillary Studies (AS)

Disease[1]	Cases reported as of 4-03	AS #	Cases committed[2]	Volume Committed (Baseline/Year 3)			
				Serum (ml)	Citrate Plasma (ml)	EDTA Plasma (ml)	DNA (µg)
CHD	1,482	83	650		1	.5	3
		110	385	1.8[3]			
		137	1060				6
		164	350			.3	
		165	800	.25			
Stroke	1,197	126	1100		1.5	1.5	3
		165	750	.25			
Hypertension	15,709	133	800			.8	3
Type 2 Diabetes	3,472	132	1800			.75	3
Hip Fracture	614	90	400	1.5			3
Breast Cancer	2,868	129	900[4]	.25			
		134	200	.3			
		149	800	.2			3
		152	900[4]				3
		155	3500	.3			3
Colorectal Cancer	607	108	800				6
		128	684				3
		129	500[4]	.25			
		152	500[4]				3
Endometrial Cancer	369	128	591				3
		129	300[4]	.25			
		152	300[4]				3
Leukemia	105	148	59				3
Ovarian Cancer	252	97	264 baseline, 132 Yr 3	1 baseline, 1 Yr 3			
		121	200	.5			
		128	282				3
Pancreatic Cancer	119	146	106			.6	3
Eye Disease	See note 5	105	1700	1.1			

[1] Some ancillary studies include cases from more than one disease
[2] Not all volume committed to all cases
[3] No more baseline sample available for selected cases
[4] AS 129 and AS 152 share cases for all diseases
[5] Determined by local ancillary study screening

8. Clinical Center Performance Monitoring

8.1 Performance Monitoring

The centralized quality assurance and performance monitoring structure serves 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, 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 September 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.

Through January, the PMC-A&R reviewed the task completeness rates for the stop Estrogen-plus-Progestin tasks. In December, the group began discussions on the future focus for the A&R PMC as the study closeout approaches. In February, the committee agreed to focus attention on two priorities: 1) outcomes collection by more closely monitoring collection of *Form 33 - Medical History Update* and focusing on retention issues affecting collection of the form, such as undeliverable addresses and lost to follow-up; and 2) adherence, by monitoring Estrogen-Alone and CaD study pill collection rates, and task completion of DM *Form 60 - FFQ*. Plans for implementing the increased focus on these two areas will be developed and implemented in April 2003.

In the same period, the O-PMC held five conference calls, reviewing 5-6 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 one CC to discuss issues with outcomes processing in more detail and to provide direction and interim goals for improving performance. Plans are underway for CCC staff to visit the CC to evaluate the outcomes procedures and make recommendations on site.

In September, the O-PMC discussed the possibility of an increase in the number of reported outcome cases with the stopping of the Estrogen-plus-Progestin study and the additional collection of a *Form 33 - Medical History Update.* A review of the number of *Form 33D - Medical History Update (Detail), Form 125 - Hospitalization*, outcome provider visits, closed cases with outcomes did not show an increase in these tasks between May and August 2002.

Plans for outcomes performance enhancement over the next six months include having CCC QA Liaisons visit 3-4 CCs having particular difficulty in processing outcomes efficiently.

The PMC report showing data as of February 28, 2003 is in *Tables 8.1-8.5.* The CCs also receive these tables quarterly.

Table 8.1
Performance Monitoring Committee Report
Data as of 2/28/03
DM

	Adjusted C-I[1]				Task Completeness Form 60 - FFQ[4]		% Stopped[5]	
	Average[2]		Mar 02 - Feb 03[3]		Jun 02 - Nov 02		Cum Feb 02	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Nevada	12.8	1	11.1	1	92.2	2	7.1	2
Oakland	11.5	1	9.3	1	93.1	1	4.5	1
Iowa City	10.8	1	8.5	1	92.5	2	5.7	1
Madison	10.8	1	8.6	1	93.4	1	4.2	1
Columbus	10.7	1	9.0	1	94.9	1	7.0	2
Stanford	10.6	1	9.3	1	87.2	3	6.6	1
Milwaukee	10.5	1	8.8	1	96.8	1	5.5	1
Pittsburgh	10.4	1	8.5	1	94.8	1	5.2	1
Seattle	10.3	1	7.7	2	90.3	2	9.0	3
Minneapolis	10.2	1	7.9	2	92.5	2	6.9	2
GWU-DC	10.2	2	8.8	1	88.8	3	6.2	1
Chicago	9.7	2	9.0	1	92.3	2	9.1	3
Irvine	9.7	2	7.2	2	90.3	2	7.0	2
Portland	9.3	2	7.1	3	83.9	4	8.9	3
Gainesville	9.2	2	8.2	2	90.8	2	6.8	2
Worcester	9.2	2	8.4	2	91.2	2	6.1	1
Chapel Hill	9.1	2	7.8	2	94.1	1	5.4	1
Torrance	9.0	2	6.7	3	82.2	4	12.6	4
UC Davis	8.9	2	8.3	2	86.5	3	9.6	3
LA	8.8	2	6.4	3	87.5	3	9.5	3
Pawtucket	8.6	3	6.8	3	89.6	3	8.6	2
Tucson	8.6	3	8.2	2	92.1	2	11.6	4
Brigham	8.6	3	5.9	4	92.8	1	7.3	2
Buffalo	8.5	3	7.1	3	94.6	1	8.1	2
Memphis	8.5	3	6.9	3	79.8	4	11.7	4
Stony Brook	8.4	3	8.0	2	92.8	1	7.8	2
Houston	8.3	3	6.8	3	84.0	4	10.2	3
Newark	8.3	3	6.0	4	81.3	4	11.2	4
Bowman	8.2	3	6.9	3	84.6	4	11.1	3
Chi-Rush	8.2	3	7.8	2	89.5	3	13.6	4
Atlanta	8.1	4	6.9	3	90.4	2	6.1	1
Cincinnati	7.9	4	6.4	4	94.4	1	8.7	2
Honolulu	7.8	4	6.3	4	87.3	3	11.0	3
NYC	7.6	4	6.4	3	91.5	2	10.7	3
LaJolla	7.5	4	5.6	4	87.3	3	13.5	4
Detroit	7.0	4	5.3	4	74.9	4	13.5	4
Birmingham	6.7	4	6.2	4	79.2	4	10.4	3
San Antonio	6.0	4	4.1	4	79.5	4	14.5	4
Medlantic	5.6	4	4.3	4	88.9	3	12.2	4
Miami	4.7	4	2.1	4	72.0	4	22.1	4
CC Average	**8.9**		**7.2**		**88.7**		**9.1**	
Ave F/U 6.1 yr	Design Assumption 11.7				Goal ≥ 90%		Design Assumption 17.0	

[1] Adjusted C-I defined as (C-I of collected FFQs) x (FFQ completion rate)

[2] Based on FFQs collected after randomization through AV8.

[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 2/28/03
HRT

	E-Alone Adherence Summary ≥ 80%				Task Completeness Jun 02 - Nov 02				% Stopped[5]	
	Average[1]		Mar 02 - Feb 03[2]		Form 10[3]		Form 85[4]		Cum Feb 02	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Oakland	77.1	1	70.8	1	99.2	1	92.1	1	12.3	1
Iowa City	68.5	1	57.6	1	98.1	2	94.0	1	15.2	1
Pittsburgh	66.7	1	55.4	1	97.0	2	93.8	1	23.3	2
Minneapolis	65.9	1	60.2	1	97.8	2	90.2	1	15.0	1
LA	65.3	1	47.2	2	89.4	4	87.7	2	16.6	1
Cincinnati	64.8	1	60.7	1	99.5	1	90.9	1	23.8	2
Stanford	64.0	1	57.8	1	97.5	2	77.0	4	17.3	1
Portland	62.3	1	52.3	2	91.8	4	89.1	2	19.0	2
Nevada	61.2	1	57.0	1	98.6	1	89.7	2	24.3	3
Milwaukee	61.2	1	59.1	1	97.3	2	87.4	2	18.1	1
Chapel Hill	60.2	2	52.7	2	98.9	1	93.2	1	17.3	1
Columbus	59.7	2	49.8	2	98.4	2	95.3	1	22.9	2
Gainesville	57.7	2	48.1	2	97.3	2	89.1	2	26.5	4
Brigham	57.4	2	56.6	1	98.7	1	92.0	1	15.9	1
Pawtucket	57.4	2	53.1	1	98.5	1	90.0	2	24.5	3
Worcester	57.1	2	52.6	2	97.1	2	94.6	1	18.8	2
Birmingham	54.9	2	45.1	3	91.3	4	84.8	3	25.9	3
Madison	54.5	2	48.2	2	98.2	2	96.5	1	21.9	2
Honolulu	54.2	2	48.5	2	93.5	3	83.5	3	17.2	1
Chicago	53.0	2	49.7	2	98.6	1	87.5	2	21.5	2
GWU-DC	52.1	3	43.7	3	95.2	3	76.0	4	14.3	1
Stony Brook	51.8	3	37.1	4	97.0	2	87.3	2	18.1	2
Seattle	51.5	3	46.9	2	89.2	4	75.0	4	24.7	3
Newark	51.3	3	41.7	4	92.0	4	83.2	3	19.7	2
Bowman	50.6	3	43.5	3	93.7	3	88.6	2	24.4	3
UC Davis	50.5	3	42.4	4	96.8	3	87.3	3	25.9	3
Buffalo	50.5	3	44.4	3	99.3	1	83.0	3	24.9	3
LaJolla	50.5	3	36.0	4	89.7	4	75.3	4	26.2	3
Torrance	50.0	3	46.5	3	92.9	4	75.4	4	25.6	3
Chi-Rush	48.8	3	45.4	3	95.9	3	89.0	2	27.6	4
NYC	48.5	4	43.2	4	94.9	3	79.8	4	21.0	2
Irvine	47.3	4	42.9	4	93.8	3	82.3	3	24.5	3
Memphis	46.8	4	44.3	3	93.3	3	83.6	3	31.2	4
Tucson	45.3	4	43.8	3	96.3	3	81.1	4	31.4	4
San Antonio	45.1	4	43.8	3	96.5	3	81.4	3	31.0	4
Atlanta	44.6	4	44.5	3	98.6	1	85.2	3	28.5	4
Detroit	43.3	4	30.6	4	80.6	4	75.1	4	28.8	4
Medlantic	37.1	4	35.3	4	99.2	1	86.1	3	29.5	4
Houston	35.5	4	28.1	4	89.6	4	73.8	4	33.5	4
Miami	27.4	4	23.2	4	93.0	4	66.4	4	35.8	4
CC Average	**54.0**		**47.6**		**95.7**		**85.8**		**22.8**	
Ave F/U 5.9 yr	-		-		Goal ≥ 90%		Goal ≥ 90%		Design Assumption 32.4	

[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 2/28/03
CaD

	Adherence Summary ≥ 80%				Task Completeness Form 17[3]		% Stopped[4]	
	Average[1]		Mar 02 – Feb 03[2]		Jun – Nov 02		Cum Feb 03	
	%	Quartile	%	Quartile	%	Quartile	%	Quartile
Oakland	80.9	1	81.8	1	99.3	1	10.5	1
Stanford	71.7	1	71.7	1	97.2	3	21.6	1
Iowa City	71.5	1	70.8	1	98.2	2	17.9	1
Minneapolis	68.4	1	67.9	1	98.1	2	18.7	1
Nevada	66.8	1	68.8	1	99.3	1	20.8	1
Columbus	66.4	1	63.5	1	99.0	1	23.6	2
Gainesville	64.8	1	62.5	2	98.1	2	28.2	3
Chapel Hill	62.5	1	63.7	1	99.5	1	14.8	1
Chi-Rush	62.4	1	61.5	2	97.4	2	29.2	3
Brigham	62.4	1	60.9	2	98.2	2	24.3	2
Portland	62.0	2	62.3	2	95.1	3	24.8	2
Pittsburgh	61.9	2	61.4	2	96.9	3	28.0	3
Pawtucket	61.4	2	63.6	1	99.0	1	24.4	2
Milwaukee	60.7	2	62.8	2	98.6	2	20.7	1
Worcester	59.0	2	60.4	2	97.7	2	17.9	1
Honolulu	58.8	2	58.5	3	93.8	3	29.5	4
Cincinnati	58.6	2	66.0	1	99.7	1	28.2	3
Madison	58.4	2	58.3	3	99.1	1	20.7	1
GWU-DC	56.8	2	53.5	3	96.6	3	25.5	2
LA	56.7	2	54.7	3	93.6	4	26.9	3
Buffalo	56.5	3	62.8	1	99.3	1	21.6	1
Torrance	56.4	3	59.1	3	89.9	4	28.3	3
UC Davis	56.3	3	59.2	2	94.7	3	27.1	3
Birmingham	56.0	3	59.5	2	93.6	4	22.2	2
Bowman	55.7	3	60.5	2	96.7	3	26.7	2
Seattle	55.0	3	58.2	3	93.8	4	27.9	3
Stony Brook	54.5	3	51.9	4	97.1	3	30.7	4
Atlanta	53.6	3	58.1	3	99.3	1	25.9	2
LaJolla	52.8	3	51.2	4	93.6	4	26.6	2
Tucson	52.5	3	58.6	3	97.7	2	34.5	4
Chicago	52.0	4	55.2	3	99.0	1	30.6	4
San Antonio	51.7	4	53.7	3	98.3	2	28.7	3
Irvine	50.7	4	47.4	4	94.9	3	29.2	3
NYC	49.0	4	52.4	4	96.2	3	31.5	4
Newark	48.7	4	52.9	4	90.8	4	28.3	3
Memphis	48.5	4	52.0	4	92.3	4	37.0	4
Houston	45.6	4	44.0	4	90.3	4	33.4	4
Detroit	45.6	4	46.1	4	84.2	4	33.8	4
Medlantic	43.3	4	46.4	4	98.2	2	26.4	2
Miami	32.5	4	36.7	4	91.5	4	45.4	4
CC Average	**57.8**		**59.0**		**96.4**		**25.9**	
Ave F/U 5.0 yr	-		-		Goal ≥ 90%		Design Assumption 24.2	

[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 2/28/03
OS

	% Stopped[1]	
	Cum Feb 03	
	%	Quartile
Brigham	3.3	1
Columbus	3.5	1
Chapel Hill	3.8	1
GWU-DC	4.0	1
Atlanta	4.1	1
Worcester	4.2	1
Madison	4.4	1
Stony Brook	4.7	1
Iowa City	5.1	1
LA	5.1	1
Pawtucket	5.2	2
Minneapolis	5.2	2
Oakland	6.0	2
UC Davis	6.3	2
Stanford	6.3	2
Buffalo	6.4	2
Medlantic	6.6	2
Gainesville	6.7	2
Portland	6.8	2
Milwaukee	6.8	2
Chicago	7.1	3
Nevada	7.3	3
Irvine	7.4	3
Newark	8.2	3
NYC	8.4	3
Birmingham	8.5	3
Honolulu	8.9	3
Cincinnati	8.9	3
Houston	9.0	3
Seattle	9.1	3
Pittsburgh	9.5	4
San Antonio	9.6	4
Chi-Rush	10.1	4
Detroit	10.4	4
Bowman	10.9	4
Memphis	11.4	4
LaJolla	11.7	4
Torrance	12.8	4
Tucson	13.6	4
Miami	20.1	4
CC Average	**7.5**	
Ave. F/U 5.5 yr.	-	

[1] 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 2/28/03
OC

	Task Completeness						Outcomes Processing Mar 02 - Feb 03							
	CT Form 33[1] Jun 02 - Nov 02		OS Form 33[2] Nov 01 - Apr 02		Form 33D[3] Mar 02- Feb 03		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
Chapel Hill	97.7	1	99.2	1	98.1	1	98.2	1	95.8	2	0.0	1	99.0	1
Nevada	97.6	1	98.6	1	97.6	2	93.1	2	88.1	3	10.2	1	90.5	1
Madison	97.5	1	99.1	1	95.7	3	93.8	1	58.2	4	19.8	2	88.6	2
Buffalo	97.5	1	98.1	1	99.7	1	93.2	1	99.1	1	26.2	3	92.2	1
Iowa City	97.4	1	96.9	2	90.3	4	91.0	2	80.5	3	29.1	3	83.6	2
Pittsburgh	97.2	1	94.0	3	99.3	1	90.7	2	100.0	1	18.0	2	90.2	2
Brigham	96.8	1	96.2	2	98.7	1	92.4	2	77.5	3	13.0	2	86.0	2
Columbus	96.5	1	98.4	1	99.2	1	94.3	1	60.1	4	11.2	1	84.7	2
Worcester	96.3	1	96.4	2	97.3	2	93.7	1	88.4	3	8.5	1	93.6	1
Minneapolis	96.2	1	94.7	2	92.5	4	96.1	1	93.0	2	14.0	2	91.4	1
Milwaukee	96.2	2	92.6	3	95.7	3	92.2	2	80.0	3	17.5	2	75.7	4
Atlanta	96.0	2	97.3	1	92.6	4	89.9	2	76.2	4	31.0	3	83.3	2
GWU-DC	95.7	2	99.1	1	97.7	2	86.1	3	99.7	1	26.1	3	79.1	3
Stony Brook	95.7	2	95.4	2	97.1	2	87.3	3	94.4	2	12.4	1	78.2	3
Stanford	95.6	2	97.4	1	99.7	1	81.9	4	91.9	2	23.2	2	77.1	3
Oakland	95.4	2	97.7	1	97.3	2	88.9	3	76.1	4	31.5	4	79.5	3
Gainesville	95.1	2	92.5	3	97.1	2	90.3	2	99.0	1	11.9	1	90.3	1
Pawtucket	94.7	2	93.5	3	95.6	3	92.0	2	54.5	4	26.7	3	77.2	3
Birmingham	94.6	2	93.4	3	99.5	1	75.1	4	98.0	1	30.3	3	58.3	4
Cincinnati	94.3	2	89.8	3	99.1	1	97.8	1	98.9	1	4.2	1	78.5	3
Chicago	93.9	3	95.1	2	97.1	2	86.5	3	99.1	1	21.8	2	79.7	2
Seattle	93.8	3	88.1	4	97.3	2	89.0	2	89.6	2	19.1	2	81.6	2
NYC	93.8	3	90.2	3	97.8	1	85.9	3	84.7	3	60.8	4	73.4	4
LA	93.1	3	98.0	1	91.6	4	79.3	4	89.2	3	33.7	4	46.7	4
Chi-Rush	93.0	3	87.5	4	95.7	3	94.7	1	96.2	2	10.9	1	90.5	1
Portland	92.5	3	91.5	3	92.9	3	86.0	3	95.7	2	41.8	4	81.0	2
UC Davis	91.8	3	95.0	2	91.2	4	80.0	4	100.0	1	41.8	4	76.2	3
Tucson	91.6	3	87.5	4	98.5	1	89.9	2	94.3	2	17.8	2	90.8	1
Medlantic	91.6	3	94.1	2	96.9	2	81.3	4	85.5	3	33.0	4	80.1	2
Irvine	91.1	3	96.9	2	95.9	3	86.8	3	91.1	2	18.2	2	75.9	3
Bowman	90.9	4	87.5	4	89.9	4	51.8	4	68.9	4	28.7	3	43.2	4
San Antonio	90.4	4	91.4	4	91.0	4	96.6	1	83.4	3	11.3	1	90.7	1
LaJolla	88.3	4	88.6	3	80.4	4	64.3	4	57.1	4	60.3	4	50.2	4
Honolulu	88.1	4	88.9	4	95.2	3	86.7	3	89.2	3	24.6	3	67.9	4
Houston	88.1	4	95.4	4	89.9	4	67.3	4	69.8	4	54.5	4	40.9	4
Memphis	87.1	4	85.6	2	96.0	3	96.9	1	97.5	1	10.4	1	94.1	1
Newark	87.1	4	89.0	4	96.3	2	87.6	3	61.2	4	33.6	4	77.5	3
Torrance	83.7	4	91.2	4	92.2	4	88.0	3	97.1	2	25.7	3	78.3	3
Miami	81.8	4	76.3	3	93.7	3	81.5	4	57.8	4	38.8	4	54.7	4
Detroit	80.0	4	89.1	4	93.0	3	73.7	4	97.9	1	29.1	3	70.9	4
CC Ave	**93.1**		**93.2**	4	**95.3**		**87.7**		**86.1**		**29.7**		**78.9**	
Goals	≥ 95.5%		≥ 95.8%		≥ 96.6%		≥ 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, 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, Psaty, Black, Manson, Wong, Francis, Grimm, Kotchen, Langer, Lasser	OS	11	Hypertension 2000;36:780-89

MS ID	Title	Authors	Data Focus	Stage	Reference
22	Pelvic Organ Prolapse: Gravity and Gravidity	**Hendrix,** Clark, Nygaard, Aragaki, Barnabei, McTiernan	CT	11	Am J Obstet Gynecol 2002;186:1160-6
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	In press
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
55	Factor Structure and Factor Invariance of the Women's Health Initiative Insomnia Rating Scale	**Levine,** Shumaker, Naughton, Kaplan, Kripke, Bowen	Gen	11	Psychological Assesment
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	Clinical Journal of Women's Health
69	Correlates of Serum Lypocene in Older Women	**Casso,** White, Patterson, Agurs-Collins, 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

MS ID	Title	Authors	Data Focus	Stage	Reference
72	Post-Menopausal Bone Loss and its Relationship to Oral Bone Loss	**Jeffcoat,** Lewis, Reddy, Wang, Redford	Gen	11	Periodontol 2000, 2000 June;23(1):94-102
85	The Women's Health Initiative: Rationale, Design and Progress Report	**Johnson,** Anderson, Barad, Stefanick	CT	11	Journal of the British Menopause Society, 1999;5:155-159
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	In press
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	Am J Med 2002;113;384-92
93	Fat Intake in Husbands of Women in the Dietary Modification Component of the Women's Health Initiative	**Shikany**	Gen	11	Nutr Res, 2002;22:577-86
98	Antioxidant Use in the Women's Health Initiative Participants	**Shikany,** Patterson, Agurs-Collins, Anderson	Gen	11	In press: Preventive 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	Am J Epidemiol 2002;156:-945-953
108	Cross-Sectional Geometry and Bone Mass in the Proximal Femur in African-American and White Postmenopausal Women	**Nelson,** Hendrix	CT	11	In press
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	11	JADA 2002;102:1631-1637

MS ID	Title	Authors	Data Focus	Stage	Reference
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	11	Cancer Causes Control 2002;13:741-751
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	11	In press
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
138	Baseline Experience with the Modified Mini-Mental State Exam: The Women's Health Initiative Memory Study	**Rapp,** Espeland, Hogan, Jones, Dugan	WHIMS	11	In Press: Aging and Mental Health
142	Coronary Artery Calcification in African-American and White Women	**Khurana,** Rosenbaum, Howard, Adams-Campbell, Detrano, Hsia, Klouj	OS	11	Am Heart J, 2003; 145 : 724-9
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	In press
171	Prevalence and Correlates of Panic Attacks in Post-Menopausal Women: Results from the Women's Health Initiative	**Smoller,** Wassertheil-Smoller, Hendrix, Jackson, Oberman, Sheps	Gen	11	In press
203	Estrogen Plus Progestin Influence on Breast Cancer and Mammography in Healthy Postmenopausal Women	**Chlebowski,** Hendrix, Langer, Stefanick, Gass, Lane, Rodabough, Gilligan, Cyr, Thomson, Kandekar, Petrovich, McTiernan	CT	11	In Press: JAMA
204	Effect of Estrogen Plus Progestin on Stroke in the Women's Health Initiative	**Wassertheil-Smoller,** Hendrix, Limacher, Heiss, Kooperberg, Baird, Kotchen, Curb, Black, Rossouw, Aragaki, Safford, Stein, Laowattana, Mysiw	CT	11	In press
210	Estrogen Plus Progestin and Risk of Coronary Heart Disease: Final Results From the Women's Health Initiative Randomized Clinical Trial	**Manson,** Hsia, Johnson, Rossouw, Assaf, Lasser, Trevisan, Black, Heckbert, Detrano, Strickland, Wong, Crouse, Stein, Cushman	CT	11	In Press: NEJM
211	Effects of Estrogen plus Progestin on Health-Related Quality of Life: Results from the Women's Health Initiative Randomized Clinical Trial	**Hays,** Ockene, Brunner, Kotchen, Manson, Patterson, Aragaki, Shumaker, Brzyski, LaCroix, Granek, Valanis	CT	11	NEJM in press (May 8th ,2003)
235	Hormone Replacement Therapy and Risk of Cardiovascular Disease	**Kuller**	CT	11	Arterioscler Thromb Vasc Biol. 2003;23: 11-16

MS ID	Title	Authors	Data Focus	Stage	Reference
240	Risks and benefits of estrogen plus progestin in healthy post-menopausal women. Principal results of the Women's Health Initiative randomized controlled trial	**The Writing Group for the WHI Investigators**	CT	11	Journal of the American Medical Association 2002;288(3):321-333.
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	
61	WHI Halfway Paper (100K Paper)	**Langer,** Kotchen, Daugherty, Lewis, Elmer, Trevisan, Noonan, Hendrix, Adams-Campbell	Gen	10	
76	Labeling as a Predictor of Dietary Maintenance	**Hopkins,** Burrows, Bowen, Tinker	CT	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	
100	The Yield of Six-Month Recall Mammography on Screening Mammograms	**Yasmeen,** Romano, Pettinger, Chlebowski, Lane, Robbins, Hendrix	Gen	10	
115	Prevalence and 3-year Incidence of Abuse in Older Women	**Mouton,** Rodabough, Rovi, Hunt, Brzyski		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	
221	Gynecologic Cancer Outcomes of the Women's Health Initiative Randomized Trial of Estrogen Plus Progestin	**Anderson,** Judd, Kaunitz, Barad, Beresford, Pettinger, Liu, McNeeley, Lopez	CT	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	
26	Special Populations Recruitment for the WHI: Success and Limitations	**Fouad,** Corbie-Smith, Curb, Howard, Mouton, Simon, Talavera, Thompson, Wang, White, Young	Gen	9	

MS ID	Title	Authors	Data Focus	Stage	Reference
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	
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	
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, Vu, Kreuter, Rolls	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	
132	Second Malignancy and Nonmelanoma Skin Cancer: The Women's Health Initiative Observational Study	**Rosenberg,** Greenland, Khadekar, Ascensao, Lopez	Gen	9	
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	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	
140	Hysterectomy is an Independent Predictor of Framingham Risk Score	**Hsia,** Barad, Rossouw, Rodabough, Wassertheil-Smoller, McGovern, Limacher, Oberman, Margolis	Gen	9	
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	
177	Validity of Self-Reports of Fractures among Postmenopausal Women in a Prospective Study Results from the Women's Health Initiative	**Chen,** Kooperberg, Pettinger, Bassford, Cauley, LaCroix, Lewis, Kipersztok, Borne, Jackson	Gen	9	

MS ID	Title	Authors	Data Focus	Stage	Reference
187	Estrogens and Cardiovascular Disease	**Rossouw**	OS	9	
189	Dietary Adherence in the WHI Dietary Modification Trial	**Patterson,** Prentice, Tinker, Perri, Parker, Mossavar-Rahmani, Rosal, Van Horn, Caan	CT	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-Rosette, Agurs-Collins	Gen	8	
51	The Relationship of Social Support and Social Burden to Breast Cancer Screening in the Women's Health Initiative	**Messina,** Lane, Glanz, Smith, Taylor, Frishman, Powell	Gen	8	
62	Self-reported Urogential Symptoms in Postmenopausal Women: The Women's Health Initiative	**Pastore,** Carter, Hulka, Wells	Gen	8	
113	Prior Use of Oral Contraceptives and Fracture Risk in Menopausal Women	**Barad,** Kooperberg, Wactawski-Wende, Hendrix, Watts, Liu	Gen	8	
145	Breast Cancer and Nonsteroidal Anti-inflammatory Drugs (NSAIDs): Prospective Results from the Women's Health Initiative	**Harris,** Chlebowski, Jackson, Frid, Ascensao, Anderson, Sparks, Rodabough, White, McTiernan	OS	8	
197	Predictors of Angina vs Myocardial Infarction: Prospective Analysis from the Women's Health Initiative	**Hsia,** Rossouw, Brunner, LaCroix	OS	8	
232	Women's Health Initiative: Statistical Aspects and Early Results	**Prentice** , Anderson	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, Wagnknecht, Johnson, 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, Snetselaar	Gen	7	

MS ID	Title	Authors	Data Focus	Stage	Reference
81	The Prevalence of Urinary Incontinence in WHI Women	**Hendrix,** Clark, Ling, Dugan, Salmieri, Hurtado, McNeeley, Laube, McTiernan, Francis	Gen	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	
192	Bone mineral density of American Indian and Alaska Native women: Results from the Women's Health Initiative Study	**Whampler,** Howard, Rossouw, Chen	Gen	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, Rodriques, 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	
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	
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, Andersen, 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, 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	
20	Correlates of Endogenous Sex Hormone Concentrations in WHI	**McTiernan,** Wactawski-Wende, Chen, Meilahn, LaValluer, 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, Cochrane, Stefanick, Wallace, Granek, Lillington, Anderson, Woods, Naughton	CT	4	
194	Predictors of Adherence to the Hormone Replacement Therapy Clinical Trial in the Women's Health Initiative	**Cochrane,** Anderson, Granek, Lillington, Naughton, Stefanick, Wallace, Woods	CT	4	
195	Predictors of Calcium/Vitamin D Supplementation Adherence in the Women's Health Initiative	**Brunner,** Cauley, Snetselaar, Jackson, Cochrane, Granek, Wactawski-Wende	CT	4	

MS ID	Title	Authors	Data Focus	Stage	Reference
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	**Vitolins,** Kritchevsky, Wodarski, Beresford	Gen	3	
47	Is a "Too Low" Fat Diet a Marker of Health or Disease	**Gilligan,** Snetselaar, St. Jeor, Van Horn, Kotchen, Patterson	CT	3	
54	Current Treatment Patterns in Women with Hypercholesterolemia	**Manson,** Freed, Chae, Levine, Shumaker, Naughton, Kaplan, Bowen	Gen	3	
56	Psychometric Evaluation of the Urinary Incontinence Scale	**Levine,** Bowen, Kaplan, Naughton, Shumaker	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	
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	

MS ID	Title	Authors	Data Focus	Stage	Reference
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, Torrens, Lawson	Gen	3	
188	Electrocardiographic Repolarization Phenotypes and Mortality Risk in Postmenopausal Women	**Rautaharju,** LaCroix, Kooperberg	CT	3	
200	Repression of Negative Emotion and Ambivalence about Negative Emotion: Associations with Psychosocial and Health-related Outcomes in the Women's Health Initiative	**Michael,** Perrin, O'Connor, Wisdon, Ritenbaugh, Bowen, Brzyski, Cochrane	Gen	3	
201	Normal Electrocardiographic Patterns in Older Adult Women. Depolarization and Repolarization Phenotypes	**Rautaharju,** Prineas, Hsia, Kadish, Lund	Gen	3	
206	Are Postmenopausal Survivors of Breast Cancer at an Increased Risk for Osteoporosis?	**Chen,** Barad, Ritenbaugh, Gass, Lopez, LeBoff, Bassford, Maricic	Gen	3	
207	Comparisons Between Never Smokers, Former Smokers and Current Smokers in the Observational Study of the WHI	**Brunner,** Johnson, Hunt, Paskett, Stevens, Ockene, Bowen	OS	3	
209	Estrogen Metabolism, Body Mass Index, Hormone Replacement Therapy and Post-menopausal Breast Cancer Risk	**Modugno,** Cochrane, Chlebowski, Kuller, Stefanick, Rohan, Lasser, Kip	OS	3	
218	The Relationship of Physical and Verbal Abuse with Mental and Emotional Health in Postmenopausal Women	**Mouton,** Rodabough, Cochrane, Brzyski, Rovi, Talamantes, Burge, Katerndahl	OS	3	
215	Stress, Personality, and Social Support in the Development of Breast Cancer	**Michael,** Ritenbaugh, Ockene, Weihs, Bowen, Chlebowski, Hays	OS	2	
250	Treatment with Estrogen + Progestin and age-related maculopathy in the Women's Health Initiative Sight Exam Study (WHISE)	**Haan,** Wallace, Klein, Hendrix, Seddon, Musch, Hyman, Klein	CT	2	

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 PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
172	Estrogen Receptor Polymorphisms and Cardiovascular Effects of HRT	David Herrington	Greg Burke	not approved	none	CT	3720	no	9/30/03-9/30/07	dropped
171	Analysis of Heart Rate Variability from Ultra-short Records: The WHI Study	Yvonne L. Michaels	Cheryl Ritenbaugh	yes	none	DM and HRT	76	no	1/03-6/03	funded
170	WHI Nutrition and Diabetes Study (WHINDS)	Karen Margolis	Karen Margolis	yes	all invited to participate	DM	14000 cases/14000 controls	no	1/1/04-12/31/06	pending; submitted 02/03
169	Risk Factors for Hemorrhagic Stroke Among Postmenopausal Women	Robert Kaplan	S. Wassertheil-Smoller	not approved	none	OS	250/250	yes	12/03-11/05	dropped
168	Plasma Inflammatory Markers and Colorectal Cancer	Gloria Ho	S. Wassertheil-Smoller	not approved	none	OS	500/500	yes	1/04-12/31/05	dropped
167	Sex Hormones, Risk Factors, and Risk of ER+ and ER- Breast Cancer	Steve Cummings	Steve Cummings	pending	none	OS	400	yes	6/04-12/05	not yet submitted
166	Estrogen Replacement Therapy and Autoantibodies	Meggan Mackay	S. Wassertheil-Smoller	not approved	none	OS	260/260	yes	9/1/02-5/30/02	dropped
165	Subclinical Thyroid Dysfunction and Risk of Myocardial Infarction and Stroke	Katherine Hartmann	Gerardo Heiss	yes	none	OS	1500/3200	yes	01/04-02/06	pending; to submit 06/03

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
164	The IGF System and Coronary Heart Disease	Robert Kaplan	S. Wassertheil-Smoller	yes	none	OS	350/350	yes	1/1/04-12/31/07	pending; submitted 01/03
163	Hormone Use Following the WHI E+P Trial Termination: A Pilot Study	Jennifer Hays	Jennifer Hays	yes	none	CT & OS	405	no	1/03-12/04	pending
162	Interactive Telephone Strategy to Maintain Diet Change	Shirley Beresford	Shirley Beresford	tabled	none	CT	310	no	7/1/03-6/30/08	not yet submitted
161	Bone Mass Response to Termination of Estrogen + Progestin	Jane Cauley	Lew Kuller	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	none	CT	250	no	7/02-8/17/02	funded
156	The Effect of Domestic Violence on Health Care Costs and Utilization	Charles Mouton	Robert Schenken	yes	none	OS	217/217	no		pending; resubmitted 04/03
155	Carotenoids, Transforming Growth Factors, and Breast Cancer Risk	Tom Rohan	S. Wassertheil-Smoller	yes	none	OS	3500/3500	yes	4/03-3/06	pending

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
153	Longitudinal Changes in Hip Geometry and Lower Limb Skeletal Muscle among Aging Women	Zhao Chen	Tamsen Bassford	pending	none	All BMD women	all BMD women	no	07/03-06/08	pending; resubmitted 11/02
152	Growth Factor Genes and Female Breast, Colorectal, and Endometrial Cancers	Gloria Ho	S. Wassertheil-Smoller	yes	none	OS	1700/900	yes	07/03-06/07	pending; submitted 10/02
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	Garnet Anderson	yes	none	OS	all OS women	no	5/02-4/04	funded
149	Gene-Environment Interactions & Human Breast Cancer Risk	Jennifer Hu	Electra Paskett	yes	none	OS	800/800	yes		not funded
148	Relationship Between Monoclonal Hemopoiesis and other Molecular Abnormalities and the Development of Leukemia in Older Women	Harvey Priesler	Henry Black	yes	none	OS	59/177	yes		not yet submitted
146	A Prospective Study of Pancreatic Cancer Pathogenesis	Charles Fuchs	JoAnn Manson	yes	none	OS	106/318	yes	03/03-02/04	funded

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
141	Periodontal Disease and Subclinical Cardiovascular Disease in Post-Menopausal Women	Joan Dorn	Maurizio Trevisan	yes	none	OS	80	no	04/01-06/01	funded
140	Environmental Epidemiology of Arrhythmogenesis in WHI	Eric Whitsel	Gerardo Heiss	yes	none	CT	all CT women	no	04/03-09/07	pending; submitted 06/03
139	Follow-up of Healthy Breast Cancer Survivors in the WHI Observational Study	Electra Paskett	Greg Burke	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	none	OS	1060/2120	yes	10/03-09/07	pending; submitted 01/03
135	Natural History of Pelvic Organ Prolapse in WHI Women	Ingrid Nygaard	Robert Wallace	yes	none	HRT	400	no	7/01-6/06	funded
134	Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer	Francesmary Modugno	Lew Kuller	yes	none	OS	200/200	yes	6/1/02-5/31/04	funded

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
133	Biochemical and Genetic Markers of Hypertension in White and Black Women	Howard Sesso	JoAnn Manson	yes	none	OS	800/800	yes	12/03-11/07	pending; submitted 02/03
132	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Simin Liu	JoAnn Manson	yes	none	OS	1800/2700	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	all	DM, HRT	3000	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	none	OS	1700/900	yes	1/15/02-12/31/05	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	none	OS	1500/1500	yes	07/03-06/07	pending; submitted 10/02

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
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	none	OS	350	no	4/1/2002-3/31/2006	funded
126	Molecular and Genetic Determinants of Stroke in the Women's Health Initiative Observational Study	Sylvia Smoller	S. Wassertheil-Smoller	yes	none	OS Umbrella Study	1100/1100	yes	07/03-06/06	pending; resubmitted 11/02
124	Sociocultural Influences on Motivation for and Maintenance of Health-Related Dietary Change Among Women	Joylin Namie	Robert Langer	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	none	DM	36	no	3/10/00-9/00	funded
121	Hyperinsulinemia and Ovarian Cancer	Francesmary Modugno	Lew Kuller	yes	none	OS	200/200	yes	9/1/02-08/01/04	funded
120	Epidemiology of Cervical and Lumbar Stenosis	Molly T. Vogt	Lew Kuller	yes	28,29	OS	4000	no		pending
118	Accuracy of Food Portion Estimation Among Postmenopausal Women	Christine L. Coy	Allan Hubbell	yes	none	DM	191	no	12/1999-4/2000	funded

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
117	Risk Factors for Dry Eye Syndrome in Postmenopausal Women	Kelley A. Kinney	Rebecca Jackson	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	none	OS	1000	no	8/1/99 - 7/31/02	funded
110	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Kathryn Rexrode	JoAnn Manson	yes	none	OS	385/385	yes	8/1/00 - 7/31/03	funded
108	Gene-environment effects and colorectal cancer	Henry Lin	Rowan Chlebowski Harbor UCLA	yes	none	OS	750/750	yes		pending
108	Gene-environment effects and colorectal cancer	Henry Lin	Rowan Chlebowski Harbor UCLA	yes	none	OS	50/150	yes	01/03-12/03	funded
105	Carotenoids in Age-Related Eye Disease Study	Julie Mares-Perlman	Catherine Allen	yes	21,66,56	OS	2880	yes	5/1/00 - 4/30/04	funded
104	Tamoxifen Prevention: Is it acceptable to women at risk?	Joy Melnikow	John Robbins	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	Sally Shumaker	yes		HRT	1800	no	4/1/99 - 3/31/05	funded

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
102	Quality of Life Improvements and Willingness to Pay: An Investigation of Selective Estrogen Receptor Modulators	Mona Fouad	Albert Oberman	yes	none	OS	120	no	10/98 - 9/98	funded
100	Genetic, Biochemical and Behavioral Determinants of Obesity	Jennifer Hays	Jennifer Hays	yes		OS	775	no	through 9/01	funded
99	GENNID Study	Rowan Chlebowski	Rowan Chlebowski	yes	none	ALL	40	no	12/1/98 - 3/31/00	funded
98	Bone mineral density as a predictor for periodontitis	Jean Wactawski-Wende	Maurizio Trevisan	yes	none	OS	1000	no	4/2002-4/2006	funded
97	Modeling serum markers for cost-effective ovarian cancer screening	Garnet Anderson	Garnet Anderson	yes	none	OS	264/528 baseline, 132/264 Yr 3	yes	9/30/01 - 9/29/04	funded
95	Work organization, psychological distress, and health among minority older women	Beatriz Rodriguez	David Curb	yes	none	OS	500	no	till 6/01	funded
93	The Epidemiology of Venous Disease	Michael Criqui	Robert Langer	yes		OS	725	no	3/11/98 - 6/30/99	funded
92	Fasting glucose in baseline plasma from all CT participants	Barbara Howard	Barbara Howard	tabled		CT		no	N/A	pending
90	Biochemical and Genetic Determinants of fracture in postmenopausal women	Steve Cummings	Steve Cummings	yes	none	OS	400/400	yes		funded

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study 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	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	none	DM+OS	260	no	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	none	OS	650/650	yes	9/1/99 - 8/30/03	funded
82	Extension of Bone Mineral Density Assessment in WHI Native American Women	Zhao Chen	Cheryl Ritenbaugh	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	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	none	DM	28	no	9/1/97 - 8/13/98	funded

AS #	Title	Study PI	WHI Investigator	D&A Approval	ID #s of Other Participating Clinics	Study Population	Sample Size (Cases / Controls)	OS Blood Speci-mens?	Proposed Study Dates	Funding Status
75	Adherence to Dietary Modification in the WHI	Milagros C. Rosal	Judith Ochene	yes	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	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	22,67,29	OS	228	no	5/1/97 - 4/30/98	funded
72	Ethnicity, Body Composition, Bone Density and Breast Cancer	Zhao Chen	Cheryl Ritenbaugh	yes	none	OS	800	no	9/1/97 - 8/30/02	funded
70	The Prevalence & Prognostic Importance of Myocardial Ischemia During Daily Life, & its Relationship to Migraine Status:WHI	David Sheps	Gerardo Heiss	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	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	Mary Jo O'Sullivan	yes	51	OS	1040	no	ongoing	funded

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65	Incidence of Benign breast disease in the DM CT - Pilot	Tom Rohan	A. McTiernan	yes	all	DM	200	no	4/1/98 - 6/30/99	funded
63	Development and Evaluation of Eating Style Index	Pam Haines	Gerardo Heiss	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	John Robbins	yes		HRT	3300	no	1/99 - 1/07	funded
61	Longitudinal Assessment of Memory Functioning in the WHI Clinical Trial	Mary Haan	John Robbins	yes		HRT	110	no	on-going	funded
60	Fat Intake in Husbands of WHI Dietary Arm Participants	James Shikany	Al Oberman	yes	none	DM Partners		no	12/1/96	funded
57	Hispanic Women's Advocacy and Retention Strategies	Cheryl Ritenbaugh	Cheryl Ritenbaugh	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	Gregory Burke	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	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	none	All	1607	no	2/1/96 - 6/30/96	funded

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47	Effect of diet intervention on motivation to make other health-related changes	Langer/Lo	Robert Langer	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	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	all except #18	HRT	4800	no	5/1/96 - 4/30/05	funded
36.1	Mammographic Density and Invasive Breast Cancer	Etta Pisano	Gerardo Heiss	yes		HRT	NA	no		pending - submitted 02/03
36	Hormone Replacement Therapy and Changes in Mammographic Density	Gerardo Heiss	Gerardo Heiss	yes		HRT	NA	no	1/98 - 12/02	funded
34	Ethnic Differences in Hip Bone Geometry by DXA and QCT	Dorothy Nelson	Susan Hendrix	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	none	OS	690	no	7/31/95 - 3/31/96	funded
31	Eye Care Use	Robert Kleinstein	Al Oberman	yes	none	OS	300	no	N/A	funded
25	Ankle-Arm Blood Pressure Index Measurement	Kamal Masaki	David Curb	yes	none	OS	2700	no	2/96 - 1/98	funded

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24	Cross-ethnic Comparisons of Skeletal Health of Postmenopausal Women in San Diego County	Diane Schneider	Robert Langer	yes	none	OS	168	no	1/3/95 - 1/2/97	funded
17	Domestic Violence in Older Women	Charles Mouton	Norm Lasser	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	none	OS	1300	no	9/16/96 - 09/15/01	funded
14	High Density Lipoprotein Metabolism	Scott Going, Tamsen Bassford	Tom Moon	yes	none	OS	200	no	7/1/94 - 6/30/96	funded
13	Prevalence and Correlates of Lumbar Spinal Stenosis	Molly Vogt	Lew Kuller	yes	none	CT	150	no	on-going	funded
11	Validation and Exploration of Sleep and Mood Predictors	Daniel Kripke	Robert Langer	yes	none	OS	600	no	8/1/95 - 7/31/99	funded
9	An investigation of oral hard tissue status in relation to skeletal bone mineral density measures and osteoporosis	Marjorie Jeffcoat	Al Oberman	yes	none	OS	650	no	6/1/95 - 5/31/04	funded
5	Explanations for the Development of Fat Distaste	Pamela Green	Deb Bowen	yes	none	DM	160	no	4/1/95 - 9/30/96	funded