Women's Health Initiative
Clinical Trial and Observational Study

Semi-Annual Progress Report
August 28, 2000 to February 28, 2001

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WHI Semi-Annual Progress Report

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Executive Summary

This report, summarizing data accumulated through February 28, 2001, presents the current status of the three clinical trial (CT) components and the observational study (OS) of the Women's Health Initiative (WHI). The primary areas for this report are adherence to the interventions, completeness of follow-up, safety, and event rates.

The Hormone Replacement Therapy (HRT) component completed accrual with 27,348 women randomized, including nearly 40% who had previously experienced a hysterectomy. The average follow-up on these women is just over 4 years. Recent drop-out rates, with estimates available through the sixth year, are close to design assumptions (5-7% per year). Drop-in rates are somewhat higher than projected. Analyses of intermediate effects, including blood biomarker analyses and bone density are provided by race/ethnicity. Vital status is known within the last 18 months for all but 884 women (3.3%). We lack recent follow-up on another 0.1%. Event rates for the primary outcome of CHD are currently 60-70% of design assumptions. Event rates for all adjudicated outcomes are presented by age, race/ethnicity, and hysterectomy strata. Summaries of self-reported events are included. A brief summary of data for two ancillary studies in HRT women looking at cognitive function (WHIMS) and age-related maculopathy (WHI-SE) are also included.

The Dietary Modification (DM) component randomized 48,837 women. Intervention adherence is monitored by the difference between the Intervention and Control arms in FFQ percent energy from fat (C-I). Study-wide, the Food Frequency Questionnaire mean difference between Intervention and Control women is 10.9% energy from fat at AV-1 decreasing to 8.5% at AV-6. The corresponding design assumptions for the C-I comparisons were 13% at year 1, diminishing to 0.25% per year though adequate power can be maintained as long as this difference remains at or above 10%. For fruit and vegetable intake, the mean difference between the arms 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 slightly less than one-half serving at AV-6. Currently 3.2% of the DM participants are lost-to-follow-up or have stopped follow-up and 1.7% of the participants are known to be deceased. The average follow-up time for DM women is approximately 4.2 years. Observed breast cancer and colorectal cancer incidence rates are near design assumptions (95% and 75%, respectively). Event rate by age and race/ethnicity are presented for all monitored outcomes.

Calcium and Vitamin D (CaD) component recruitment, designed to occur at a CT participant's first annual follow-up visit, has ended with 36,283 randomizations. Adherence to CaD supplements, though still lower than desirable (58%-63% consuming at least 80% of assigned dose), continued to improve slightly over the last six months. Follow-up rates for CaD participants are better than for the other CT components; only 1.5% have unknown vital status and <0.1% have not provided recent outcomes data. Hip fracture incidence rates are still lower than projected (40% of design). Age and racial/ethnic specific event rates are presented for all monitored outcomes.

Observational Study recruitment ended with 93,721 enrollments. Follow-up rates suggest strong retention overall as only 2.8% are considered lost-to-follow-up or have stopped follow-up, and <3% have not provided recent outcomes data. Responses to mailings are generally high (>93%). Approximately 83% of the 3-year clinic visits due have been conducted, as judged by task

completeness. Event rates by age and racial/ethnic categories are presented for all adjudicated outcomes.

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

1. Preliminary Remarks

This report documents study activities of the Women's Health Initiative (WHI) Clinical Trial (CT) through February 28, 2001. 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, major milestones, emphases, and changes have included:

- Conclusion of CaD randomizations.
- Completion of the execution of the DSMB recommendation to inform HRT women of an early increased risk of cardiovascular disease.
- Finalizing all logistical and contractual aspects of the WHI substudy on CVD biomarkers in the HRT trial.
- Conclusion of the motivational interviewing protocol implemented to improve adherence to the DM intervention.
- Launching of "Targeted Message Campaign" as the next initiative to support the DM Intervention.
- An outcomes clinic staff workshop held in November 2000 to provide additional training and support on outcomes collection processing.
- The addition of two neurologists to provide central adjudication on all strokes occurring in HRT women.
- Continued effort to prepare and analyze the full baseline dataset for reporting in a special edition of the Annals of Epidemiology.

All reports summarize Clinical Center (CC) data provided to the CCC by February 28, 2001. All data presented are derived from WHILMA, the study database. Data managed in WHILMA are those defined by standardized data collection procedures and instruments (see *WHI Manuals, Vol. 2 - Procedures and Vol. 3 - Forms*).

Clinical Center locations and Principal Investigators (PI) are listed in Table 1.1.

Table 1.1
Database Abbreviations for WHI CCs

Abbreviation	CC Institution and Location	Principal Investigator
ATLANTA	Emory University Atlanta (Decatur), Georgia	Nelson Watts, MD
BIRMING	University of Alabama at Birmingham Birmingham, Alabama	Cora Lewis, MD MSPH
BOWMAN	Bowman Gray School of Medicine Winston-Salem (Greensboro), North Carolina	Electra Paskett, PhD
BRIGHAM	Brigham and Women's Hospital Boston (Chestnut Hill), Massachusetts	Joann Manson, MD DrPH
BUFFALO	State University of New York, Buffalo Buffalo, New York	Maurizio Trevisan, MD MS
CHAPHILL	University of North Carolina at Chapel Hill Chapel Hill, North Carolina	Gerardo Heiss, MD MPH
CHICAGO	Northwestern University Chicago and Evanston, Illinois	Linda Van Horn, PhD RD
CHI-RUSH	Rush Presbyterian- St. Luke's Medical Center Chicago, Illinois	Henry Black, MD
CINCINNA	University of Cincinnati Cincinnati, Ohio	James Liu, MD
COLUMBUS	Ohio State University Columbus, Ohio	Rebecca Jackson, MD
DETROIT	Wayne State University Detroit, Michigan	Susan Hendrix, DO
GAINESVI	University of Florida Gainesville and Jacksonville, Florida	Marian Limacher, MD
GWU-DC	George Washington University Washington, DC	Judith Hsia, MD
HONOLULU	University of Hawaii Honolulu, Hawaii	David Curb, MD
HOUSTON	Baylor College of Medicine Houston, Texas	Jennifer Hays, PhD
IOWACITY	University of Iowa Iowa City and Bettendorf, Iowa	Robert Wallace, MD

Table 1.1 (continued)
Database Abbreviations for WHI CCs

Abbreviation	CC Institution and Location	Principal Investigator
IRVINE	University of California, Irvine Irvine, California	Allan Hubbell, MD
LA	University of California, Los Angeles Los Angeles, California	Howard Judd, MD
LAJOLLA	University of California, San Diego La Jolla and Chula Vista, California	Robert Langer, MD MPH
MADISON	University of Wisconsin Madison, Wisconsin	Catherine Allen, PhD
MEDLAN	Medlantic Research Institute Washington, D.C.	Barbara Howard, PhD
MEMPHIS	University of Tennessee Memphis, Tennessee	Karen Johnson, MD
MIAMI	University of Miami Miami, Florida	Mary-Jo O'Sullivan, MD
MILWAUKE	Medical College of Wisconsin Milwaukee, Wisconsin	Jane Morley Kotchen MD MPH
MINNEAPO	University of Minnesota Minneapolis, Minnesota	Richard Grimm, MD
NEVADA	University of Nevada Reno, Nevada	Robert Brunner PhD
NEWARK	University of Medicine and Dentistry Newark, New Jersey	Norman Lasser, MD PhD
NY-CITY	Albert Einstein College of Medicine Bronx, New York	Sylvia Wassertheil-Smoller, PhD
OAKLAND	Kaiser Foundation Research Institute Oakland, California	Bette Caan, PhD
PAWTUCK	Memorial Hospital of Rhode Island Pawtucket, Rhode Island	Annalouise Assaf, PhD
PITTSBUR	University of Pittsburgh Pittsburgh, Pennsylvania	Lewis Kuller, MD DrPH
PORTLAND	Kaiser Foundation Research Institute Portland, Oregon	Cheryl Ritenbaugh, PhD

Table 1.1 (continued)
Database Abbreviations for WHI CCs

Abbreviation	CC Institution and Location	Principal Investigator
SANANTON	University of Texas San Antonio, Texas	Robert Schenken, MD
SEATTLE	Fred Hutchinson Cancer Research Center Seattle, Washington	Shirley Beresford, PhD
STANFORD	Stanford University San Jose, California	Marcia Stefanick, PhD
STONYBRK	Research Foundation of SUNY, Stony Brook Stony Brook, NY	Dorothy Lane, MD MPH
TORRANCE	University of California, Los Angeles Torrance, California	Rowan Chlebowski, MD PhD
TUCSON	University of Arizona Tucson and Phoenix, Arizona	Tamsen Bassford, MD
UCDAVIS	University of California, Davis Sacramento, California	John Robbins, MD
WORCESTR	University of Massachusetts Worcester, Massachusetts	Judith Ockene, PhD

2. HRT Component

2.1 Recruitment

Recruitment into the HRT component, completed in October of 1998, reached 27,348 women (99.4% of goal). Of these, 10,739 women had a prior hysterectomy (39%) and were randomized to either unopposed estrogen (ERT) or placebo in equal proportions. The remaining 16,609 women with an intact uterus were randomized to combined estrogen/progestin (PERT) or its placebo, again in equal proportions for most of the recruitment period. *Table 2.1* documents the distribution by age and ethnicity of this population.

2.2 Adherence

Women randomized to HRT are required to come for a clinic visit six and twelve months after randomization and annually thereafter. Adherence to medications is determined at all visits by weighing returned bottles, if available, or by self-report in the small proportion of women with missed pill collection. Symptoms and outcomes are also ascertained at these visits. Telephone contacts or visits are also required on the anniversary of each woman's six-month visit. These contacts serve mostly to assure safety, address possible adherence and retention issues, ascertain outcomes and promote bonding. Adherence data from these telephone contacts are limited so we do not report them here.

Table 2.2 – HRT Adherence Summary gives descriptive data on all women who are considered due for each contact by hysterectomy strata. Rates of visits conducted, visits within window, stopping intervention and taking protocol-assigned medications are shown by stratum for each interval for which we have adherence data. Only summary information across strata is provided for visits that were complete in the last report. For stopping intervention and medication rates, we excluded the 331 who were moved from ERT to PERT in early 1995 after our protocol change since their experience is unique in the trial. The final column is the adherence summary, defined as the number of women known to have consumed more than 80% of their assigned HRT pills during that interval as a proportion of the number randomized and eligible for this visit. 77% of women were adherent at AV-1, 68% were adherent at AV-2, and 53% at AV-6. Differences between strata are relatively small but suggest that women without a uterus have somewhat (3%-5%) lower adherence.

Importantly, there have been no noteworthy changes in adherence measures since the last report, which was based on data collected before the HRT update was complete. *Figure 2.1* shows the adherence summary over calendar time for each visit type and for each hysterectomy strata on the subsequent page. The results for each hysterectomy stratum suggest that the changes seen in the last six months are not distinguishable from random variability.

Table 2.3 presents drop-in and drop-out rates and associated design assumptions. The results in AV-3 through AV-6 suggest a trend toward decreasing drop-outs, whereas the design assumed a constant drop-out rate after year 1. Thus, though our initial rates were poorer than expected, the cumulative rates at AV-6 (36.6% in women without a uterus and 35.0% for women with a uterus) are close to the assumed rate of 32.7%. 66.6% of participants were active at their last contact.

A small proportion (1.5% per year) of the HRT participants were expected to stop study pills and begin taking hormones outside of the trial. Among women without a uterus the observed (assumed)

cumulative rates are 2.9% (1.5%) at AV-1, 7.0% (4.4%) at AV-3, and 11.9% (8.7%) at AV-6. Similarly, in women with a uterus, the "drop-in" rates were 2.1%, 5.6%, and 8.6%.

Table 2.4 shows reasons for stopping assigned pills by hysterectomy strata. Multiple reasons may be reported. With the exception of vaginal bleeding, the proportion of women citing each reason is similar across hysterectomy strata. Among the most commonly mentioned reasons are "Other symptoms" of HRT use (27%), "Advised not to participate by health care provider" (> 15%), and "Study conflicts with other health issues" (14%). Note the list of reasons for stopping was expanded with version 3.0 of *Form 7 – Participation Status*, and interpretation of these data is complicated by this change. This display represents an attempt to map the data from the two versions of this form.

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 are shown in *Tables 2.5* and *2.6*, respectively. Reports of bleeding in women with a uterus reached a high of about 29% at 6 months (SAV-1) and have since fallen to 5-6% after AV-3. Reports of breast changes dropped to 3% by AV-1 and have since exhibited a pattern of modest decline in both strata.

2.4 Safety Monitoring

Table 2.7 presents results of endometrial aspirations by time since randomization. As routine post-randomization biopsies are required of only a small sample (6%) of women at AV-3, AV-6, and AV-9, the vast majority of these tests represent non-routine aspirations performed in response to bleeding problems. Among 4,355 total biopsies, 101 (2.3%) yielded an abnormal result: 60 cystic, 12 adenomatous, 22 atypia, and 7 cancer.

2.5 Laboratory Studies

Table 2.8 presents results of blood specimen analyses from a small (8.6%) cohort of HRT women selected randomly at baseline for these prospective analyses. The results for micronutrients, clotting factors, glucose, insulin and lipoproteins are shown here by hysterectomy strata. This subsample incorporated over-sampling of minorities, so the estimates presented here are weighted to represent the entire WHI-CT population. Race/ethnicity specific results are presented in Tables 2.9. In this table we observe a trend toward higher serum levels of micronutrients among Asian/Pacific Islanders, lower levels of Factor VII Activity and Factor VII C in Blacks, higher levels of glucose in American Indians, higher insulin levels in American Indians, Blacks and Hispanic women, and somewhat better lipid profiles in Asian/Pacific Islanders and Hispanic women.

The CVD biomarker study, designed to investigate the association between markers of thrombosis and inflammation, HRT and risk of CHD, stroke and thromboembolic events occurring during the first two years of follow-up, has begun. Bloods have been shipped to laboratories for processing and the results will be analyzed over the next few months. These results will be presented to the DSMB at their next meeting.

2.6 Intermediate Outcomes

Bone mineral density (BMD) measures are collected in three clinical centers (Pittsburgh, Birmingham, and Tucson) at baseline and at follow-up years 1, 3, 6, and 9. These data, shown in *Table 2.10*, suggest small increases in BMD between baseline and AV-1, AV-3, and AV-6 for women in both cohorts (with and without uterus), with the largest change in the BMD of the spine, followed by whole body and hip. Race/ethnicity specific results are presented for Blacks, Hispanics and Whites in *Table 2.11*.

2.7 Vital Status

Table 2.12 presents data on the vital status and the participation status of participants in the HRT trial. A detailed description of CCC and clinic activities to actively locate participants who do not complete their periodic visits is given in *Section 5 – Outcomes*. 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 3.3% of the HRT participants are lost-to-follow-up or have stopped follow-up (an increase of 0.4% compared to six months ago), and 2.0% 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 HRT participants is about 4.1 years, suggesting that approximately 11.7% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions. Follow-up in women with a uterus is slightly better than in women who have had a hysterectomy.

2.8 Outcomes

Table 2.13 contains counts of the number of locally verified major WHI outcomes for HRT participants by age and race/ethnicity. The estimates of annualized incidence rates for many event types in several racial/ethnic subgroups should be viewed with caution as the small number of events observed to-date results in unstable estimates. Approximately 6% 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.

CHD deaths has until now always included atherosclerotic cardiac death as well as other and unknown cardiovascular death. The reason for including these later two subclasses was that we assumed that a substantial number of these deaths were in fact CHD deaths that were missclassified because of limited information. Recent comparisons of local and central adjudication results for death and central adjudication suggested that this is true for about 30% of the other and unknown cardiovascular deaths, but for approximately 70% of the other and unknown cardiovascular deaths, there is no evidence that these were CHD deaths. Thus, the categories "other cardiovascular" and "unknown cardiovascular" should *not* be included in CHD death. For the sake of continuity, we still use the old definition of CHD death in most tables, but we have added an outcome "CHD death (corrected)," which includes only atherosclerotic cardiac deaths. The corresponding category "CHD (corrected)" combines "Total MI" and "CHD (corrected)." All other combined outcome classifications use the old definition for CHD. In the future, we will use only the corrected outcome classification.

An additional complication with the CHD death classification is that since the end of 1999 atherosclerotic cardiac deaths have been further subclassified as "definite CHD death" or "possible

CHD death." Definite CHD death is defined as: "No known non-CHD cause and at least one of the following: (1)-chest pain within 72 hours of death or (2)-history of chronic ischemic heart disease in the absence of valvular heart disease or non-CHD, and death certificate consistent with CHD as the underlying cause." Possible CHD death is defined as "No known non-CHD cause, and death certificate consistent with CHD as the underlying cause." A couple of our senior cardiovascular advisors and central adjudicators on the Morbidity and Mortality committee have advised that only "definite CHD death" be included in the composite CHD outcome. To avoid further complications of the tables, we have not made this change, but we provide these subclassifications by arm in the cause of death tables (*6.14*).

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

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

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

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

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

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

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

6. Unable to categorize based on available documentation.

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

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

Table 2.15 compares the stroke diagnosis for HRT participants with and without a uterus. The distribution of the subtype of stroke appears to be similar for the women with and without a uterus. *Table 2.16* compares the Glasgow scale for strokes among HRT participants. From this table it appears that the largest number of strokes fall in Glasgow classes 1 and 2, the less disabling strokes.

Table 2.17 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 numbers in this table should be taken as an upper bound on the number of events that have occurred in HRT participants.

2.9 Power Considerations

The power under the design assumptions for adherence and overall incidence rates and values derived from the observed data through February 29, 2000 are shown in *Table 2.18*. Because no significant changes have been observed in the key design parameters since that time, these calculations have not been further updated. These calculations use a drop-out rate of 7% in years 1 and 2, and 4% per year through the remaining follow-up (independent of the 3% lost-to-follow-up rates). The drop-in rates are 2.5% per year throughout follow-up. CHD incidence rates were adjusted to reflect the lower rates observed in the early follow-up period. In addition to the 33% reduction for healthy volunteer effect that the design assumed throughout follow-up, incidence rates in years 1, 2, and 3 were further reduced by 67%, 50%, and 37%, respectively. These changes produced a power for the ERT vs. Placebo comparison on CHD rates of 63% compared to the design value of 81%. For the PERT comparison the power drops from 88% to 76%.

2.10 WHI Memory Study—WHIMS

The WHI Memory Study is an ancillary study in the HRT component, funded by Wyeth Ayerst through a grant to Dr. Sally Shumaker, Wake Forest University. The aim of this study is to determine whether hormone replacement therapy reduces the incidence of dementia in women over 65 years of age. 7,526 women were enrolled in the 39 participating centers, representing approximately 61% of the age eligible cohort and 28% of the entire HRT study cohort. Baseline characteristics of WHIMS participants are shown in *Table 2.19* by hysterectomy strata.

HRT women over 65 years of age are to be administered the Modified Mini-Mental Status instrument (*Form 39—Cognitive Function*) at baseline and years 1, 3, 6, and 9 of follow-up as part of WHI. The WHIMS protocol asks that the same instrument be administered to WHIMS participants in the intervening years. *Table 2.20* presents the 25th and 50th percentile of the distribution of F39 scores in the entire HRT cohort and the subset participating in WHIMS by treatment arm and visit type. Percentile scores are reported as the scores for this population are highly skewed. These data suggest that participants who enrolled in WHIMS have slightly better F39 cognitive function scores than those who declined to participate.

Women who score below an education-adjusted threshold are referred for an intensive cognitive and neurological evaluation (Phase II/III). The results of these tests are used to classify participants into four categories: probable dementia (PD); minor cognitive impairment (MCI); no dementia (ND); or refused the Phase II/III exam (REF). *Table 2.21* describes this cascade of events by hysterectomy strata.

2.11 WHI Sight Examination Study (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 and is expected to be completed in December 2001, with a target sample size of 4,500. Currently 1,127 women have been enrolled in the 19 participating centers representing approximately 6.5% of the age eligible cohort and 4% of the entire HRT study. Baseline characteristics of WHI-SE participants are shown in *Table 2.22* by hysterectomy status.

Table 2.23 presents the prevalence of various diagnoses of eye conditions at the time of entry into WHI-SE. Note this entry time is at a minimum about 2 years after randomization to HRT. 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 will occur during 2004-2005.

2.12 Issues

The primary issues of concern in the HRT trial have been around adherence and the notification to participants of the early adverse effects. The notification has taken place to almost all HRT participants with clinics now making final efforts to contact women who have left the study. For the most part, the participants have accepted the information without alarm. Importantly, there has been no evidence of an increase in drop-out rates in the last year, confirming this sense of acceptance.

Regarding adherence, though the rates in WHI are far better than observed in the general population, study investigators and staff are motivated to improve upon the current rates. Aspects of motivational interviewing and problem solving skills were shared with key staff for the HRT/CaD component at a workshop in May 2000, and some staff are employing these tools in their routine contacts with participants. Some investigators are looking specifically at adherence patterns among minority women to determine whether other approaches may be needed.

The key event rates in the HRT are approaching projected rates. Clinical centers are, for the most part, able to provide timely ascertainment and adjudication of events so that outcomes for monitoring purposes are up-to-date. The limited information shared with investigators regarding study results in the first two years of follow-up have motivated a CVD biomarker study, the results of which are expected in the next few months. The aim of this study is to determine whether biomarkers of thrombosis and/or inflammation can shed some light on the HERS-like effect suggested by the early WHI data. These results will be presented to the WHI DSMB for their consideration. No release of these data, either to WHI investigators or to the public, will be entertained without prior approval of the DSMB.

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

Data as of: February 28, 2001

HRT Participants	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age				
Overall	**27,348**			
50-54	3426	125%	13%	10
55-59	5408	99%	20%	20
60-69	12364	100%	45%	45
70-79	6150	90%	22%	25
Without Uterus	**10,739**			
50-54	1396	113%	13%	10
55-59	1916	78%	18%	20
60-69	4852	88%	45%	45
70-79	2575	84%	24%	25
With uterus	**16,609**			
50-54	2030	135%	12%	10
55-59	3492	116%	21%	20
60-69	7512	111%	45%	45
70-79	3575	95%	22%	25
Race/Ethnicity				
Overall	**27,348**			
American Indian	131		<1%	
Asian	527		2%	
Black	2739		10%	
Hispanic	1538		6%	
White	22030		81%	
Other/unspecified	383		1%	
Without Uterus	**10,739**			
American Indian	75		1%	
Asian	164		2%	
Black	1617		15%	
Hispanic	651		6%	
White	8084		75%	
Other/unspecified	148		1%	
With uterus	**16,609**			
American Indian	56		<1%	
Asian	363		2%	
Black	1122		7%	
Hispanic	887		5%	
White	13946		84%	
Other/unspecified	235		1%	

Table 2.2
HRT Adherence Summary

Data as of: February 28, 2001

Contact	Due N	Conducted N	Conducted %	Conducted in Window N	Conducted in Window %	Stopped HRT during interval N	Stopped HRT during interval %	Missed Pill Collection N	Missed Pill Collection %	Total with Collections N	Total with Collections %	Medication Rate[1] <50% N	Medication Rate[1] <50% %	Medication Rate[1] 50%-80% N	Medication Rate[1] 50%-80% %	Medication Rate[1] 80% + N	Medication Rate[1] 80% + %	Adherence Summary[2] %
Semi-Annual Visit-1	27348	26692	98	22784	83	1369	5	1451	5	25526	95	1037	4	1904	8	22585	89	84
Annual Visit-1	27348	26498	97	21883	80	1292	5	1423	6	23777	94	1026	4	2066	9	20685	87	77
Annual Visit-2	27348	25898	95	20503	75	2495	9	2416	10	21161	90	755	4	2025	10	18381	87	69
Without Uterus	10739	10065	94	7943	74	1069	10	1055	11	8264	89	271	3	887	11	7106	86	67
With Uterus	16609	15833	95	12560	76	1426	9	1361	10	12897	91	484	4	1138	9	11275	87	70
Annual Visit –3	24777	23229	94	17598	71	1795	7	1598	8	17602	92	681	4	1694	10	15227	87	63
Without Uterus	9742	9048	93	6861	70	766	8	686	9	6833	91	245	4	733	11	5855	86	61
With Uterus	15035	14181	94	10737	71	1029	7	912	8	10769	92	436	4	961	9	9372	87	64
Annual Visit –4	15899	14612	92	10753	68	976	6	914	8	10371	92	409	4	925	9	9037	87	59
Without Uterus	6303	5682	90	4204	67	430	7	409	9	4040	91	156	4	384	10	3500	87	57
With Uterus	9596	8930	93	6549	68	546	6	505	7	6331	93	253	4	541	9	5537	88	61
Annual Visit –5	7666	6979	91	5168	67	387	5	437	9	4569	91	169	4	415	9	3985	87	56
Without Uterus	3073	2770	90	2063	67	162	5	178	9	1826	91	67	4	187	10	1572	86	52
With Uterus	4593	4209	92	3105	68	225	5	259	9	2743	91	102	4	228	8	2413	88	58
Annual Visit –6	2858	2601	91	1816	64	103	4	127	8	1506	92	62	4	131	9	1313	87	53
Without Uterus	1203	1084	90	765	64	43	4	58	8	677	92	28	4	58	9	591	87	51
With Uterus	1655	1517	92	1051	64	60	5	69	8	829	92	34	4	73	9	722	87	56

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

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

Data as of February 28, 2001

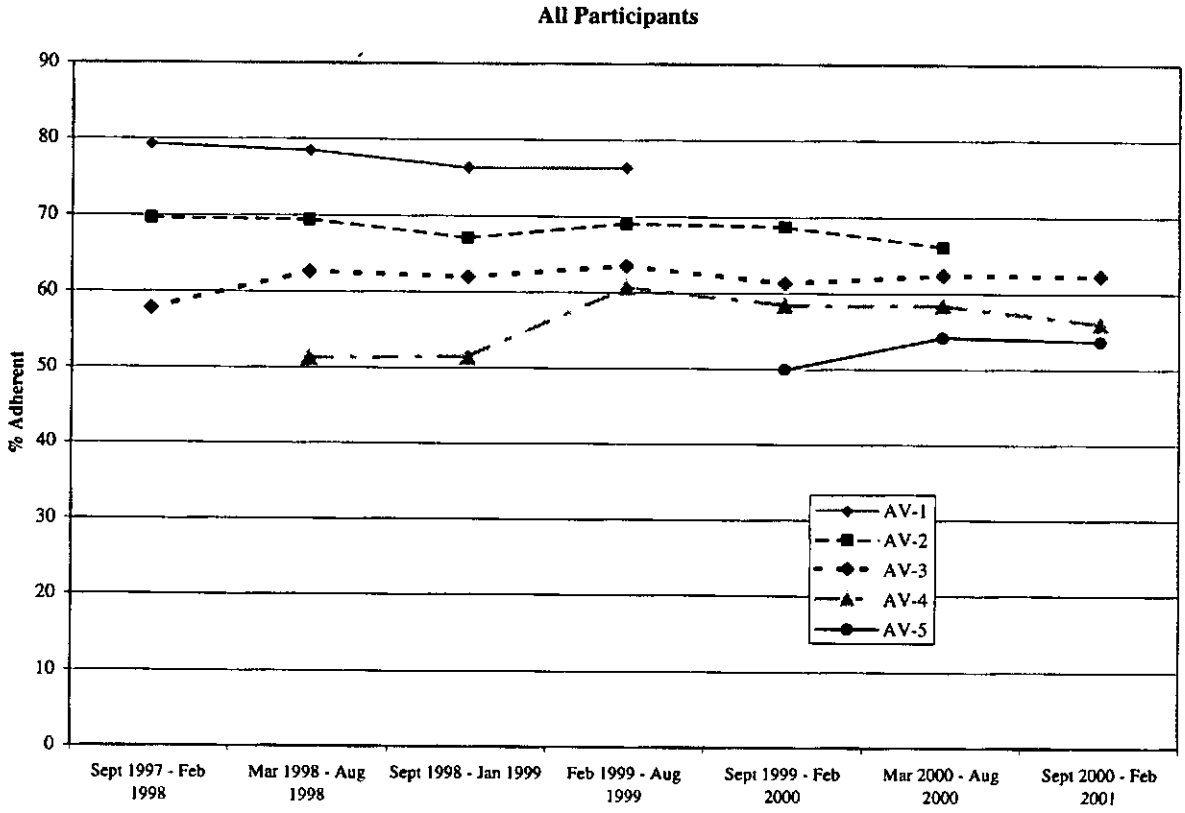
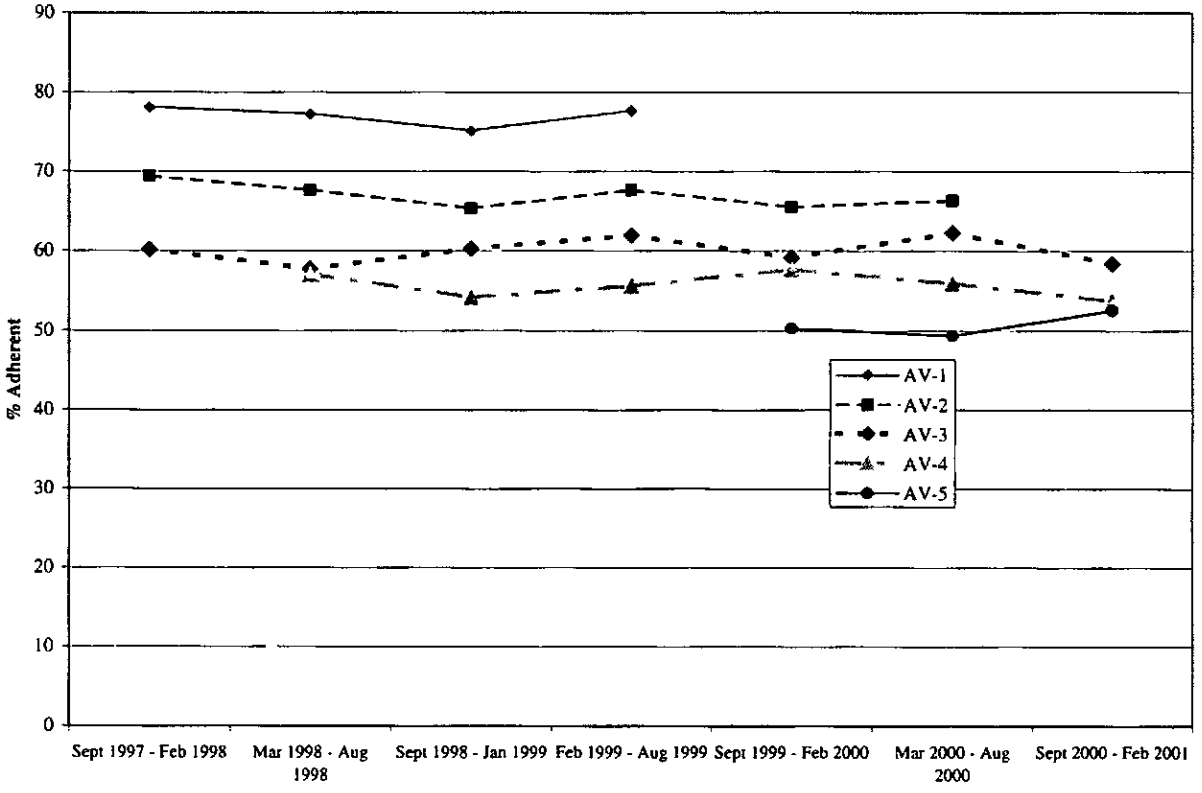


Figure 2.1 (continued)
HRT Adherence Summary
% Participants Due for a Visit Who Took at Least 80% of Study Pills

Data as of February 28, 2001

Participants Without Uterus



Participants With Uterus

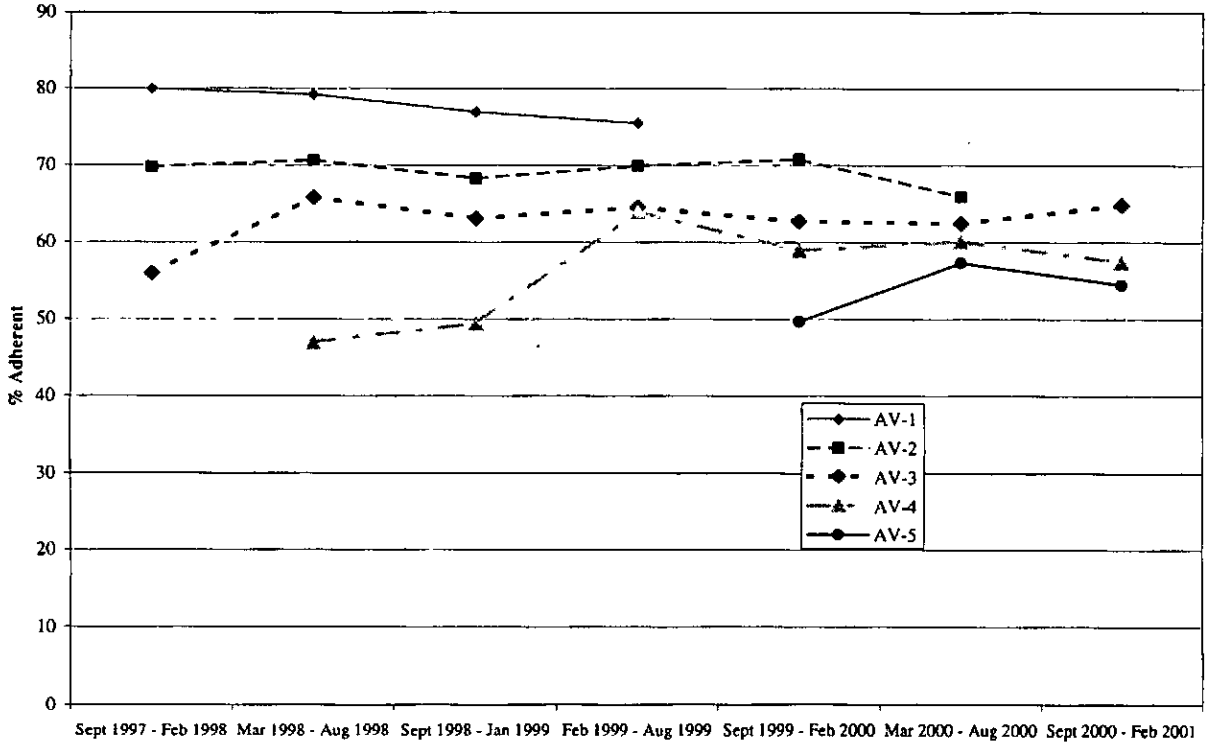


Table 2.3
HRT Drop-Out and Drop-In Rates by Follow-Up Time
(Design-specified values in parentheses)

Data as of: February 28, 2001

	Without Uterus				With Uterus				Overall Total			
	Interval[1]		Cumulative[2]		Interval		Cumulative		Interval		Cumulative	
Drop-Outs[3]												
AV-1	9.7%	(8.8)	9.7%	(8.8)	9.6%	(8.8)	9.6%	(8.8)	9.7%	(8.8)	9.7%	(8.8)
AV-2	10.0%	(5.9)	18.7%	(14.2)	8.8%	(5.9)	17.5%	(14.2)	9.3%	(5.9)	18.1%	(14.2)
AV-3	8.0%	(5.9)	25.2%	(19.2)	7.1%	(5.9)	23.4%	(19.2)	7.4%	(5.9)	24.1%	(19.2)
AV-4	7.0%	(5.9)	30.4%	(24.0)	6.0%	(5.9)	28.0%	(24.0)	6.4%	(5.9)	29.0%	(24.0)
AV-5	5.4%	(5.9)	34.2%	(28.5)	5.4%	(5.9)	31.9%	(28.5)	5.4%	(5.9)	32.8%	(28.5)
AV-6	3.7%	(5.9)	36.6%	(32.7)	4.6%	(5.9)	35.0%	(32.7)	4.2%	(5.9)	35.6%	(32.7)
Drop-Ins[4]												
AV-1	2.9%	(1.5)	2.9%	(1.5)	2.1%	(1.5)	2.1%	(1.5)	2.4%	(1.5)	2.4%	(1.5)
AV-3	4.2%	(2.9)	7.0%	(4.4)	3.6%	(2.9)	5.6%	(4.4)	3.9%	(2.9)	6.2%	(4.4)
AV-6	5.3%	(4.4)	11.9%	(8.7)	3.2%	(4.4)	8.6%	(8.7)	4.3%	(4.4)	10.2%	(8.7)

[1] Estimates of stopping or starting hormones in the Interval
[2] Estimates of cumulative rates
[3] Drop-out rates derived from Form 7 by date. Cumulative rates calculated as life-table estimates.
[4] 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

Data as of February 28, 2001

Reasons[1]	Without Uterus (N = 3810)		With Uterus (N = 5353)	
Personal/family				
Demands of work	79	(2.1%)	100	(1.9%)
Family illness, emergency or other family demands	167	(4.4%)	189	(3.5%)
Financial problems	9	(0.2%)	4	(0.1%)
Lack of cooperation/support from family/friends	35	(0.9%)	50	(0.9%)
Living in nursing home	5	(0.1%)	13	(0.2%)
Issues of interest in study	73	(1.9%)	86	(1.6%)
Travel				
Too far to CC	137	(3.6%)	137	(2.6%)
Moved out of area or refuses to be followed to another CC	19	(0.5%)	22	(0.4%)
Other travel issues	77	(2.0%)	58	(1.1%)
Visits & Procendures				
Doesn't like visits, calls	47	(1.2%)	33	(0.6%)
Mammogram Issues	9	(0.2%)	12	(0.2%)
Doesn't like gynecologic procedures	9	(0.2%)	38	(0.7%)
Docsn't like required forms or safety procedures	65	(1.7%)	86	(1.6%)
Problems with other procedures	10	(0.3%)	20	(0.4%)
Worried about health effects of medical tests/procedures	19	(0.5%)	22	(0.4%)
Wants test results	1	(<0.1%)	1	(<0.1%)
Problems with CC	25	(0.7%)	44	(0.8%)

[1] Multiple reasons may be reported for a woman

Table 2.4 (Continued)
Reasons for Stopping HRT

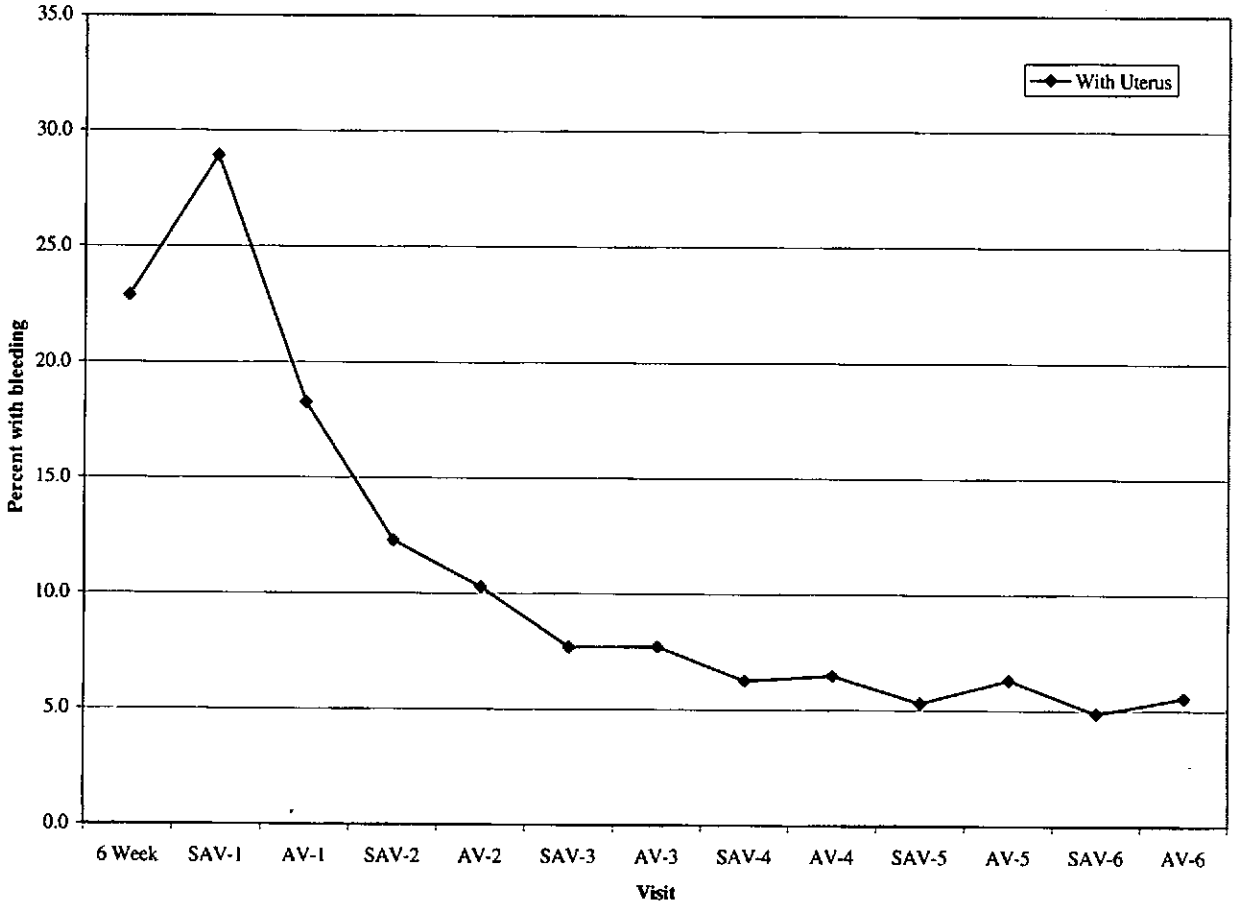
Data as of February 28, 2001

Reasons[1]	Without Uterus (N = 3810)		With Uterus (N = 5353)	
Symptoms				
Vaginal Bleeding	4	(0.1%)	454	(8.5%)
Breast Symptoms	149	(3.9%)	241	(4.5%)
Vaginal Changes	14	(0.4%)	8	(0.1%)
Hot flashes/night sweats	22	(0.6%)	5	(0.1%)
Other	1011	(26.5%)	1445	(27.0%)
Health Conditions				
Breast Cancer	37	(1.0%)	69	(1.3%)
Complex or atypical hyperplasia	0	(0.0%)	2	(<0.1%)
Endometrial cancer	2	(0.1%)	10	(0.2%)
Venous thromboembolism	17	(0.4%)	44	(0.8%)
High triglycerides (> 1000 mg/dL)	1	(<0.1%)	4	(0.1%)
Malignant melanoma	4	(0.1%)	8	(0.1%)
Gallbladder disease	4	(0.1%)	4	(0.1%)
Heart Attack	24	(0.6%)	17	(0.3%)
Stroke	36	(0.9%)	48	(0.9%)
Meningioma	3	(0.1%)	1	(<0.1%)
Depression	8	(0.2%)	8	(0.1%)
Cholesterol (high or concern about levels)	7	(0.2%)	1	(<0.1%)
Osteoporosis	24	(0.6%)	35	(0.7%)
Cognitive/memory changes	6	(0.2%)	18	(0.3%)
Other	321	(8.4%)	505	(9.4%)
Intervention				
Doesn't like randomized nature of intervention	79	(2.1%)	117	(2.2%)
Expected some benefit from intervention	37	(1.0%)	40	(0.7%)
Feels guilty, unhappy, or like a failure for not meeting study goals of intervention	2	(0.1%)	4	(0.1%)
Takes too many pills	15	(0.4%)	15	(0.3%)
Other pill issues	106	(2.8%)	123	(2.3%)
CaD Issues	16	(0.4%)	16	(0.3%)
DM Issues	3	(0.1%)	10	(0.2%)
Taking active HRT	130	(3.4%)	122	(2.3%)
Will not be on any HRT	145	(3.8%)	193	(3.6%)
Taking SERMs or other hormone medications	25	(0.7%)	40	(0.7%)
Other Health Issues				
Worried about cost if adverse effects occur	11	(0.3%)	6	(0.1%)
Expected more health care	12	(0.3%)	14	(0.3%)
Advised not to participate by health care provider	604	(15.9%)	815	(15.2%)
Study conflicts with other health issues	560	(14.7%)	702	(13.1%)
Other				
Other reasons not listed above	850	(22.3%)	1144	(21.4%)
Refuses to give a reason	64	(1.7%)	79	(1.5%)

[1] Multiple reasons may be reported for a woman

Table 2.5
Reports of Bleeding

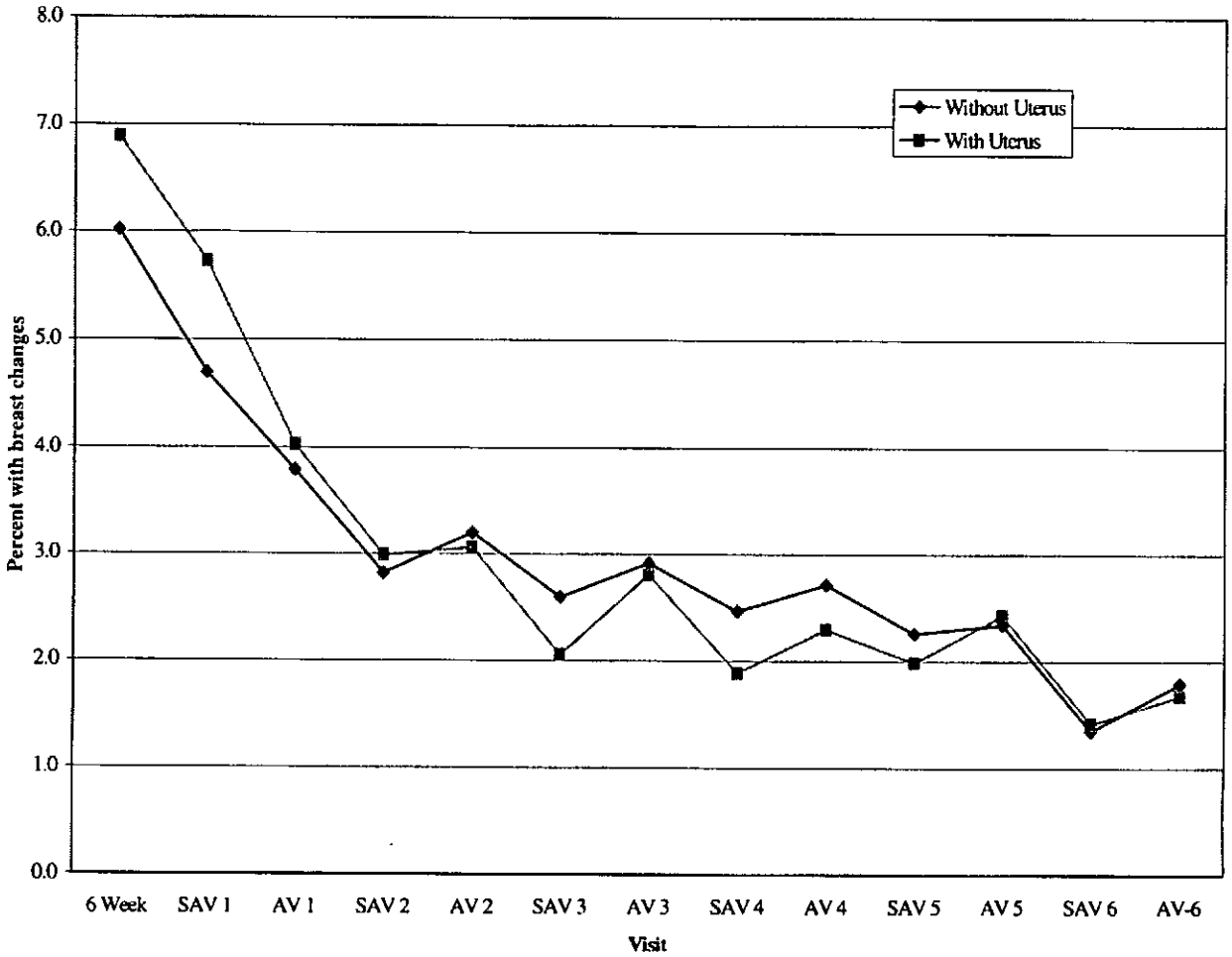
Data as of: February 28, 2001



Contact	With Uterus	
Semi-Annual Visit 3 – Number with Bleeding	1187	(7.7%)
Annual Visit 3 – Number with Bleeding	1095	(7.7%)
Semi-Annual Visit 4 – Number with Bleeding	728	(6.2%)
Annual Visit 4 – Number with Bleeding	579	(6.5%)
Semi-Annual Visit 5 – Number with Bleeding	328	(5.3%)
Annual Visit 5 – Number with Bleeding	265	(6.3%)
Semi-Annual Visit 6 – Number with Bleeding	125	(4.9%)
Annual Visit 6 – Number with Bleeding	84	(5.5%)

Table 2.6
Reports of Breast Changes

Data as of: February 28, 2001



Contact	Without Uterus		With Uterus	
Semi-Annual Visit 3 – Number with Breast Changes	217	(2.6%)	272	(2.1%)
Annual Visit 3 – Number with Breast Changes	221	(2.9%)	337	(2.8%)
Semi-Annual Visit 4 – Number with Breast Changes	148	(2.5%)	180	(1.9%)
Annual Visit 4 – Number with Breast Changes	122	(2.7%)	166	(2.3%)
Semi-Annual Visit 5 – Number with Breast Changes	70	(2.3%)	98	(2.0%)
Annual Visit 5 – Number with Breast Changes	49	(2.3%)	80	(2.4%)
Semi-Annual Visit 6 – Number with Breast Changes	17	(1.3%)	28	(1.4%)
Annual Visit 6 – Number with Breast Changes	14	(1.8%)	19	(1.7%)

Table 2.7
Endometrial Aspiration Results

Data as of: February 28, 2001

Months since randomized	N of aspirations[2,3]	Number with Abnormal Results[1]				
		Cystic	Adenomatous	Atypia	Cancer	Total[4]
0-6	104	5	1	1	-	2
6-12	723	11	2	4	-	6
12-18	707	13	3	3	3	9
18-24	529	15	4	3	-	7
24-36	400	3	-	1	-	1
36-42	664	1	-	4	3	7
42-48	564	3	2	2	1	5
48-54	226	3	-	-	-	-
54-60	174	2	-	1	-	1
60-66	108	2	-	-	-	-
66-72	61	1	-	-	-	-
72-78	52	-	-	-	-	-
78-84	40	1	-	2	-	2
84-90	3	-	-	1	-	1
Total	4355	60	12	22	7	41

[1] Abnormal results are based on local readings with the following groupings defined as follows:
Cystic is cystic hyperplasia without atypia
Adenomatous is adenomatous hyperplasia without atypia
Atypia is atypia or cystic or adenomatous hyperplasia with atypia

[2] All endometrial aspirations after first adenomatous or worse result removed. If participants had more than one endometrial aspiration within a 30-day period, the latest was used. Please note that routine aspirations for the Endometrial Aspiration subsample are included in this table.

[3] ERT-TO-PERT removed.

[4] Row totals combine adenomatous, atypias and cancer categories

Table 2.8
Blood Specimen Analysis: HRT Participants

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	993	0.07	0.07	1318	0.09	0.08
AV-1	990	0.07	0.06	1318	0.08	0.08
AV-1 - Baseline	988	-0.01	0.06	1317	-0.01	0.06
Beta-Carotene (µg/ml)						
Baseline	992	0.28	0.26	1318	0.35	0.34
AV-1	989	0.26	0.25	1319	0.31	0.30
AV-1 – Baseline	987	-0.03	0.22	1318	-0.04	0.21
Alpha-tocopherol (µg/ml)						
Baseline	993	16.16	7.12	1318	16.36	7.79
AV-1	990	17.78	8.97	1319	16.85	7.42
AV-1 – Baseline	988	1.62	6.29	1318	0.49	5.74
Gamma-tocopherol (µg/ml)						
Baseline	993	2.50	1.69	1318	2.21	1.39
AV-1	990	2.20	1.85	1319	1.84	1.24
AV-1 – Baseline	988	-0.30	1.13	1318	-0.37	0.93
Beta-Cryptoxanthine (µg/ml)						
Baseline	993	0.08	0.07	1318	0.10	0.10
AV-1	990	0.08	0.07	1318	0.09	0.09
AV-1 - Baseline	988	0.00	0.06	1317	-0.01	0.07
Lycopene (µg/ml)						
Baseline	993	0.40	0.20	1318	0.41	0.20
AV-1	990	0.39	0.20	1319	0.40	0.19
AV-1 - Baseline	988	-0.01	0.17	1318	-0.01	0.17
Lutein and Zeaxanthin (µg/ml)						
Baseline	993	0.20	0.10	1318	0.21	0.10
AV-1	990	0.20	0.10	1319	0.21	0.10
AV-1 - Baseline	988	0.00	0.07	1318	0.00	0.07
Retinol (µg/ml)						
Baseline	993	0.60	0.15	1318	0.60	0.15
AV-1	990	0.63	0.16	1319	0.61	0.15
AV-1 - Baseline	988	0.03	0.11	1318	0.01	0.10

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

Table 2.8 (Continued)
Blood Specimen Analysis: HRT Participants

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	963	129.39	29.19	1271	123.86	28.59
AV-1	943	139.39	35.44	1273	129.94	31.26
AV-1 – Baseline	917	10.42	25.53	1234	5.88	22.59
Factor VII C (%)						
Baseline	944	129.77	27.34	1252	124.99	27.19
AV-1	931	136.12	31.91	1263	125.02	28.02
AV-1 – Baseline	889	6.12	23.96	1207	-0.52	21.87
Fibrinogen (mg/dl)						
Baseline	961	312.00	63.29	1269	307.07	59.61
AV-1	941	301.61	61.86	1270	298.50	59.03
AV-1 – Baseline	913	-11.40	52.64	1229	-8.28	52.91
Hormones / Other						
Glucose (mg/dl)						
Baseline	990	105.48	34.98	1315	100.80	27.12
AV-1	988	102.94	31.95	1316	98.97	24.79
AV-1 – Baseline	983	-2.75	21.42	1312	-1.84	17.29
Insulin (μIU/ml)						
Baseline	972	12.70	8.27	1280	11.48	6.95
AV-1	975	12.07	8.08	1276	11.38	7.22
AV-1 – Baseline	954	-0.72	5.99	1252	-0.08	5.59

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

Table 2.8 (Continued)
Blood Specimen Analysis: HRT Participants

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	992	162.36	102.16	1318	145.85	74.16
AV-1	988	175.75	133.79	1317	148.44	71.75
AV-1 – Baseline	985	13.63	73.83	1316	2.58	54.03
Total Cholesterol (mg/dl)						
Baseline	992	230.03	41.03	1318	225.04	37.03
AV-1	988	223.94	40.49	1318	216.12	35.31
AV-1 – Baseline	985	-5.96	30.00	1317	-8.94	28.26
LDL-C (mg/dl)						
Baseline	971	142.27	37.00	1297	138.73	33.09
AV-1	967	128.90	35.75	1296	127.25	32.57
AV-1 – Baseline	954	-13.24	27.42	1283	-11.41	25.71
HDL-C (mg/dl)						
Baseline	988	55.99	14.60	1313	57.07	14.48
AV-1	986	60.20	16.85	1318	59.34	14.96
AV-1 – Baseline	981	4.17	9.37	1312	2.27	8.16
HDL-2 (mg/dl)						
Baseline	964	17.39	7.63	1276	17.95	7.68
AV-1	963	19.52	8.81	1286	19.24	8.17
AV-1 – Baseline	940	2.07	5.06	1250	1.20	4.70
HDL-3 (mg/dl)						
Baseline	965	38.71	8.41	1276	39.04	8.13
AV-1	965	40.98	9.52	1287	40.15	8.21
AV-1 – Baseline	942	2.14	5.77	1251	1.04	5.24
Lp(a) (mg/dl)						
Baseline	975	26.47	26.57	1299	27.04	28.00
AV-1	973	25.38	27.19	1305	25.05	27.51
AV-1 – Baseline	960	-1.04	10.81	1288	-1.92	10.76

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

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

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	27	0.06	0.05	25	0.06	0.05
AV-1	27	0.07	0.08	25	0.05	0.05
AV-1 - Baseline	27	0.01	0.06	25	0.00	0.03
Beta-Carotene (µg/ml)						
Baseline	27	0.35	0.40	25	0.26	0.22
AV-1	27	0.34	0.39	25	0.29	0.31
AV-1 – Baseline	27	-0.02	0.24	25	0.03	0.16
Alpha-tocopherol (µg/ml)						
Baseline	27	17.86	8.05	25	12.94	5.28
AV-1	27	19.18	10.00	25	15.02	8.12
AV-1 – Baseline	27	1.33	6.21	25	2.08	8.00
Gamma-tocopherol (µg/ml)						
Baseline	27	2.60	1.68	25	3.04	1.88
AV-1	27	2.64	2.73	25	2.31	1.02
AV-1 – Baseline	27	0.04	1.81	25	-0.73	1.91
Beta-Cryptoxanthine (µg/ml)						
Baseline	27	0.09	0.12	25	0.06	0.03
AV-1	27	0.08	0.06	25	0.07	0.05
AV-1 - Baseline	27	-0.01	0.10	25	0.01	0.04
Lycopene (µg/ml)						
Baseline	27	0.36	0.19	25	0.38	0.14
AV-1	27	0.40	0.21	25	0.42	0.18
AV-1 - Baseline	27	0.03	0.21	25	0.04	0.16
Lutein and Zeaxanthin (µg/ml)						
Baseline	27	0.22	0.10	25	0.18	0.09
AV-1	27	0.25	0.15	25	0.18	0.09
AV-1 - Baseline	27	0.03	0.09	25	0.00	0.05
Retinol (µg/ml)						
Baseline	27	0.61	0.19	25	0.51	0.12
AV-1	27	0.65	0.19	25	0.55	0.15
AV-1 - Baseline	27	0.05	0.07	25	0.03	0.09

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

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	25	139.24	35.44	22	122.00	32.58
AV-1	26	154.77	44.02	25	126.16	35.97
AV-1 – Baseline	24	13.08	28.42	22	2.41	20.31
Factor VII C (%)						
Baseline	25	135.56	27.59	22	120.18	33.02
AV-1	25	141.24	30.15	25	125.24	32.27
AV-1 – Baseline	23	6.70	16.45	22	4.18	22.57
Fibrinogen (mg/dl)						
Baseline	25	331.76	57.88	22	320.64	73.35
AV-1	26	315.69	83.44	25	308.72	76.48
AV-1 – Baseline	24	-9.04	75.45	22	-11.95	51.16
Hormones / Other						
Glucose (mg/dl)						
Baseline	27	115.89	45.22	25	112.60	43.59
AV-1	27	112.30	42.55	25	113.28	60.40
AV-1 – Baseline	27	-3.59	41.95	25	0.68	27.95
Insulin (µIU/ml)						
Baseline	27	14.08	8.46	25	12.41	7.92
AV-1	27	13.22	7.68	24	12.47	7.37
AV-1 – Baseline	27	-0.86	3.72	24	-0.25	2.82

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

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	26	177.81	106.80	25	151.56	85.92
AV-1	27	214.63	159.36	25	163.88	98.77
AV-1 – Baseline	26	35.85	98.82	25	12.32	56.01
Total Cholesterol (mg/dl)						
Baseline	26	237.15	41.24	25	211.96	40.66
AV-1	27	230.78	47.19	25	210.48	42.05
AV-1 – Baseline	26	-4.23	27.84	25	-1.48	20.01
LDL-C (mg/dl)						
Baseline	24	144.21	28.37	25	128.36	38.76
AV-1	23	125.13	38.01	24	124.83	39.89
AV-1 – Baseline	22	-15.77	25.61	24	-5.42	21.78
HDL-C (mg/dl)						
Baseline	26	55.00	13.69	25	53.24	13.30
AV-1	27	59.44	15.82	25	55.36	12.84
AV-1 – Baseline	26	5.04	7.68	25	2.12	8.16
HDL-2 (mg/dl)						
Baseline	26	17.08	6.12	25	16.40	5.88
AV-1	26	19.42	7.17	25	16.36	5.84
AV-1 – Baseline	25	2.68	3.67	25	-0.04	5.01
HDL-3 (mg/dl)						
Baseline	27	37.81	7.99	25	36.84	8.21
AV-1	26	40.69	9.38	25	39.00	8.75
AV-1 – Baseline	26	2.69	4.87	25	2.16	4.40
Lp(a) (mg/dl)						
Baseline	26	32.58	39.67	25	14.56	15.10
AV-1	26	32.08	43.78	25	12.64	14.37
AV-1 – Baseline	26	-0.50	14.62	25	-1.92	5.40

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

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	44	0.13	0.11	113	0.12	0.07
AV-1	44	0.09	0.07	113	0.11	0.07
AV-1 - Baseline	44	-0.04	0.09	113	-0.01	0.07
Beta-Carotene (µg/ml)						
Baseline	44	0.53	0.45	113	0.54	0.38
AV-1	44	0.39	0.33	113	0.44	0.27
AV-1 – Baseline	44	-0.14	0.30	113	-0.10	0.30
Alpha-tocopherol (µg/ml)						
Baseline	44	20.51	8.05	113	18.84	9.18
AV-1	44	21.40	8.75	113	19.53	10.20
AV-1 – Baseline	44	0.90	5.85	113	0.69	6.09
Gamma-tocopherol (µg/ml)						
Baseline	44	1.56	1.10	113	1.52	1.06
AV-1	44	1.33	1.16	113	1.26	1.00
AV-1 – Baseline	44	-0.23	0.66	113	-0.26	0.76
Beta-Cryptoxanthine (µg/ml)						
Baseline	44	0.16	0.13	113	0.25	0.38
AV-1	44	0.17	0.20	113	0.23	0.34
AV-1 - Baseline	44	0.02	0.13	113	-0.02	0.25
Lycopene (µg/ml)						
Baseline	44	0.42	0.22	113	0.40	0.21
AV-1	44	0.35	0.19	113	0.36	0.19
AV-1 - Baseline	44	-0.07	0.19	113	-0.04	0.19
Lutein and Zeaxanthin (µg/ml)						
Baseline	44	0.30	0.14	113	0.28	0.11
AV-1	44	0.28	0.13	113	0.28	0.12
AV-1 - Baseline	44	-0.02	0.08	113	-0.01	0.09
Retinol (µg/ml)						
Baseline	44	0.62	0.13	113	0.60	0.15
AV-1	44	0.65	0.15	113	0.61	0.19
AV-1 - Baseline	44	0.03	0.11	113	0.01	0.11

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

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	42	127.88	24.54	111	123.52	28.35
AV-1	42	143.71	41.88	109	127.39	27.16
AV-1 – Baseline	40	19.08	33.73	108	3.82	21.88
Factor VII C (%)						
Baseline	42	127.79	25.16	111	125.07	25.20
AV-1	42	134.45	25.19	109	123.45	27.26
AV-1 – Baseline	40	8.90	19.55	108	-1.48	16.86
Fibrinogen (mg/dl)						
Baseline	42	295.33	55.97	111	300.43	54.95
AV-1	42	287.38	65.65	109	285.02	54.02
AV-1 – Baseline	40	-5.40	58.03	108	-13.99	49.10
Hormones / Other						
Glucose (mg/dl)						
Baseline	44	106.11	29.75	113	102.14	24.70
AV-1	44	105.75	36.70	113	101.22	22.91
AV-1 – Baseline	44	-0.36	12.65	113	-0.92	12.16
Insulin (μIU/ml)						
Baseline	43	12.39	8.58	108	10.53	7.84
AV-1	43	11.67	9.56	108	10.10	7.03
AV-1 – Baseline	42	-0.91	5.60	107	-0.43	5.33

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

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	44	178.18	88.75	113	148.58	74.12
AV-1	44	196.43	103.00	112	160.96	103.09
AV-1 – Baseline	44	18.25	80.11	112	12.00	80.72
Total Cholesterol (mg/dl)						
Baseline	44	235.02	32.96	113	222.98	34.15
AV-1	44	220.20	34.17	112	211.75	32.48
AV-1 – Baseline	44	-14.82	22.10	112	-10.92	26.78
LDL-C (mg/dl)						
Baseline	42	139.50	32.14	112	132.72	31.02
AV-1	43	118.77	36.40	109	120.61	30.10
AV-1 – Baseline	41	-22.61	28.73	109	-12.96	27.33
HDL-C (mg/dl)						
Baseline	44	60.11	17.87	113	59.88	15.93
AV-1	44	64.00	18.55	112	60.29	15.84
AV-1 – Baseline	44	3.89	8.39	112	0.88	8.49
HDL-2 (mg/dl)						
Baseline	43	18.58	9.69	112	19.03	8.60
AV-1	43	20.49	9.78	109	20.07	8.61
AV-1 – Baseline	42	1.62	6.58	109	1.32	4.52
HDL-3 (mg/dl)						
Baseline	43	41.19	9.42	112	40.61	8.37
AV-1	43	43.56	11.38	110	40.15	7.98
AV-1 – Baseline	42	1.98	5.95	110	-0.39	5.94
Lp(a) (mg/dl)						
Baseline	44	21.43	14.82	112	20.03	19.45
AV-1	44	16.75	14.85	112	17.03	17.70
AV-1 – Baseline	44	-4.68	7.89	111	-3.04	12.22

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

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	332	0.07	0.08	255	0.06	0.06
AV-1	330	0.06	0.08	254	0.06	0.07
AV-1 - Baseline	330	0.00	0.06	254	0.00	0.05
Beta-Carotene (µg/ml)						
Baseline	331	0.36	0.38	255	0.31	0.26
AV-1	329	0.35	0.36	255	0.29	0.26
AV-1 – Baseline	329	-0.01	0.20	255	-0.02	0.19
Alpha-tocopherol (µg/ml)						
Baseline	332	14.29	6.30	255	14.54	6.47
AV-1	330	14.38	5.42	255	14.60	6.50
AV-1 – Baseline	330	0.12	5.10	255	0.06	5.08
Gamma-tocopherol (µg/ml)						
Baseline	332	2.49	1.37	255	2.49	1.41
AV-1	330	2.32	1.38	255	2.29	1.32
AV-1 – Baseline	330	-0.18	0.91	255	-0.20	0.95
Beta-Cryptoxanthine (µg/ml)						
Baseline	332	0.09	0.06	255	0.09	0.06
AV-1	330	0.09	0.07	255	0.08	0.06
AV-1 - Baseline	330	0.00	0.06	255	0.00	0.06
Lycopene (µg/ml)						
Baseline	332	0.38	0.21	255	0.39	0.21
AV-1	330	0.38	0.21	255	0.37	0.21
AV-1 - Baseline	330	0.00	0.18	255	-0.02	0.19
Lutein and Zeaxanthin (µg/ml)						
Baseline	332	0.25	0.13	255	0.23	0.11
AV-1	330	0.25	0.12	255	0.24	0.11
AV-1 - Baseline	330	0.00	0.08	255	0.02	0.08
Retinol (µg/ml)						
Baseline	332	0.56	0.16	255	0.56	0.16
AV-1	330	0.57	0.15	255	0.57	0.15
AV-1 - Baseline	330	0.01	0.10	255	0.01	0.08

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

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	324	113.42	23.27	243	113.85	26.63
AV-1	321	119.04	28.64	246	118.21	30.64
AV-1 – Baseline	314	5.70	20.64	236	4.69	18.61
Factor VII C (%)						
Baseline	314	117.74	27.05	237	117.12	29.48
AV-1	317	118.60	26.68	245	115.49	27.54
AV-1 – Baseline	300	1.44	19.10	229	-1.91	20.60
Fibrinogen (mg/dl)						
Baseline	324	326.07	64.58	243	319.74	67.50
AV-1	320	325.38	67.19	246	314.46	63.74
AV-1 – Baseline	313	-1.76	52.35	236	-4.91	47.22
Hormones / Other						
Glucose (mg/dl)						
Baseline	331	110.79	42.04	255	108.86	39.46
AV-1	330	108.82	41.13	254	109.60	41.38
AV-1 – Baseline	329	-1.12	36.94	254	0.64	26.19
Insulin (μIU/ml)						
Baseline	324	14.97	14.10	252	13.44	8.51
AV-1	328	14.41	13.60	254	13.23	7.82
AV-1 – Baseline	320	-0.83	8.40	251	-0.14	6.25

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

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	332	118.05	51.48	255	120.51	62.49
AV-1	330	122.08	50.54	255	118.22	54.10
AV-1 – Baseline	330	4.57	38.61	255	-2.29	39.97
Total Cholesterol (mg/dl)						
Baseline	332	225.42	41.85	255	221.56	42.37
AV-1	330	220.17	40.92	255	214.84	38.62
AV-1 – Baseline	330	-4.88	29.25	255	-6.73	24.97
LDL-C (mg/dl)						
Baseline	331	144.73	39.83	253	140.37	39.02
AV-1	330	134.49	39.06	253	132.55	37.84
AV-1 – Baseline	330	-9.95	27.53	252	-8.51	22.51
HDL-C (mg/dl)						
Baseline	331	57.08	13.14	254	56.72	13.42
AV-1	330	61.21	15.47	255	59.21	14.52
AV-1 – Baseline	330	4.11	9.70	254	2.47	8.04
HDL-2 (mg/dl)						
Baseline	329	17.91	6.96	248	17.28	7.26
AV-1	328	20.19	8.50	254	18.88	8.25
AV-1 – Baseline	326	2.24	5.49	248	1.59	5.17
HDL-3 (mg/dl)						
Baseline	329	39.17	7.82	248	39.40	7.30
AV-1	330	41.08	8.90	254	40.21	7.74
AV-1 – Baseline	327	1.85	5.82	248	0.76	4.85
Lp(a) (mg/dl)						
Baseline	326	39.34	31.54	249	38.80	29.53
AV-1	328	38.50	31.58	254	37.27	28.10
AV-1 – Baseline	324	-1.01	12.71	249	-2.11	10.94

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

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	144	0.10	0.12	184	0.10	0.09
AV-1	143	0.08	0.06	184	0.09	0.07
AV-1 - Baseline	143	-0.02	0.11	184	-0.01	0.08
Beta-Carotene (µg/ml)						
Baseline	144	0.34	0.53	184	0.32	0.29
AV-1	143	0.27	0.26	184	0.28	0.22
AV-1 – Baseline	143	-0.07	0.39	184	-0.05	0.25
Alpha-tocopherol (µg/ml)						
Baseline	144	15.52	7.52	184	15.80	6.49
AV-1	143	16.80	7.51	184	16.55	7.43
AV-1 – Baseline	143	1.28	6.03	184	0.75	5.11
Gamma-tocopherol (µg/ml)						
Baseline	144	2.28	1.38	184	2.21	1.39
AV-1	143	2.07	1.36	184	1.93	1.29
AV-1 – Baseline	143	-0.21	0.98	184	-0.28	0.95
Beta-Cryptoxanthine (µg/ml)						
Baseline	144	0.13	0.18	184	0.13	0.12
AV-1	143	0.11	0.11	184	0.12	0.11
AV-1 - Baseline	143	-0.02	0.15	184	-0.01	0.09
Lycopene (µg/ml)						
Baseline	144	0.40	0.19	184	0.46	0.21
AV-1	143	0.37	0.18	184	0.40	0.19
AV-1 - Baseline	143	-0.03	0.15	184	-0.05	0.17
Lutein and Zeaxanthin (µg/ml)						
Baseline	144	0.20	0.09	184	0.23	0.11
AV-1	143	0.20	0.09	184	0.22	0.11
AV-1 - Baseline	143	0.00	0.06	184	-0.01	0.08
Retinol (µg/ml)						
Baseline	144	0.52	0.13	184	0.56	0.14
AV-1	143	0.55	0.13	184	0.56	0.14
AV-1 - Baseline	143	0.02	0.08	184	0.00	0.09

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

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	137	121.37	24.97	173	124.06	28.42
AV-1	130	128.44	26.54	178	128.96	28.53
AV-1 – Baseline	123	9.42	24.53	169	4.18	22.97
Factor VII C (%)						
Baseline	132	124.00	28.43	166	123.49	26.94
AV-1	127	126.90	24.79	173	123.43	25.92
AV-1 – Baseline	117	3.45	26.60	159	-0.86	19.82
Fibrinogen (mg/dl)						
Baseline	137	318.08	67.20	173	319.40	66.41
AV-1	130	309.63	60.54	177	315.36	61.11
AV-1 – Baseline	123	-5.77	54.43	168	-6.35	52.37
Hormones / Other						
Glucose (mg/dl)						
Baseline	142	103.13	27.63	184	105.65	31.02
AV-1	143	105.90	36.43	184	104.58	30.27
AV-1 – Baseline	141	3.00	23.70	184	-1.07	17.78
Insulin (µIU/ml)						
Baseline	141	13.64	8.86	183	13.61	7.96
AV-1	141	13.37	8.13	181	13.22	6.64
AV-1 – Baseline	139	-0.35	6.26	181	-0.39	5.99

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

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	144	159.47	69.02	184	167.12	83.34
AV-1	143	168.32	68.62	183	174.49	86.51
AV-1 – Baseline	143	8.41	51.74	183	8.98	66.76
Total Cholesterol (mg/dl)						
Baseline	144	219.06	39.03	184	226.65	38.04
AV-1	143	212.62	35.36	184	214.95	35.29
AV-1 – Baseline	143	-6.18	27.27	184	-11.70	23.79
LDL-C (mg/dl)						
Baseline	142	132.16	33.53	180	139.89	35.46
AV-1	142	122.48	31.79	177	126.99	33.77
AV-1 – Baseline	140	-9.51	26.15	175	-13.90	24.29
HDL-C (mg/dl)						
Baseline	143	54.41	13.02	184	53.25	12.44
AV-1	143	57.03	14.85	184	53.91	13.10
AV-1 – Baseline	142	2.61	9.43	184	0.66	7.13
HDL-2 (mg/dl)						
Baseline	143	16.50	6.70	181	15.80	6.82
AV-1	142	17.97	7.91	184	16.68	6.77
AV-1 – Baseline	141	1.40	5.24	181	0.90	4.42
HDL-3 (mg/dl)						
Baseline	143	37.92	7.48	181	37.37	7.25
AV-1	142	39.04	8.08	184	37.23	7.58
AV-1 – Baseline	141	1.20	5.44	181	-0.30	4.76
Lp(a) (mg/dl)						
Baseline	142	16.87	18.20	184	21.65	22.98
AV-1	140	16.29	17.96	183	20.03	21.39
AV-1 – Baseline	139	-0.74	7.24	183	-1.72	10.78

Table 2.9 (Continued)
Blood Specimen Analysis: White Women

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	423	0.07	0.06	714	0.09	0.08
AV-1	423	0.06	0.05	714	0.08	0.08
AV-1 - Baseline	421	-0.01	0.05	714	-0.01	0.06
Beta-Carotene (µg/ml)						
Baseline	423	0.27	0.20	714	0.35	0.34
AV-1	423	0.24	0.22	714	0.31	0.31
AV-1 – Baseline	421	-0.02	0.20	714	-0.04	0.21
Alpha-tocopherol (µg/ml)						
Baseline	423	16.28	7.08	714	16.55	7.91
AV-1	423	18.14	9.25	714	17.07	7.36
AV-1 – Baseline	421	1.86	6.43	714	0.51	5.81
Gamma-tocopherol (µg/ml)						
Baseline	423	2.53	1.75	714	2.20	1.38
AV-1	423	2.21	1.92	714	1.80	1.22
AV-1 – Baseline	421	-0.32	1.16	714	-0.40	0.92
Beta-Cryptoxanthine (µg/ml)						
Baseline	423	0.08	0.05	714	0.09	0.07
AV-1	423	0.07	0.06	713	0.08	0.07
AV-1 - Baseline	421	0.00	0.04	713	-0.01	0.06
Lycopene (µg/ml)						
Baseline	423	0.40	0.20	714	0.41	0.19
AV-1	423	0.39	0.19	714	0.40	0.19
AV-1 - Baseline	421	-0.01	0.17	714	-0.01	0.17
Lutein and Zeaxanthin (µg/ml)						
Baseline	423	0.20	0.09	714	0.21	0.09
AV-1	423	0.20	0.10	714	0.21	0.09
AV-1 - Baseline	421	0.00	0.06	714	0.00	0.06
Retinol (µg/ml)						
Baseline	423	0.61	0.14	714	0.61	0.15
AV-1	423	0.64	0.15	714	0.62	0.14
AV-1 - Baseline	421	0.03	0.11	714	0.01	0.10

Table 2.9 (Continued)
Blood Specimen Analysis: White Women

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	412	131.78	29.41	694	125.13	28.62
AV-1	401	142.28	35.43	688	131.57	31.27
AV-1 – Baseline	393	10.85	25.78	672	6.18	23.09
Factor VII C (%)						
Baseline	409	131.61	26.97	688	126.09	26.79
AV-1	397	138.84	32.33	684	126.33	27.95
AV-1 – Baseline	387	6.76	24.52	662	-0.37	22.28
Fibrinogen (mg/dl)						
Baseline	410	309.95	62.92	692	304.75	57.73
AV-1	400	298.43	60.01	686	295.93	57.79
AV-1 – Baseline	390	-12.90	51.92	668	-8.45	53.73
Hormones / Other						
Glucose (mg/dl)						
Baseline	423	104.86	34.35	710	99.39	24.56
AV-1	421	101.84	29.97	712	97.15	20.58
AV-1 – Baseline	419	-3.38	18.13	708	-2.24	15.84
Insulin (μIU/ml)						
Baseline	414	12.39	7.13	684	11.15	6.58
AV-1	413	11.71	6.99	681	11.09	7.13
AV-1 – Baseline	403	-0.73	5.64	661	-0.05	5.52

Table 2.9 (Continued)
Blood Specimen Analysis: White Women

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	423	167.57	107.26	713	147.67	74.17
AV-1	421	181.95	142.53	714	150.24	70.17
AV-1 – Baseline	419	14.65	77.56	713	2.49	53.75
Total Cholesterol (mg/dl)						
Baseline	423	230.82	41.06	713	225.59	36.28
AV-1	421	224.84	40.63	714	216.50	34.86
AV-1 – Baseline	419	-5.91	30.41	713	-9.12	28.92
LDL-C (mg/dl)						
Baseline	410	142.36	36.92	699	138.77	32.11
AV-1	406	128.64	35.32	705	126.80	31.63
AV-1 – Baseline	399	-13.63	27.44	695	-11.70	26.06
HDL-C (mg/dl)						
Baseline	421	55.87	14.78	709	57.27	14.61
AV-1	419	60.17	17.10	714	59.67	15.03
AV-1 – Baseline	416	4.25	9.38	709	2.39	8.22
HDL-2 (mg/dl)						
Baseline	400	17.36	7.72	683	18.14	7.72
AV-1	402	19.51	8.90	686	19.43	8.19
AV-1 – Baseline	384	2.09	4.97	660	1.17	4.66
HDL-3 (mg/dl)						
Baseline	400	38.66	8.52	683	39.06	8.25
AV-1	402	41.00	9.63	686	40.32	8.28
AV-1 – Baseline	384	2.21	5.79	660	1.20	5.28
Lp(a) (mg/dl)						
Baseline	414	25.46	25.75	701	26.16	27.97
AV-1	413	24.38	26.42	703	24.15	27.68
AV-1 – Baseline	405	-0.99	10.75	692	-1.86	10.66

Table 2.9 (Continued)
Blood Specimen Analysis: Other/Unspecified Women

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	23	0.10	0.06	27	0.11	0.14
AV-1	23	0.10	0.09	28	0.08	0.10
AV-1 - Baseline	23	0.00	0.07	27	-0.03	0.05
Beta-Carotene (µg/ml)						
Baseline	23	0.37	0.32	27	0.43	0.48
AV-1	23	0.35	0.25	28	0.35	0.32
AV-1 – Baseline	23	-0.03	0.16	27	-0.07	0.30
Alpha-tocopherol (µg/ml)						
Baseline	23	17.97	8.44	27	17.25	8.00
AV-1	23	18.94	11.06	28	17.31	6.31
AV-1 – Baseline	23	0.97	5.11	27	0.01	5.73
Gamma-tocopherol (µg/ml)						
Baseline	23	2.14	1.09	27	1.88	1.09
AV-1	23	2.00	0.87	28	1.75	1.07
AV-1 – Baseline	23	-0.14	0.99	27	-0.09	0.71
Beta-Cryptoxanthine (µg/ml)						
Baseline	23	0.09	0.08	27	0.11	0.13
AV-1	23	0.11	0.07	28	0.08	0.07
AV-1 - Baseline	23	0.01	0.05	27	-0.02	0.08
Lycopene (µg/ml)						
Baseline	23	0.49	0.21	27	0.33	0.21
AV-1	23	0.44	0.23	28	0.33	0.22
AV-1 - Baseline	23	-0.06	0.24	27	0.00	0.16
Lutein and Zeaxanthin (µg/ml)						
Baseline	23	0.20	0.10	27	0.20	0.15
AV-1	23	0.20	0.11	28	0.21	0.12
AV-1 - Baseline	23	-0.01	0.07	27	0.01	0.11
Retinol (µg/ml)						
Baseline	23	0.59	0.15	27	0.59	0.14
AV-1	23	0.64	0.19	28	0.59	0.13
AV-1 - Baseline	23	0.06	0.13	27	0.00	0.13

Table 2.9 (Continued)
Blood Specimen Analysis: Other/Unspecified Women

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	23	124.57	23.33	28	123.25	22.54
AV-1	23	133.00	26.98	27	131.15	27.67
AV-1 – Baseline	23	8.43	26.66	27	8.70	16.35
Factor VII C (%)						
Baseline	22	124.64	23.74	28	124.96	22.66
AV-1	23	130.57	20.25	27	127.74	27.67
AV-1 – Baseline	22	7.41	19.63	27	3.48	19.05
Fibrinogen (mg/dl)						
Baseline	23	318.52	56.73	28	332.46	74.49
AV-1	23	294.04	64.72	27	306.67	60.67
AV-1 – Baseline	23	-24.48	53.87	27	-24.52	51.39
Hormones / Other						
Glucose (mg/dl)						
Baseline	23	98.87	20.65	28	102.93	29.00
AV-1	23	103.04	28.07	28	99.96	19.35
AV-1 – Baseline	23	4.17	14.54	28	-2.96	14.71
Insulin (μIU/ml)						
Baseline	23	10.30	6.84	28	10.94	5.21
AV-1	23	10.90	7.41	28	11.05	6.70
AV-1 – Baseline	23	0.61	6.25	28	0.11	3.51

Table 2.9 (Continued)
Blood Specimen Analysis: Other/Unspecified Women

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Lipoproteins						
Triglyceride (mg/dl)						
Baseline	23	156.57	92.42	28	161.57	77.61
AV-1	23	168.13	68.18	28	162.18	76.35
AV-1 – Baseline	23	11.57	62.43	28	0.61	38.46
Total Cholesterol (mg/dl)						
Baseline	23	241.43	42.05	28	221.86	37.22
AV-1	23	236.48	36.92	28	219.54	39.19
AV-1 – Baseline	23	-4.96	28.61	28	-2.32	29.73
LDL-C (mg/dl)						
Baseline	22	155.55	37.38	28	135.50	34.76
AV-1	23	143.65	35.75	28	131.64	41.51
AV-1 – Baseline	22	-10.27	23.25	28	-3.86	29.22
HDL-C (mg/dl)						
Baseline	23	54.57	12.33	28	54.04	15.58
AV-1	23	59.17	13.34	28	55.39	15.33
AV-1 – Baseline	23	4.61	7.45	28	1.36	4.27
HDL-2 (mg/dl)						
Baseline	23	16.48	6.93	27	15.85	8.56
AV-1	22	18.73	7.25	28	17.21	9.31
AV-1 – Baseline	22	1.91	5.08	27	1.07	3.23
HDL-3 (mg/dl)						
Baseline	23	38.09	6.53	27	37.63	8.19
AV-1	22	41.50	6.84	28	38.18	7.38
AV-1 – Baseline	22	3.00	4.86	27	0.11	3.42
Lp(a) (mg/dl)						
Baseline	23	20.22	23.07	28	27.43	27.15
AV-1	22	20.23	23.22	28	23.75	19.83
AV-1 – Baseline	22	-0.55	3.20	28	-3.68	16.10

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

Data as of: February 28, 2001

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan						
Baseline	938	1.01	0.11	1025	0.99	0.10
AV1	843	1.01	0.11	929	1.00	0.10
AV3	766	1.03	0.12	848	1.02	0.10
AV6	211	1.03	0.12	242	1.02	0.11
AV1 % Change from baseline BMD[2]	841	0.42	2.78	927	0.27	2.35
AV3 % Change from baseline BMD[3]	764	2.20	4.39	846	1.97	3.82
AV6 % Change from baseline BMD[4]	211	2.04	5.19	241	2.95	5.29
Spine Scan						
Baseline	911	0.97	0.16	998	0.95	0.16
AV1	824	0.99	0.16	901	0.97	0.16
AV3	758	1.00	0.17	833	0.99	0.17
AV6	215	1.00	0.16	242	0.98	0.17
AV1 % Change from baseline BMD	820	1.91	4.56	898	2.08	4.35
AV3 % Change from baseline BMD	753	3.58	6.17	831	4.05	5.99
AV6 % Change from baseline BMD	214	3.53	6.96	241	5.33	7.44
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	769	0.88	0.15	854	0.86	0.14
AV6	216	0.89	0.15	252	0.85	0.12
AV1 % Change from baseline BMD	838	0.73	3.32	927	0.62	3.16
AV3 % Change from baseline BMD	766	2.25	4.86	853	2.15	4.80
AV6 % Change from baseline BMD	215	1.01	5.62	251	1.89	5.70

[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 2.11
Bone Mineral Density[1] Analysis: HRT Participants by Race/Ethnicity

Data as of: February 28, 2001

	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	99	1.08	0.11	66	1.03	0.10	61	1.02	0.11	686	0.99	0.10	843	0.98	0.09
AV1	153	1.07	0.11	86	1.08	0.11	44	1.04	0.10	50	1.03	0.10	636	1.00	0.10	776	0.99	0.09
AV3	146	1.09	0.11	86	1.10	0.12	51	1.05	0.12	45	1.06	0.11	560	1.01	0.12	701	1.00	0.10
AV6	35	1.11	0.12	15	1.08	0.12	10	1.09	0.15	6	1.14	0.22	164	1.01	0.10	216	1.01	0.10
AV1 % Change from baseline BMD[2]	153	0.75	2.95	86	0.91	2.86	44	-0.16	2.30	50	0.06	2.57	634	0.38	2.76	774	0.21	2.27
AV3 % Change from baseline BMD[3]	146	2.15	3.43	86	2.15	3.20	51	1.66	4.58	45	3.34	5.51	558	2.26	4.61	699	1.86	3.77
AV6 % Change from baseline BMD[4]	35	0.29	4.01	15	0.88	4.86	10	8.38	7.25	6	7.82	2.01	164	2.07	5.02	215	3.00	5.34
Spine Scan																		
Baseline	171	1.04	0.15	99	1.08	0.19	65	0.96	0.13	61	0.92	0.14	663	0.95	0.16	816	0.93	0.15
AV1	150	1.05	0.16	86	1.09	0.19	44	0.97	0.11	49	0.95	0.15	620	0.97	0.16	749	0.96	0.16
AV3	144	1.07	0.17	86	1.11	0.20	51	0.95	0.13	45	0.94	0.14	554	0.99	0.17	686	0.97	0.16
AV6	35	1.09	0.17	15	1.10	0.25	10	0.97	0.19	6	1.04	0.24	168	0.98	0.15	216	0.97	0.16
AV1 % Change from baseline BMD	150	1.89	4.37	86	1.75	4.81	44	-0.65	4.45	49	1.71	6.86	616	2.12	4.56	746	2.14	4.11
AV3 % Change from baseline BMD	144	3.54	6.14	86	2.89	6.33	51	-0.31	5.62	45	3.14	7.07	549	3.97	6.09	684	4.25	5.84
AV6 % Change from baseline BMD	35	2.22	6.76	15	1.30	7.30	10	5.34	6.96	6	5.23	9.86	167	3.73	7.03	215	5.58	7.34
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	635	0.83	0.13	775	0.83	0.12
AV3	147	0.98	0.14	86	0.99	0.15	50	0.89	0.13	45	0.88	0.13	563	0.85	0.14	707	0.84	0.13
AV6	36	1.01	0.13	16	0.96	0.13	10	0.86	0.18	6	0.86	0.16	168	0.86	0.13	225	0.84	0.12
AV1 % Change from baseline BMD	153	1.15	2.95	86	1.14	3.43	43	0.31	3.62	50	1.03	3.46	632	0.66	3.38	774	0.54	3.12
AV3 % Change from baseline BMD	147	2.01	3.81	86	1.48	3.85	50	2.65	5.36	45	4.60	5.92	560	2.29	5.06	706	2.04	4.80
AV6 % Change from baseline BMD	36	-1.05	5.04	16	-1.91	5.76	10	4.24	6.41	6	5.02	6.28	167	1.33	5.58	224	2.09	5.58

[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 2.12
Lost-to-Follow-up and Vital Status by Hysterectomy Status

Data as of: February 28, 2001

	Without Uterus (N=10,739)		With Uterus (N=16,609)		HRT Participants (N=27,348)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	248	2.3	292	1.8	540	2.0
Alive: Current Participation[1]	9818	91.4	15517	93.4	25335	92.6
Alive: Recent Participation[2]	260	2.4	310	1.9	570	2.1
Alive: Past/Unknown Participation[3]	10	0.1	9	0.1	19	0.1
Stopped Follow-Up[4]	213	2.0	272	1.6	485	1.8
Lost to Follow-Up[5]	190	1.8	209	1.3	399	1.5

[1] Participants who have filled in a Form 33 within the last 9 months.
[2] Participants who last filled in a Form 33 between 9 and 18 months ago.
[3] Participiants 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 2.13

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

Data as of: February 28, 2001

Outcomes	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	27348		3426		5408		12364		6150	
Mean follow-up (months)	48.6		53.9		50.6		47.6		46.0	
Cardiovascular										
CHD[1]	417	(0.38%)	24	(0.16%)	38	(0.17%)	194	(0.40%)	161	(0.68%)
CHD (corrected)[2]	381	(0.34%)	23	(0.15%)	33	(0.14%)	179	(0.37%)	146	(0.62%)
CHD death[3]	128	(0.12%)	6	(0.04%)	14	(0.06%)	54	(0.11%)	54	(0.23%)
CHD death (corrected)[4]	88	(0.08%)	5	(0.03%)	9	(0.04%)	37	(0.08%)	37	(0.16%)
Total MI[5]	321	(0.29%)	19	(0.12%)	26	(0.11%)	152	(0.31%)	124	(0.53%)
Clinical MI	312	(0.28%)	18	(0.12%)	26	(0.11%)	145	(0.30%)	123	(0.52%)
Definite Silent MI	19	(0.02%)	2	(0.01%)	1	(<0.01%)	13	(0.03%)	3	(0.01%)
Possible Silent MI	71	(0.06%)	6	(0.04%)	8	(0.04%)	30	(0.06%)	27	(0.11%)
Angina	542	(0.49%)	18	(0.12%)	68	(0.30%)	255	(0.52%)	201	(0.85%)
CABG/PTCA	501	(0.45%)	19	(0.12%)	61	(0.27%)	239	(0.49%)	182	(0.77%)
Carotid artery disease	109	(0.10%)	0	(0.00%)	10	(0.04%)	54	(0.11%)	45	(0.19%)
Congestive heart failure	286	(0.26%)	12	(0.08%)	32	(0.14%)	115	(0.23%)	127	(0.54%)
Stroke	286	(0.26%)	8	(0.05%)	34	(0.15%)	129	(0.26%)	115	(0.49%)
Non-disabling stroke	174	(0.16%)	8	(0.05%)	22	(0.10%)	81	(0.17%)	63	(0.27%)
Fatal/disabling stroke	67	(0.06%)	0	(0.00%)	4	(0.02%)	28	(0.06%)	35	(0.15%)
Unknown status from stroke	45	(0.04%)	0	(0.00%)	8	(0.04%)	20	(0.04%)	17	(0.07%)
PVD	79	(0.07%)	4	(0.03%)	8	(0.04%)	37	(0.08%)	30	(0.13%)
DVT	173	(0.16%)	10	(0.06%)	23	(0.10%)	81	(0.17%)	59	(0.25%)
PE	102	(0.09%)	5	(0.03%)	17	(0.07%)	43	(0.09%)	37	(0.16%)
CHD[1]/Possible Silent MI	478	(0.43%)	30	(0.19%)	44	(0.19%)	219	(0.45%)	185	(0.78%)
Coronary disease[6]	1179	(1.06%)	55	(0.36%)	133	(0.58%)	541	(1.10%)	450	(1.91%)
DVT/PE	228	(0.21%)	12	(0.08%)	30	(0.13%)	108	(0.22%)	78	(0.33%)
Total CVD	1721	(1.55%)	78	(0.51%)	197	(0.86%)	805	(1.64%)	641	(2.72%)
Cancer										
Breast cancer[7]	379	(0.34%)	44	(0.29%)	55	(0.24%)	195	(0.40%)	85	(0.36%)
Invasive breast cancer	298	(0.27%)	34	(0.22%)	48	(0.21%)	148	(0.30%)	68	(0.29%)
Non-invasive breast cancer	84	(0.08%)	10	(0.06%)	7	(0.03%)	50	(0.10%)	17	(0.07%)
Ovary cancer	40	(0.04%)	1	(0.01%)	6	(0.03%)	23	(0.05%)	10	(0.04%)
Endometrial cancer[8]	31	(0.05%)	0	(0.00%)	3	(0.02%)	16	(0.05%)	12	(0.09%)
Colorectal cancer	152	(0.14%)	8	(0.05%)	17	(0.07%)	79	(0.16%)	48	(0.20%)
Other cancer[9]	512	(0.46%)	40	(0.26%)	66	(0.29%)	239	(0.49%)	167	(0.71%)
Total cancer	1094	(0.99%)	93	(0.60%)	145	(0.64%)	541	(1.10%)	315	(1.34%)
Fractures										
Hip fracture	113	(0.10%)	3	(0.02%)	4	(0.02%)	34	(0.07%)	72	(0.31%)
Vertebral fracture	115	(0.10%)	5	(0.03%)	14	(0.06%)	42	(0.09%)	54	(0.23%)
Other fracture[9]	1643	(1.48%)	189	(1.23%)	260	(1.14%)	773	(1.58%)	421	(1.79%)
Total fracture	1822	(1.64%)	195	(1.27%)	275	(1.21%)	832	(1.70%)	520	(2.20%)
Deaths										
Cardiovascular deaths	171	(0.15%)	7	(0.05%)	16	(0.07%)	69	(0.14%)	79	(0.33%)
Cancer deaths	230	(0.21%)	12	(0.08%)	22	(0.10%)	108	(0.22%)	88	(0.37%)
Deaths: other known cause	66	(0.06%)	6	(0.04%)	10	(0.04%)	26	(0.05%)	24	(0.10%)
Deaths: unknown cause	30	(0.03%)	3	(0.02%)	5	(0.02%)	11	(0.02%)	11	(0.05%)
Deaths: not yet adjudicated	43	(0.04%)	3	(0.02%)	2	(0.01%)	16	(0.03%)	22	(0.09%)
Total death	540	(0.49%)	31	(0.20%)	55	(0.24%)	230	(0.47%)	224	(0.95%)

[1] "CHD" includes clinical MI, definite silent MI, and CHD death.

[2] "CHD (corrected)" includes clinical MI, evolving Q-wave MI, and CHD death (corrected), see also p2-4.

[3] "CHD death" includes definite and possible CHD death and "other" and "unknown" cardiovascular death.

[4] "CHD death (corrected)" includes definite and possible CHD death.

[5] "Total MI" includes clinical MI and definite silent MI.

[6] "Coronary disease" includes clinical MI, definite silent MI, possible silent MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

[7] Excludes four cases with borderline malignancy.

[8] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.

[9] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

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

Data as of: February 28, 2001

Outcomes	Race/Ethnicity: American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	131	527	2739	1538	22030	383
Mean follow-up (months)	47.7	45.5	48.1	47.3	48.9	44.9
Cardiovascular						
CHD[1]	1 (0.19%)	4 (0.20%)	44 (0.40%)	13 (0.21%)	349 (0.39%)	6 (0.42%)
CHD (corrected)[2]	1 (0.19%)	4 (0.20%)	38 (0.35%)	13 (0.21%)	319 (0.36%)	6 (0.42%)
CHD death[3]	1 (0.19%)	2 (0.10%)	22 (0.20%)	3 (0.05%)	98 (0.11%)	2 (0.14%)
CHD death (corrected)[4]	1 (0.19%)	2 (0.10%)	16 (0.15%)	3 (0.05%)	64 (0.07%)	2 (0.14%)
Total MI[5]	0 (0.00%)	3 (0.15%)	27 (0.25%)	10 (0.16%)	276 (0.31%)	5 (0.35%)
Clinical MI	0 (0.00%)	3 (0.15%)	26 (0.24%)	10 (0.16%)	268 (0.30%)	5 (0.35%)
Definite Silent MI	0 (0.00%)	0 (0.00%)	1 (0.01%)	0 (0.00%)	17 (0.02%)	1 (0.07%)
Possible Silent MI	0 (0.00%)	1 (0.05%)	8 (0.07%)	3 (0.05%)	58 (0.06%)	1 (0.07%)
Angina	4 (0.77%)	8 (0.40%)	53 (0.48%)	26 (0.43%)	446 (0.50%)	5 (0.35%)
CABG/PTCA	2 (0.38%)	4 (0.20%)	41 (0.37%)	20 (0.33%)	428 (0.48%)	6 (0.42%)
Carotid artery disease	1 (0.19%)	1 (0.05%)	6 (0.05%)	0 (0.00%)	101 (0.11%)	0 (0.00%)
Congestive heart failure	2 (0.38%)	2 (0.10%)	43 (0.39%)	6 (0.10%)	230 (0.26%)	3 (0.21%)
Stroke	2 (0.38%)	6 (0.30%)	38 (0.35%)	10 (0.16%)	226 (0.25%)	4 (0.28%)
Non-disabling stroke	1 (0.19%)	4 (0.20%)	26 (0.24%)	8 (0.13%)	133 (0.15%)	2 (0.14%)
Fatal/disabling stroke	1 (0.19%)	1 (0.05%)	9 (0.08%)	1 (0.02%)	54 (0.06%)	1 (0.07%)
Unknown status from stroke	0 (0.00%)	1 (0.05%)	3 (0.03%)	1 (0.02%)	39 (0.04%)	1 (0.07%)
PVD	1 (0.19%)	0 (0.00%)	8 (0.07%)	2 (0.03%)	68 (0.08%)	0 (0.00%)
DVT	1 (0.19%)	1 (0.05%)	16 (0.15%)	3 (0.05%)	152 (0.17%)	0 (0.00%)
PE	2 (0.38%)	1 (0.05%)	8 (0.07%)	1 (0.02%)	90 (0.10%)	0 (0.00%)
CHD[1]/Possible Silent MI	1 (0.19%)	5 (0.25%)	49 (0.45%)	16 (0.26%)	400 (0.45%)	7 (0.49%)
Coronary disease[6]	6 (1.15%)	14 (0.70%)	130 (1.18%)	45 (0.74%)	970 (1.08%)	14 (0.98%)
DVT/PE	3 (0.58%)	1 (0.05%)	20 (0.18%)	3 (0.05%)	201 (0.22%)	0 (0.00%)
Total CVD	12 (2.30%)	22 (1.10%)	182 (1.66%)	57 (0.94%)	1430 (1.59%)	18 (1.26%)
Cancer						
Breast cancer[7]	0 (0.00%)	8 (0.40%)	27 (0.25%)	14 (0.23%)	329 (0.37%)	1 (0.07%)
Invasive breast cancer	0 (0.00%)	7 (0.35%)	23 (0.21%)	8 (0.13%)	259 (0.29%)	1 (0.07%)
Non-invasive breast cancer	0 (0.00%)	1 (0.05%)	4 (0.04%)	6 (0.10%)	73 (0.08%)	0 (0.00%)
Ovary cancer	0 (0.00%)	0 (0.00%)	2 (0.02%)	0 (0.00%)	38 (0.04%)	0 (0.00%)
Endometrial cancer[8]	1 (0.46%)	0 (0.00%)	0 (0.00%)	1 (0.03%)	29 (0.05%)	0 (0.00%)
Colorectal cancer	0 (0.00%)	5 (0.25%)	17 (0.15%)	9 (0.15%)	119 (0.13%)	2 (0.14%)
Other cancer[9]	3 (0.58%)	11 (0.55%)	41 (0.37%)	13 (0.21%)	437 (0.49%)	7 (0.49%)
Total cancer	4 (0.77%)	24 (1.20%)	85 (0.77%)	36 (0.59%)	935 (1.04%)	10 (0.70%)
Fractures						
Hip fracture	0 (0.00%)	1 (0.05%)	3 (0.03%)	2 (0.03%)	107 (0.12%)	0 (0.00%)
Vertebral fracture	0 (0.00%)	2 (0.10%)	1 (0.01%)	0 (0.00%)	112 (0.12%)	0 (0.00%)
Other fracture[9]	7 (1.34%)	23 (1.15%)	85 (0.77%)	60 (0.99%)	1452 (1.62%)	16 (1.12%)
Total fracture	7 (1.34%)	25 (1.25%)	89 (0.81%)	61 (1.01%)	1624 (1.81%)	16 (1.12%)
Deaths						
Cardiovascular deaths	1 (0.19%)	3 (0.15%)	30 (0.27%)	3 (0.05%)	131 (0.15%)	3 (0.21%)
Cancer deaths	1 (0.19%)	10 (0.50%)	19 (0.17%)	3 (0.05%)	194 (0.22%)	3 (0.21%)
Deaths: other known cause	2 (0.38%)	1 (0.05%)	6 (0.05%)	0 (0.00%)	57 (0.06%)	0 (0.00%)
Deaths: unknown cause	1 (0.19%)	0 (0.00%)	5 (0.05%)	1 (0.02%)	23 (0.03%)	0 (0.00%)
Deaths: not yet adjudicated	0 (0.00%)	1 (0.05%)	7 (0.06%)	1 (0.02%)	32 (0.04%)	2 (0.14%)
Total death	5 (0.96%)	15 (0.75%)	67 (0.61%)	8 (0.13%)	437 (0.49%)	8 (0.56%)

[1] "CHD" includes clinical MI, definite silent MI, and CHD death.
[2] "CHD (corrected)" includes clinical MI, evolving Q-wave MI, and CHD death (corrected), see also p2-4.
[3] "CHD death" includes definite and possible CHD death and "other" and "unknown" cardiovascular death.
[4] "CHD death (corrected)" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and definite silent MI.
[6] "Coronary disease" includes clinical MI, definite silent MI, possible silent MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[7] Excludes four cases with borderline malignancy.
[8] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[9] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

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

Data as of: February 28, 2001

Outcomes	Without Uterus		With Uterus	
Number randomized	10739		16609	
Mean follow-up (months)	48.7		48.6	
Cardiovascular				
CHD[1]	180	(0.41%)	237	(0.35%)
CHD (corrected)[2]	162	(0.37%)	219	(0.33%)
CHD death[3]	61	(0.14%)	67	(0.10%)
CHD death (corrected)[4]	43	(0.10%)	45	(0.07%)
Total MI[5]	132	(0.30%)	189	(0.28%)
Clinical MI	127	(0.29%)	185	(0.28%)
Definite Silent MI	8	(0.02%)	11	(0.02%)
Possible Silent MI	25	(0.06%)	46	(0.07%)
Angina	293	(0.67%)	249	(0.37%)
CABG/PTCA	246	(0.56%)	255	(0.38%)
Carotid artery disease	55	(0.13%)	54	(0.08%)
Congestive heart failure	161	(0.37%)	125	(0.19%)
Stroke	133	(0.31%)	153	(0.23%)
Non-disabling stroke	84	(0.19%)	90	(0.13%)
Fatal/disabling stroke	26	(0.06%)	41	(0.06%)
Unknown status from stroke	23	(0.05%)	22	(0.03%)
PVD	38	(0.09%)	41	(0.06%)
DVT	54	(0.12%)	119	(0.18%)
PE	30	(0.07%)	72	(0.11%)
CHD[1]/Possible Silent MI	200	(0.46%)	278	(0.41%)
Coronary disease[6]	580	(1.33%)	599	(0.89%)
DVT/PE	71	(0.16%)	157	(0.23%)
Total CVD	808	(1.86%)	913	(1.36%)
Cancer				
Breast cancer[7]	128	(0.29%)	251	(0.37%)
Invasive breast cancer	96	(0.22%)	202	(0.30%)
Non-invasive breast cancer	33	(0.08%)	51	(0.08%)
Ovary cancer	12	(0.03%)	28	(0.04%)
Endometrial cancer	0	(0.00%)	31	(0.05%)
Colorectal cancer	75	(0.17%)	77	(0.11%)
Other cancer[8]	195	(0.45%)	317	(0.47%)
Total cancer	406	(0.93%)	688	(1.02%)
Fractures				
Hip fracture	39	(0.09%)	74	(0.11%)
Vertebral fracture	41	(0.09%)	74	(0.11%)
Other fracture[8]	642	(1.47%)	1001	(1.49%)
Total fracture	704	(1.62%)	1118	(1.66%)
Deaths				
Cardiovascular deaths	78	(0.18%)	93	(0.14%)
Cancer deaths	103	(0.24%)	127	(0.19%)
Deaths: other known cause	28	(0.06%)	38	(0.06%)
Deaths: unknown cause	18	(0.04%)	12	(0.02%)
Deaths: not yet adjudicated	21	(0.05%)	22	(0.03%)
Total death	248	(0.57%)	292	(0.43%)

[1] "CHD" includes clinical MI, definite silent MI, and CHD death.
[2] "CHD (corrected)" includes clinical MI, evolving Q-wave MI, and CHD death (corrected), see also p2-4.
[3] "CHD death" includes definite and possible CHD death and "other" and "unknown" cardiovascular death.
[4] "CHD death (corrected)" includes definite and possible CHD death.
[5] "Total MI" includes clinical MI and definite silent MI.
[6] "Coronary disease" includes clinical MI, definite silent MI, possible silent MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[7] Excludes four cases with borderline malignancy.
[8] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer and fractures indicated as pathological.

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

Data as of: February 28, 2001

	Without Uterus		With Uterus	
Number randomized	10739		16609	
Mean follow-up (months)	48.7		48.6	
Stroke Diagnosis				
Subarachoid hemorrhage	8	6.0%	9	5.9%
Intracerebral hemorrhage	15	11.3%	20	13.1%
Other intracranial hemorrhage	2	1.5%	0	0.0%
Occlusion of cerebral arteries with infarction	74	55.6%	91	59.5%
Acute cerebrovascular disease	28	21.1%	27	17.6%
Central nervous system complications	6	4.5%	6	3.9%
Total	133	100.0%	153	100.0%

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

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

Data as of: February 28, 2001

	Without Uterus		With Uterus	
Number randomized	10739		16609	
Glasgow scale				
Good recovery	45	33.8%	45	29.4%
Moderately disabled	39	29.3%	45	29.4%
Severely disabled	11	8.3%	21	13.7%
Vegetative survival	0	0.0%	4	2.6%
Death or death within 1 month	15	11.3%	16	10.5%
Unable to categorize stroke	8	6.0%	7	4.6%
Not yet categorized	15	11.3%	15	9.8%
Total	133	100.0%	153	100.0%

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

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

Data as of: February 28, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	27348	3426	5408	12364	6150
Mean follow-up (months)	48.6	53.9	50.6	47.6	46.0
Hospitalizations					
Ever	8309 (7.50%)	753 (4.89%)	1293 (5.67%)	3855 (7.86%)	2408 (10.21%)
Two or more	3370 (3.04%)	272 (1.77%)	489 (2.14%)	1553 (3.17%)	1056 (4.48%)
Other					
Diabetes (treated)	1089 (1.04%)	149 (1.01%)	218 (1.01%)	486 (1.05%)	236 (1.06%)
Gallbladder disease[1]	1121 (1.21%)	153 (1.15%)	246 (1.26%)	521 (1.28%)	201 (1.05%)
Hysterectomy	343 (0.51%)	29 (0.32%)	59 (0.40%)	171 (0.57%)	84 (0.62%)
Glaucoma	1470 (1.38%)	124 (0.82%)	230 (1.03%)	709 (1.51%)	407 (1.86%)
Osteoporosis	2885 (2.75%)	175 (1.16%)	398 (1.80%)	1404 (3.02%)	908 (4.27%)
Osteoarthritis[2]	2563 (3.80%)	312 (2.76%)	504 (3.25%)	1170 (4.07%)	577 (4.86%)
Rheumatoid arthritis	889 (0.84%)	117 (0.79%)	199 (0.91%)	368 (0.79%)	205 (0.92%)
Intestinal polyps	1685 (1.63%)	157 (1.05%)	267 (1.22%)	883 (1.94%)	378 (1.81%)
Lupus	154 (0.14%)	21 (0.14%)	31 (0.14%)	75 (0.15%)	27 (0.11%)
Kidney Stones[2]	320 (0.39%)	37 (0.35%)	61 (0.37%)	148 (0.40%)	74 (0.42%)
Cataracts[2]	4266 (5.91%)	182 (1.70%)	548 (3.36%)	2261 (6.88%)	1275 (10.39%)
Pills for hypertension	3818 (4.85%)	424 (3.41%)	733 (4.17%)	1709 (5.03%)	952 (6.44%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African Am	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	131	527	2739	1538	22030	383
Mean follow-up (months)	47.7	45.5	48.1	47.3	48.9	44.9
Hospitalizations						
Ever	42 (8.07%)	96 (4.80%)	857 (7.81%)	354 (5.84%)	6869 (7.65%)	91 (6.36%)
Two or more	20 (3.84%)	32 (1.60%)	362 (3.30%)	119 (1.96%)	2809 (3.13%)	28 (1.96%)
Other						
Diabetes (treated)	9 (2.01%)	24 (1.32%)	194 (2.02%)	104 (1.86%)	744 (0.87%)	14 (1.05%)
Gallbladder disease[1]	8 (2.02%)	16 (0.88%)	99 (1.00%)	61 (1.35%)	923 (1.24%)	14 (1.19%)
Hysterectomy	1 (0.46%)	0 (0.00%)	15 (0.34%)	13 (0.37%)	310 (0.55%)	4 (0.46%)
Glaucoma	6 (1.23%)	30 (1.56%)	193 (1.90%)	87 (1.48%)	1133 (1.31%)	21 (1.57%)
Osteoporosis	14 (2.85%)	66 (3.43%)	129 (1.22%)	133 (2.36%)	2496 (2.93%)	47 (3.47%)
Osteoarthritis[2]	17 (4.93%)	49 (3.52%)	271 (4.15%)	183 (4.43%)	1997 (3.69%)	46 (5.05%)
Rheumatoid arthritis	6 (1.30%)	20 (1.05%)	157 (1.56%)	130 (2.26%)	564 (0.65%)	12 (1.30%)
Intestinal polyps	6 (1.24%)	25 (1.37%)	164 (1.60%)	83 (1.43%)	1396 (1.67%)	11 (1.24%)
Lupus	0 (0.00%)	3 (0.15%)	17 (0.16%)	10 (0.17%)	124 (0.14%)	0 (0.00%)
Kidney Stones[2]	2 (0.55%)	11 (0.73%)	33 (0.41%)	31 (0.70%)	242 (0.37%)	1 (0.09%)
Cataracts[2]	21 (6.01%)	70 (5.28%)	378 (5.31%)	223 (5.18%)	3526 (6.07%)	48 (5.09%)
Pills for hypertension	24 (6.55%)	70 (5.02%)	374 (6.89%)	238 (5.24%)	3065 (4.64%)	47 (6.55%)

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

Table 2.18
Sensitivity of HRT Study Power to Adherence and Incidence Rate Assumptions[1]

Outcome	Year	Intervention Effect[2] (%)	Percentage of Cases[2]				Power				
			Intervention		Control		ERT vs. Placebo		PERT vs. Placebo		Combined HRT vs. Placebo
			Design	Revised[3]	Design	Revised[3]	Design[4]	Revised Adherence & Incidence Rates[5]	Design[4]	Revised Adherence & Incidence Rates[5]	
CHD	2001	17	2.71	2.01	3.26	2.41	46	32	54	41	63
		21	2.60	1.93	3.26	2.40	62	44	70	56	79
		24	2.49	1.84	3.25	2.39	76	57	84	70	91
	2004	17	4.16	3.50	5.03	4.15	64	47	73	59	82
		21	3.97	3.35	5.02	4.13	81	63	88	76	94
		24	3.79	3.20	5.01	4.11	92	77	96	88	99

[1] Analysis has not been updated from that of February 29, 2000.

[2] Intervention Effects and Percentage of Cases are shown for original Design assumptions. The other adherence patterns would produce greater incidence rates in Intervention women and a corresponding reduction in the estimated treatment effect.

[3] Revised incidence rates reflect greater healthy volunteer effects (67%, 50%, 37%) in years 1-3.

[4] Combined Drop-out and loss to follow-up rates of 7.9% in year 1, 4.9% per year thereafter; Drop-in rate of 1.5% per year.

[5] Combined Drop-out and loss to follow-up rates of 9.8% in year 1, 8.4% in year 2, and 6.9% per year thereafter; Drop-in rate of 2.5% per year; Average follow-up is 8.5 years.

Table 2.19
Baseline Characteristics of HRT Participants Enrolled in WHIMS

Data as of: February 28, 2001

	HRT Participants			
	Without Uterus		With Uterus	
Total HRT Participants	10739		16609	
Eligible HRT Population	4943		7302	
Enrolled in WHIMS	2970		4556	
% Enrolled of Total HRT		28%		27%
% Enrolled of Eligible		60%		62%
WHIMS Participants	**(N = 2970)**		**(N = 4556)**	
Age at Screening				
< 70	1423	(47.9%)	2293	(50.3%)
70-74	1062	(35.8%)	1540	(33.8%)
75+	485	(16.3%)	723	(15.9%)
Education				
Missing	10	(0.3%)	21	(0.5%)
0-8 years	67	(2.3%)	68	(1.5%)
Some high school	213	(7.2%)	231	(5.1%)
High school diploma/GED	705	(23.7%)	945	(20.7%)
School after high school	1246	(42.0%)	1773	(38.9%)
College degree or higher	729	(24.5%)	1518	(33.3%)
Ethnicity				
White	2457	(82.7%)	4064	(89.2%)
Black	326	(11.0%)	216	(4.7%)
Hispanic	84	(2.8%)	105	(2.3%)
American Indian	16	(0.5%)	10	(0.2%)
Asian/Pacific Islander	37	(1.2%)	91	(2.0%)
Other/Unspecified	50	(1.7%)	70	(1.5%)
Family Income				
Missing	182	(6.1%)	275	(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%)	930	(20.4%)
$50,000 - $74,999	324	(10.9%)	660	(14.5%)
$75,000 +	176	(5.9%)	380	(8.3%)

Table 2.20
Cognitive Function Screening Scores for HRT Participants Enrolled in WHIMS

Data as of: February 28, 2001

	HRT Participants			
	Without Uterus		With Uterus	
	N	F39 Score	N	F39 Score
Baseline				
WHIMS	2939		4514	
25th Percentile		92		94
Median		96		97
Non-WHIMS	633		888	
25th Percentile		90		92
Median		95		96
Annual Visit 1				
WHIMS	2793		4311	
25th Percentile		94		95
Median		97		97
Non-WHIMS	1054		1605	
25th Percentile		92		93
Median		95		96
Annual Visit 2				
WHIMS	2607		4108	
25th Percentile		94		95
Median		97		97
Annual Visit 3				
WHIMS	2119		3294	
25th Percentile		94		95
Median		97		98
Non-WHIMS	1642		2411	
25th Percentile		92		93
Median		96		96
Annual Visit 4				
WHIMS	595		953	
25th Percentile		95		96
Median		97		98

Table 2.21
Incidence of Probable Dementia in HRT Participants Enrolled in WHIMS

Data as of: February 28, 2001

	Without Uterus	With Uterus	All
Baseline			
F39 Completed	2939	4514	7453
Positive Screen	17	11	28
Diagnosis[1]			
PD	2	1	3
MCI	5	4	9
ND	10	6	16
Unknown	0	0	0
AV1			
F39 Completed	2793	4311	7104
Positive Screen	79	86	165
Diagnosis[1]			
PD	7	10	17
MCI	20	22	42
ND	39	44	83
Unknown	13	10	23
Deceased	0	1	1
AV2			
F39 Completed	2607	4108	6715
Positive Screen	114	120	234
Diagnosis[1]			
PD	8	14	22
MCI	29	36	65
ND	48	51	99
Unknown	29	19	48
AV3			
F39 Completed	2119	3294	5413
Positive Screen	74	74	148
Diagnosis[1]			
PD	5	5	10
MCI	12	18	30
ND	19	18	37
Unknown	38	33	71
AV4			
F39 Completed	595	953	1548
Positive Screen	32	22	54
Diagnosis[1]			
PD	2	3	5
MCI	5	2	7
ND	4	1	5
Unknown	21	16	37

[1] Diagnoses: PD – Probable Dementia
MCI – Minor Cognitive Impairment
ND – No Dementia
Unknown -- Refused phase 2/3 or materials are under review

Table 2.22
Baseline Characteristics of HRT Participants Enrolled in WHI-SE

Data as of: February 28, 2001

	HRT Participants			
	Without Uterus		With Uterus	
Total HRT Participants	10739		16609	
Eligible HRT Population	6864		10177	
Enrolled in WHI-SE	442		685	
% Enrolled of Total HRT		4.12%		4.12%
% Enrolled of Eligible		6.44%		6.73%
WHI-SE Participants	**(N = 442)**		**(N = 685)**	
Age at Screening				
< 70	295	(66.7%)	471	(68.8%)
70-74	107	(24.2%)	156	(22.8%)
75+	40	(9.0%)	58	(8.5%)
Education				
Missing	2	(0.5%)	4	(0.6%)
0-8 years	6	(1.4%)	6	(0.9%)
Some high school	17	(3.8%)	26	(3.8%)
High school diploma/GED	114	(25.8%)	160	(23.4%)
School after high school	176	(39.8%)	232	(33.9%)
College degree or higher	127	(28.7%)	257	(37.5%)
Ethnicity				
White	395	(89.4%)	648	(94.6%)
Black	32	(7.2%)	18	(2.6%)
Hispanic	5	(1.1%)	11	(1.6%)
American Indian	3	(0.7%)	0	(0.0%)
Asian/Pacific Islander	3	(0.7%)	2	(0.3%)
Other/Unspecified	4	(0.9%)	6	(0.9%)
Family Income				
Missing	27	(6.1%)	31	(4.5%)
< $10,000	23	(5.2%)	24	(3.5%)
$10,000 - $19,999	103	(23.3%)	99	(14.5%)
$20,000 - $34,999	127	(28.7%)	220	(32.1%)
$35,000 - $49,999	95	(21.5%)	145	(21.2%)
$50,000 - $74,999	41	(9.3%)	108	(15.8%)
$75,000 +	26	(5.9%)	58	(8.5%)

Table 2.23
Prevalence of WHI-SE Outcomes in HRT Participants at Baseline

Data as of: February 28, 2001

	Without Uterus	With Uterus	All
Age-Related Maculopathy			
Left eye	42	58	100
Right eye	43	50	93
Both eyes	24	30	54
Either eye	61	78	139
Diabetic Retinopathy			
Left eye	10	16	26
Right eye	13	16	29
Both eyes	10	9	19
Either eye	13	23	36

3. DM Component

3.1 Recruitment

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

3.2 Adherence

Nutrient intake data for adherence monitoring are presented in *Tables 3.2-3.4* 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 8.5% at AV-6. The decrease in C-I continues to be of concern, although the AV-6 value must be interpreted in view of the early cohort effect. That is, women randomized early in WHI received higher fat gram goals than the majority of WHI participants who were randomized after implementation of reduced fat gram goals. At AV-2 through AV-5, the C-I difference is slightly larger for women who have reduced fat gram goals than the original goals (*Table 3.3*). Overall, 81% of DM Intervention participants have the reduced fat gram goals. The C-I value in minority women is roughly 1-2 percentage points below that for the full sample. This report presents nutrient intake comparisons for each racial/ethnic group separately (*Table 3.4*). The differences between intervention and control arms in energy from fat intake follows a generally similar pattern in all of these groups, but the small sample sizes available at some time points and for some groups make these estimates unstable. In addition, 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 roughly 2 to 3 percentage points lower than the design assumptions. Refer to *Sections 3.7* and *3.8* for a discussion of the impact of the C-I on study power and of the advanced adherence initiatives that are underway. For fruit and vegetable intake, the mean difference between the arms of the trial remains about 1.4 more servings per day for Intervention vs. Control women. Compared to Control women, Intervention women consumed almost 1 more serving per day of grains at AV-1, decreasing to one-half serving at AV-6.

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 3.5*). The only participant characteristic that is consistently associated with a lower C-I difference was being older than 60-69 ($p<0.01$) or being younger (aged 50-54, $p<0.05$). 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 higher (i.e., better) C-I values. Body weight data are presented in *Table 3.6*. The difference in body weight between Control and Intervention participants at AV-1 was almost 2 kg, with a return to 0 kg at AV-6. Participants with revised fat gram goals have maintained a C-I difference of 0.5 kg at AV-5. 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 a considerable amount (4-6 kg), producing marginally significant differences. Hispanic women in the Intervention appear be less successful in weight control than the control arm, though the magnitude of this difference is generally small. No clear trend in weight changes is seen for Black/African Americans. Some of these results are based on sparse data.

Table 3.7 gives reasons for stopping DM categorized by general type. The major reasons given by participants were family responsibilities (15%), demands of work (13%), and issues of interest in the study (11%). Travel to CC was cited as a barrier by almost 7% of participants. Reasons for stopping DM specifically related to the Intervention were rarely mentioned, with only 2% of participants indicating that they do not like attending classes. Twenty-two percent of women indicated that there were other reasons for stopping DM that were not listed on the form and 5% declined to provide a reason.

3.3 Blood Specimen and Bone Density Analyses

Tables 3.8-3.9 present the results of blood specimens analyses from a small (4.3%) cohort of DM women selected randomly at baseline for these prospective analyses. This subsample incorporated oversampling of minorities. The results shown here are weighted to reflect the overall WHI distribution of race/ethnicity. Differences between baseline and AV-1 are mostly modest, with reductions of approximately 5% in LDL cholesterol and about 3% in total cholesterol for Intervention and Control women combined. There are no substantial changes in HDL-cholesterol or triglycerides in the combined groups. Blood specimen analyses are presented by race/ethnicity group and appear to be consistent with the dietary data. For example, LDL cholesterol reductions averaged 5% in white women but are slightly lower among minority groups (2% in Hispanic/Latinas and 4% in Blacks/African Americans). Note that baseline and AV-1 specimens were batched together for concurrent analyses by Medical Research Labs.

Tables 3.10-3.11 present blinded bone mineral density data from the DM bone density subsample. Changes from baseline to AV-1 or AV-3 are interesting with increases in mean bone mineral density in the whole body scan as well as the spine and hip scan. There were no consistent patterns by race/ethnicity group. An increase in BMD was not expected from this intervention. Possible reasons for this observation include use of calcium supplements and/or HRT, selection of health-conscious women, incomplete BMD data (12.6% missing at AV-3) or measurement issues.

3.4 Adherence to Follow-up

Table 3.12 summarizes adherence to follow-up contacts by treatment arm and contact type. The goal for collection of outcome data specified by the Steering Committee was 98% at AV-1, with a decline of no more than ½% per year. WHI follow-up contact adherence rates are holding at about 4 percentage points below these rates for years 1 through 6, with no substantial difference by arm.

3.5 Vital Status

Table 3.13 presents data on the vital status and the participation status of participants in the DM trial. A detailed description of CCC and clinic activities to actively locate participants who do not complete their periodic visits is given in *Section 5 – Outcomes.* 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 3.2% of the DM participants are lost-to-follow-up or have stopped follow-up (an increase of 0.2% compared to the Fall 2000 report), and 1.7% 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 4.2 years, suggesting that approximately 12.0% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

3.6 Outcomes

Table 3.14 contains counts of the number of locally verified major WHI outcomes for DM participants by race/ethnicity and age. Approximately 6% 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. The category CHD death (corrected) and CHD (corrected) do not include death from "other cardiovascular" and "unknown cardiovascular" causes. These corrected categories are the ones that we plan to use for further reporting. The (uncorrected) CHD and CHD death categories are provided for comparison with previous reports. See also *Section 2.8 HRT-Outcomes*. Compared to the design assumptions, we have observed almost 100% of the expected number of breast cancers, 70% of the expected number of colorectal cancers, about 65% of the expected number of CHD events, and about 30% of the expected number hip fractures.

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

3.7 Power Considerations

The power under the design assumptions for adherence and overall incidence rates and values derived from the observed data through February 28, 2001 are shown in *Table 3.16*. While the observed Comparison - Intervention (C-I) differences represent a substantial achievement, they fall short of the assumptions of 13% C-I at AV-1 and subsequent decline of 0.25% per year. The lower than anticipated value of C-I at AV-1 will reduce the overall power of the study, but the size of the impact depends considerably on the degree of adherence throughout the remaining years of follow-up. The power calculations shown in *Table 3.15* were calculated under two patterns of adherence assumptions. The first set is based on existing C-I values of 11% at AV-1, and 10% at AV-2 with a projected decline to 9% by year 10. The second scenario again starts at 11% but stays at 10% throughout the remaining follow-up. Using the final sample size and age distribution of DM participants and 8.5 years of follow-up on average, the study has about 63% power for breast cancer and 79% power for colorectal cancer under the first adherence assumptions. We could obtain 73%

power for breast cancer and 80% for colorectal cancer if the C-I values were 11% at AV-1 and 10% at all subsequent time points. These calculations suggest that this second adherence pattern is the level of performance we must aim to achieve. We note that the intervention effect modeling for design considerations was based on percent of energy from fat. Other changes associated with the low fat eating pattern (e.g., increases in fruits, vegetables, and grains) would likely improve the power as these changes may have additional, complementary prevention effects.

3.8 Issues

As noted above, the C-I difference is less than the design assumptions. The WHI investigators and staff have undertaken a number of activities addressing adherence. In summer 1999, the DM Intervention incorporated an Intensive Intervention Program (IIP) that consisted of interviews using motivational enhancement techniques. Nutritionists targeted "medium adherers," defined as women who are attending some sessions but not meeting their fat gram goal or not self-monitoring (about 40% of intervention women). This protocol was completed on March 30, 2001. A preliminary evaluation of the IIP among intervention participants indicated that these contacts had a positive effect on fat intake among medium adherers. Specifically, when examining change (increases) in fat intake from AV-1 to "now," participants who received IIP contact had an increase in fat intake that was 0.89 percentage points less (i.e., had less slippage) than intervention women who did not receive IIP ($p<0.05$).

Currently all intervention women are participating in a Targeted Message Campaign (TMC). The campaign began with a 2000 Fall/Winter Kickoff Newsletter to raise awareness and excitement. Starting in January 2001, participants receive a mailing introducing five themes to help them rediscover their intrinsic motivation(s) for participating in WHI. This first mailing is followed by a motivational enhancement phone call that supports participants in the process of identifying their primary motivation. Finally, based on information collected on the call, a second targeted mailing allows a woman to select an action consistent with her readiness to enhance her intervention adherence. This campaign will continue until the end of 2001.

Additional DM intervention boosters are under consideration by investigators. In particular, a newly assembled Dietary Modification Working Group has recommended use of tailored, food-based, feedback to facilitate dietary goal setting for participants. As proposed, the assessment would be performed using a specially designed assessment tool that focuses on usual fat-intake over past 2-4 weeks. After scanning, computerized algorithms would provide printed, individualized feedback on estimated grams of fat consumed (by foods) and food-specific behavioral change suggestions. The questionnaire would be administered in groups and the written feedback would be reinforced in group sessions, with individual follow-up of group non-attenders by phone or mail.

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

Data as of: February 28, 2001

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**48,837**			
50-54	6961	149%	14%	10
55-59	11044	118%	23%	20
60-69	22714	108%	47%	45
70-79	8118	70%	17%	25
Race/Ethnicity	**48,837**			
American Indian	203		<1%	
Asian	1105		2%	
Black	5262		11%	
Hispanic	1846		4%	
White	39763		81%	
Other/Unspecified	658		1%	

Table 3.2
Nutrient Intake Monitoring

Data as of: February 28, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	19542	38.8	5.0	29295	38.8	5.0	0.0	0.0	0.82
FFQ Year 1[3]	18092	25.2	7.5	26758	36.1	6.9	10.9	0.1	0.00
FFQ Year 2[4]	5910	26.3	7.6	8644	36.3	7.0	9.9	0.1	0.00
FFQ Year 3[5]	3061	27.5	7.9	4621	37.3	7.1	9.8	0.2	0.00
FFQ Year 4[6]	3212	28.1	8.1	5007	37.6	7.1	9.5	0.2	0.00
FFQ Year 5[7]	1935	28.4	8.2	2937	37.7	7.5	9.3	0.2	0.00
FFQ Year 6[8]	1120	28.9	8.1	1735	37.4	7.2	8.5	0.3	0.00
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	0.00
24 Hr Recall, Post-baseline	226	23.0	9.2	262	32.1	7.6	9.2	0.8	0.00
24 Hr Recall, Year 1	221	22.4	7.8	268	32.6	7.7	10.2	0.7	0.00
24 Hr Recall, Year 2	203	23.8	9.8	228	32.5	8.2	8.7	0.9	0.00
24 Hr Recall, Year 3	147	25.3	9.4	179	33.2	8.3	8.0	1.0	0.00
24 Hr Recall, Year 3 Cohort	651	24.7	8.5	957	33.0	7.6	8.3	0.4	0.00
24 Hr Recall, Year 4	82	25.5	8.6	96	32.8	8.8	7.3	1.3	0.00
24 Hr Recall, Year 5	26	26.7	9.2	51	31.7	8.5	5.0	2.1	0.03
Total Energy (kcal)									
FFQ Baseline	19542	1789	713	29295	1789	707	0	6.6	0.94
FFQ Year 1	18092	1474	534	26758	1585	642	111	5.8	0.00
FFQ Year 2	5910	1479	535	8644	1576	626	96	10.0	0.00
FFQ Year 3	3061	1477	529	4621	1571	642	94	14.0	0.00
FFQ Year 4	3212	1451	529	5007	1571	633	121	13.4	0.00
FFQ Year 5	1935	1481	540	2937	1583	640	102	17.6	0.00
FFQ Year 6	1120	1442	523	1735	1536	608	95	22.1	0.00
4DFR Baseline	892	1707	454	1351	1713	459	6	19.7	0.79
4DFR Year 1	805	1423	356	1171	1627	447	204	18.9	0.00
24 Hr Recall, Post-baseline	226	1520	418	262	1653	516	133	43.0	0.00
24 Hr Recall, Year 1	221	1482	418	268	1636	477	154	41.0	0.00
24 Hr Recall, Year 2	203	1449	427	228	1605	527	156	46.6	0.01
24 Hr Recall, Year 3	147	1469	435	179	1641	531	172	54.6	0.00
24 Hr Recall, Year 3 Cohort	651	1441	395	957	1605	495	164	23.2	0.00
24 Hr Recall, Year 4	82	1541	392	96	1543	455	2	64.3	0.79
24 Hr Recall, Year 5	26	1463	401	51	1555	553	93	122.3	0.72

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 4951 (27%) Intervention women had <=20% energy from fat at year 1.
[4] 1266 (21%) Intervention women had <=20% energy from fat at year 2.
[5] 546 (18%) Intervention women had <=20% energy from fat at year 3.
[6] 526 (16%) Intervention women had <=20% energy from fat at year 4.
[7] 317 (16%) Intervention women had <=20% energy from fat at year 5.
[8] 134 (12%) Intervention women had <=20% energy from fat at year 6.

Table 3.2 (continued)
Nutrient Intake Monitoring
Data as of: February 28, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Total Fat (g)									
FFQ Baseline	19542	77.9	35.3	29295	77.8	34.7	0.0	0.3	0.87
FFQ Year 1	18092	41.5	21.8	26758	64.5	31.8	23.0	0.3	0.00
FFQ Year 2	5910	43.4	22.3	8644	64.5	31.3	21.0	0.5	0.00
FFQ Year 3	3061	45.6	23.2	4621	66.0	32.4	20.4	0.7	0.00
FFQ Year 4	3212	45.7	23.3	5007	66.6	32.2	20.9	0.7	0.00
FFQ Year 5	1935	47.4	25.0	2937	67.2	33.0	19.9	0.9	0.00
FFQ Year 6	1120	46.3	22.0	1735	64.6	30.3	18.3	1.0	0.00
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	26.4	0.9	0.00
24 Hr Recall, Post-baseline	226	39.6	21.9	262	60.5	26.9	20.9	2.2	0.00
24 Hr Recall, Year 1	221	36.9	17.1	268	60.6	25.1	23.7	2.0	0.00
24 Hr Recall, Year 2	203	39.1	22.5	228	59.3	27.5	20.3	2.4	0.00
24 Hr Recall, Year 3	147	41.7	20.9	179	62.1	28.9	20.4	2.9	0.00
24 Hr Recall, Year 3 Cohort	651	39.9	18.9	957	60.4	26.0	20.5	1.2	0.00
24 Hr Recall, Year 4	82	43.2	17.5	96	57.7	25.3	14.5	3.3	0.00
24 Hr Recall, Year 5	26	43.5	19.2	51	56.6	25.6	13.0	5.7	0.08
Saturated Fat (g)									
FFQ Baseline	19542	27.4	13.4	29295	27.3	13.2	0.1	0.1	0.85
FFQ Year 1	18092	14.2	8.1	26758	22.5	11.9	8.4	0.1	0.00
FFQ Year 2	5910	14.8	8.2	8644	22.5	11.7	7.7	0.2	0.00
FFQ Year 3	3061	15.5	8.7	4621	23.0	12.2	7.5	0.3	0.00
FFQ Year 4	3212	15.5	8.6	5007	23.3	12.3	7.8	0.2	0.00
FFQ Year 5	1935	16.2	9.4	2937	23.8	12.8	7.5	0.3	0.00
FFQ Year 6	1120	15.7	8.0	1735	22.7	11.6	7.0	0.4	0.00
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	0.00
24 Hr Recall, Post-baseline	226	12.9	7.9	262	20.1	9.6	7.2	0.8	0.00
24 Hr Recall, Year 1	221	11.7	6.2	268	20.1	10.1	8.4	0.8	0.00
24 Hr Recall, Year 2	203	12.4	8.2	228	19.5	10.0	7.1	0.9	0.00
24 Hr Recall, Year 3	147	13.9	7.9	179	20.8	11.2	6.8	1.1	0.00
24 Hr Recall, Year 3 Cohort	651	12.4	6.9	957	19.8	9.4	7.4	0.4	0.00
24 Hr Recall, Year 4	82	14.0	6.6	96	19.3	10.6	5.4	1.4	0.00
24 Hr Recall, Year 5	26	13.7	6.9	51	19.9	10.3	6.2	2.2	0.02

(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

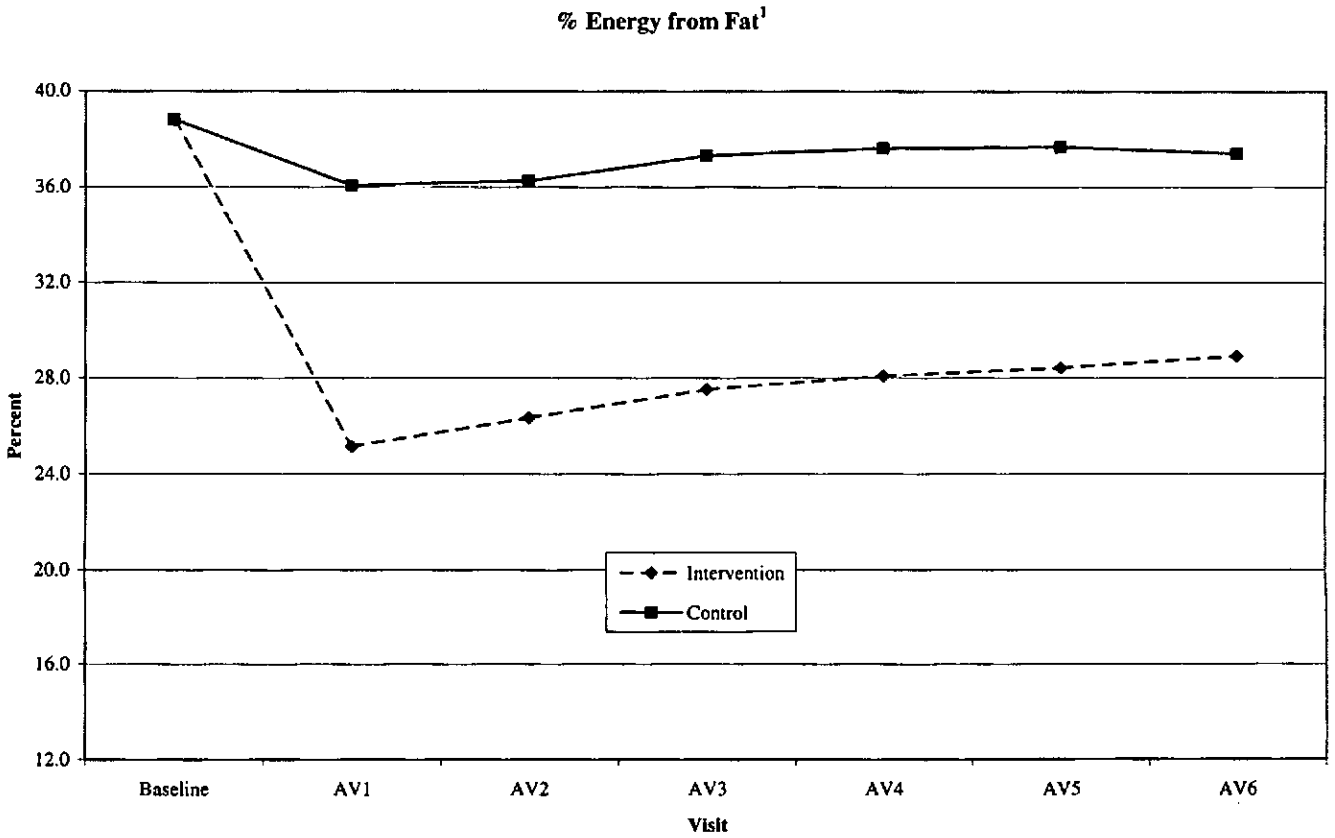
Data as of: February 28, 2001

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Polyunsaturated Fat (g)									
FFQ Baseline	19542	15.3	7.7	29295	15.3	7.6	0.0	0.1	0.78
FFQ Year 1	18092	7.9	4.4	26758	12.5	6.7	4.6	0.1	0.00
FFQ Year 2	5910	8.3	4.5	8644	12.4	6.5	4.1	0.1	0.00
FFQ Year 3	3061	8.8	4.7	4621	12.8	6.7	4.0	0.1	0.00
FFQ Year 4	3212	8.8	4.8	5007	12.9	6.7	4.0	0.1	0.00
FFQ Year 5	1935	9.1	5.1	2937	12.9	6.8	3.8	0.2	0.00
FFQ Year 6	1120	9.1	4.7	1735	12.4	6.3	3.4	0.2	0.00
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	0.00
24 Hr Recall, Post-baseline	226	8.3	5.0	262	12.6	7.3	4.3	0.6	0.00
24 Hr Recall, Year 1	221	7.8	4.4	268	12.4	6.3	4.7	0.5	0.00
24 Hr Recall, Year 2	203	8.4	5.7	228	12.4	7.7	4.0	0.7	0.00
24 Hr Recall, Year 3	147	8.5	5.2	179	12.9	6.9	4.4	0.7	0.00
24 Hr Recall, Year 3 Cohort	651	8.6	4.6	957	12.5	7.0	3.8	0.3	0.00
24 Hr Recall, Year 4	82	9.1	4.7	96	11.8	6.9	2.7	0.9	0.00
24 Hr Recall, Year 5	26	9.5	4.8	51	10.5	5.2	1.1	1.2	0.57
Fruits and Vegetables (servings)									
FFQ Baseline	19471	3.6	1.8	29217	3.6	1.8	0.0	0.0	0.69
FFQ Year 1	18011	5.1	2.3	26676	3.9	2.0	1.2	0.0	0.00
FFQ Year 2	5887	5.1	2.4	8612	3.9	2.0	1.2	0.0	0.00
FFQ Year 3	3054	5.2	2.5	4610	3.9	2.0	1.3	0.1	0.00
FFQ Year 4	3202	5.2	2.5	4997	3.8	2.0	1.4	0.0	0.00
FFQ Year 5	1916	5.2	2.4	2920	3.9	2.1	1.3	0.1	0.00
FFQ Year 6	1110	5.2	2.4	1722	3.8	2.0	1.4	0.1	0.00
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	19469	4.7	2.5	29215	4.8	2.5	0.0	0.0	0.43
FFQ Year 1	18007	5.1	2.7	26666	4.2	2.3	0.8	0.0	0.00
FFQ Year 2	5886	4.9	2.5	8606	4.1	2.2	0.8	0.0	0.00
FFQ Year 3	3053	4.7	2.5	4605	4.0	2.2	0.7	0.1	0.00
FFQ Year 4	3200	4.5	2.4	4987	3.9	2.2	0.6	0.1	0.00
FFQ Year 5	1916	4.4	2.3	2916	3.9	2.1	0.5	0.1	0.00
FFQ Year 6	1110	4.3	2.4	1722	3.8	2.1	0.5	0.1	0.00

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

Figure 3.1
Nutrient Intake: Intervention vs. Control

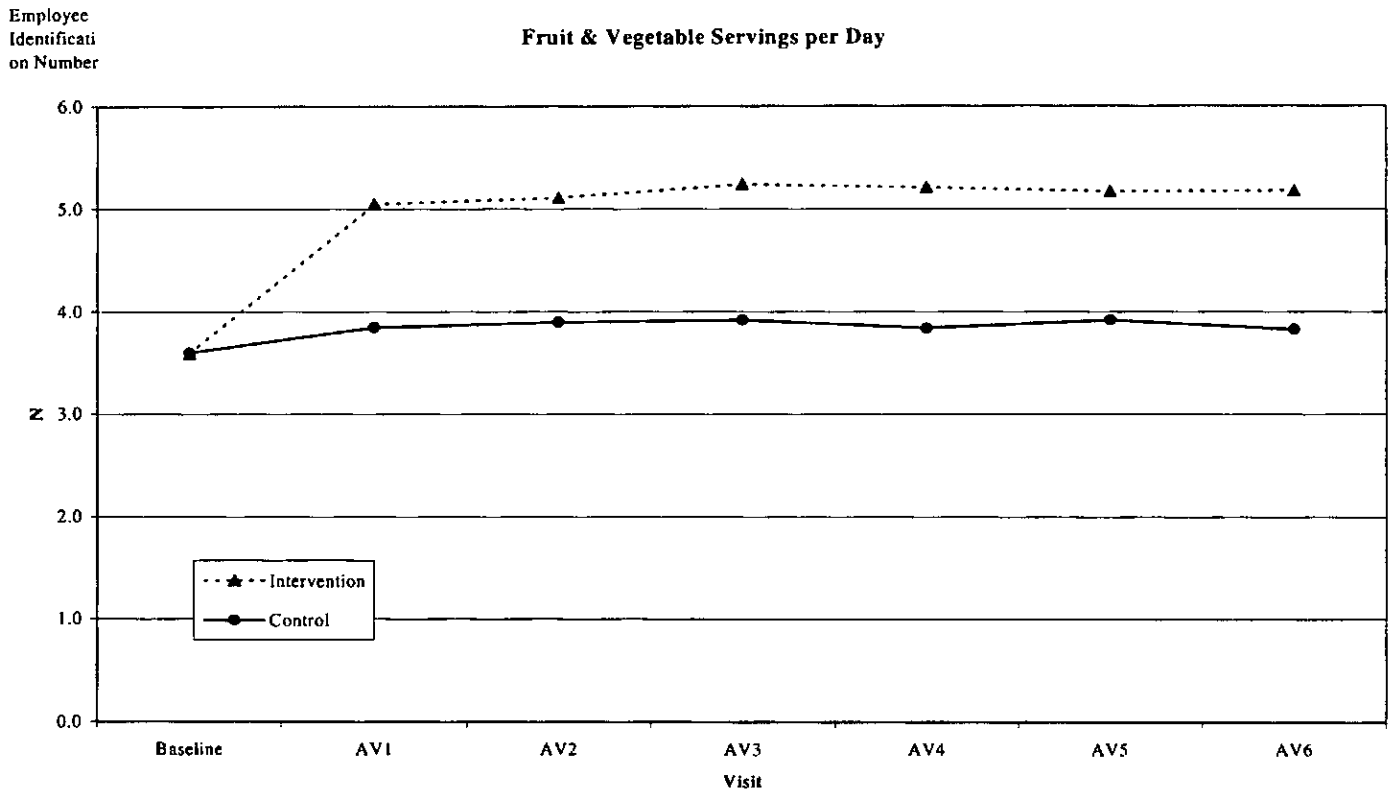
Data as of: February 28, 2001



[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: Intervention vs. Control

Data as of: February 28, 2001



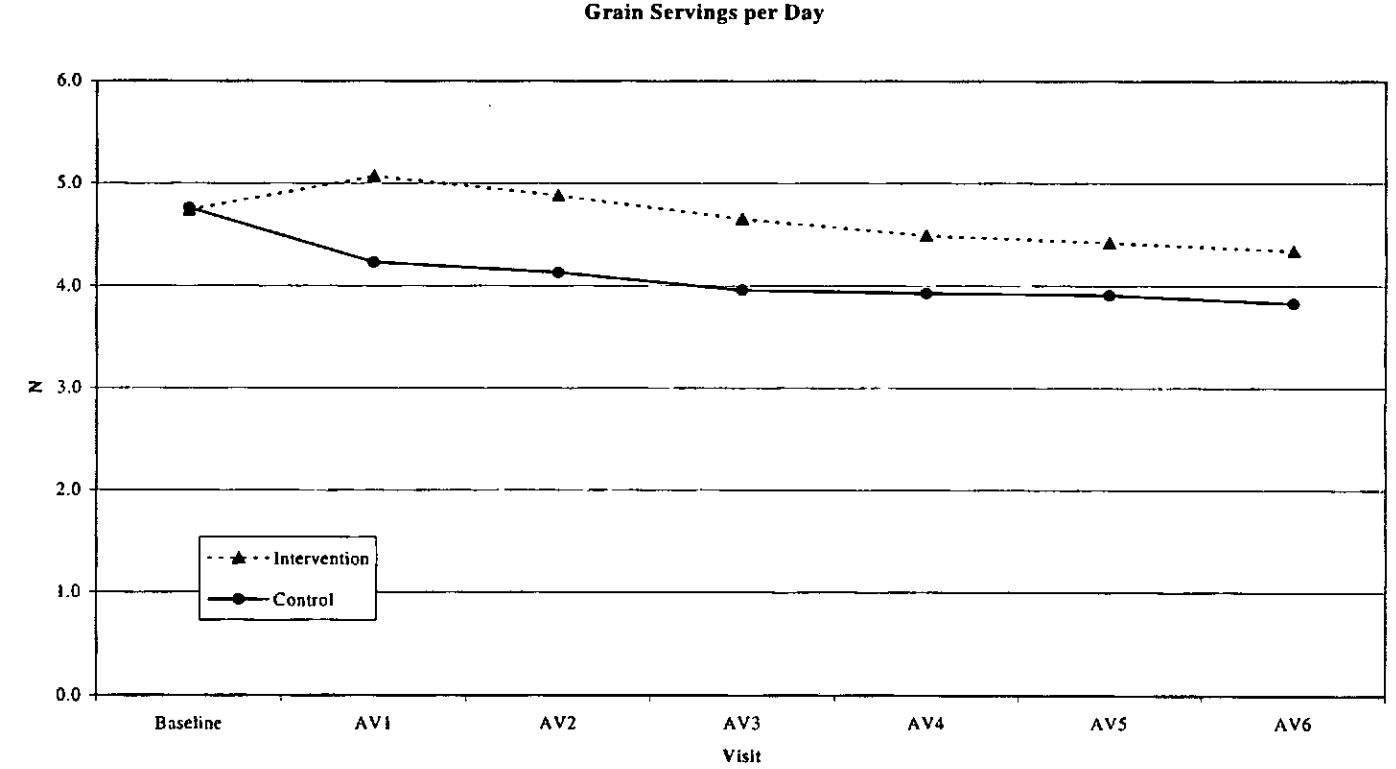


Table 3.3
Nutrient Intake Monitoring For Women With Revised Fat Gram Goals

Data as of: February 28, 2001

	Intervention[1]			Control[2]			Difference		
	N	Mean	SD	N	Mean	SD	Mean[3]	SE	p-value[4]
% Energy from Fat									
FFQ Baseline	15860	38.8	5.0	23754	38.8	5.0	0.0	0.1	0.49
FFQ Year 1	14665	25.3	7.6	21750	36.2	6.9	10.9	0.1	0.00
FFQ Year 2	4853	26.5	7.7	6984	36.6	7.0	10.1	0.1	0.00
FFQ Year 3	2643	27.8	8.0	4079	37.6	7.0	9.8	0.2	0.00
FFQ Year 4	2884	28.1	8.1	4526	37.8	7.1	9.7	0.2	0.00
FFQ Year 5	1479	28.4	8.4	2260	37.8	7.5	9.5	0.3	0.00
4DFR Baseline	691	32.4	6.5	1038	33.0	6.9	0.6	0.3	0.06
4DFR Year 1	622	21.6	7.5	892	33.1	6.9	11.5	0.4	0.00
24 Hr Recall, Post-baseline	186	23.4	9.4	205	32.1	7.7	8.7	0.9	0.00
24 Hr Recall, Year 1	172	22.1	7.8	200	32.7	7.6	10.6	0.8	0.00
24 Hr Recall, Year 2	166	23.5	9.4	167	32.4	8.2	8.9	1.0	0.00
24 Hr Recall, Year 3	98	24.8	9.7	117	32.2	8.2	7.4	1.2	0.00
24 Hr Recall, Year 3 Cohort	482	24.7	8.6	702	33.3	7.8	8.6	0.5	0.00
24 Hr Recall, Year 4	40	24.5	9.1	36	33.8	10.8	9.3	2.3	0.00
Total Energy (kcal)									
FFQ Baseline	15860	1780	701	23754	1786	706	7	7.2	0.47
FFQ Year 1	14665	1468	533	21750	1588	644	120	6.4	0.00
FFQ Year 2	4853	1470	537	6984	1577	629	107	11.1	0.00
FFQ Year 3	2643	1471	522	4079	1574	644	104	14.9	0.00
FFQ Year 4	2884	1444	530	4526	1574	636	131	14.2	0.00
FFQ Year 5	1479	1481	552	2260	1587	650	106	20.5	0.00
4DFR Baseline	691	1688	455	1038	1713	469	25	22.7	0.30
4DFR Year 1	622	1405	362	892	1621	447	216	21.6	0.00
24 Hr Recall, Post-baseline	186	1499	418	205	1640	524	141	48.3	0.00
24 Hr Recall, Year 1	172	1477	424	200	1654	489	177	47.9	0.00
24 Hr Recall, Year 2	166	1441	423	167	1583	502	142	50.9	0.04
24 Hr Recall, Year 3	98	1478	464	117	1595	545	117	69.8	0.12
24 Hr Recall, Year 3 Cohort	482	1430	394	702	1586	498	156	27.1	0.00
24 Hr Recall, Year 4	40	1553	388	36	1527	436	26	94.5	0.67
Total Fat (g)									
FFQ Baseline	15860	77.4	34.7	23754	77.6	34.6	0.2	0.4	0.62
FFQ Year 1	14665	41.6	22.0	21750	64.9	32.0	23.3	0.3	0.00
FFQ Year 2	4853	43.5	22.7	6984	65.0	31.6	21.6	0.5	0.00
FFQ Year 3	2643	45.7	23.0	4079	66.6	32.7	20.8	0.7	0.00
FFQ Year 4	2884	45.4	23.3	4526	66.9	32.5	21.6	0.7	0.00
FFQ Year 5	1479	47.4	25.8	2260	67.6	33.4	20.2	1.0	0.00
4DFR Baseline	691	61.6	23.4	1038	63.8	25.1	2.2	1.2	0.12
4DFR Year 1	622	33.6	14.9	892	60.5	23.9	27.0	1.1	0.00
24 Hr Recall, Post-baseline	186	39.7	22.1	205	60.2	27.7	20.5	2.5	0.00
24 Hr Recall, Year 1	172	36.1	16.3	200	61.5	25.4	25.4	2.3	0.00
24 Hr Recall, Year 2	166	38.5	22.2	167	58.3	26.5	19.8	2.7	0.00
24 Hr Recall, Year 3	98	41.4	22.3	117	58.5	28.3	17.2	3.5	0.00
24 Hr Recall, Year 3 Cohort	482	39.6	18.8	702	60.3	26.5	20.7	1.4	0.00
24 Hr Recall, Year 4	40	41.9	18.0	36	58.4	25.6	16.5	5.0	0.01

(continues)

[1] Intervention group is defined as women randomized to Intervention after 6/15/95 that have revised fat gram goals.
[2] Control group is defined as women randomized to Control after 6/15/95.
[3] Absolute difference.
[4] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.3 (continued)
Nutrient Intake Monitoring For Women With Revised Fat Gram Goals

Data as of: February 28, 2001

	Intervention[1]			Control[2]			Difference		
	N	Mean	SD	N	Mean	SD	Mean[3]	SE	p-value[4]
Saturated Fat (g)									
FFQ Baseline	15860	27.2	13.2	23754	27.2	13.1	0.0	0.1	0.81
FFQ Year 1	14665	14.2	8.1	21750	22.6	11.9	8.5	0.1	0.00
FFQ Year 2	4853	14.8	8.4	6984	22.7	11.8	7.9	0.2	0.00
FFQ Year 3	2643	15.5	8.6	4079	23.1	12.3	7.6	0.3	0.00
FFQ Year 4	2884	15.4	8.6	4526	23.4	12.4	8.1	0.3	0.00
FFQ Year 5	1479	16.2	9.7	2260	23.9	13.0	7.7	0.4	0.00
4DFR Baseline	691	20.0	8.8	1038	20.8	9.5	0.8	0.5	0.16
4DFR Year 1	622	10.3	5.3	892	19.3	8.3	9.0	0.4	0.00
24 Hr Recall, Post-baseline	186	13.0	8.0	205	20.0	9.7	7.0	0.9	0.00
24 Hr Recall, Year 1	172	11.3	5.9	200	20.4	10.2	9.1	0.9	0.00
24 Hr Recall, Year 2	166	12.1	8.3	167	19.1	9.3	7.0	1.0	0.00
24 Hr Recall, Year 3	98	13.9	8.3	117	19.4	11.6	5.5	1.4	0.00
24 Hr Recall, Year 3 Cohort	482	12.2	6.9	702	19.7	9.5	7.5	0.5	0.00
24 Hr Recall, Year 4	40	13.2	6.9	36	18.9	10.3	5.6	2.0	0.02
Polyunsaturated Fat (g)									
FFQ Baseline	15860	15.1	7.4	23754	15.1	7.4	0.0	0.1	0.54
FFQ Year 1	14665	7.9	4.4	21750	12.5	6.7	4.6	0.1	0.00
FFQ Year 2	4853	8.3	4.6	6984	12.5	6.6	4.2	0.1	0.00
FFQ Year 3	2643	8.8	4.6	4079	12.9	6.8	4.1	0.2	0.00
FFQ Year 4	2884	8.8	4.8	4526	12.9	6.7	4.1	0.1	0.00
FFQ Year 5	1479	9.1	5.3	2260	13.0	6.8	3.9	0.2	0.00
4DFR Baseline	691	12.8	5.7	1038	13.5	6.3	0.7	0.3	0.06
4DFR Year 1	622	7.4	3.5	892	12.9	6.5	5.5	0.3	0.00
24 Hr Recall, Post-baseline	186	8.3	5.1	205	12.4	7.4	4.1	0.6	0.00
24 Hr Recall, Year 1	172	7.6	4.3	200	12.6	6.2	4.9	0.6	0.00
24 Hr Recall, Year 2	166	8.4	5.4	167	12.1	7.4	3.7	0.7	0.00
24 Hr Recall, Year 3	98	8.4	5.4	117	12.3	6.6	3.9	0.8	0.00
24 Hr Recall, Year 3 Cohort	482	8.6	4.5	702	12.4	7.1	3.8	0.4	0.00
24 Hr Recall, Year 4	40	9.2	5.3	36	13.4	8.5	4.2	1.6	0.01
Fruits and Vegetables (servings)									
FFQ Baseline	15819	3.6	1.8	23708	3.6	1.9	0.0	0.0	0.63
FFQ Year 1	14616	5.0	2.4	21694	3.9	2.0	1.2	0.0	0.00
FFQ Year 2	4838	5.1	2.4	6966	3.9	2.0	1.2	0.0	0.00
FFQ Year 3	2640	5.3	2.5	4075	3.9	2.0	1.3	0.1	0.00
FFQ Year 4	2877	5.2	2.5	4523	3.8	2.0	1.4	0.1	0.00
FFQ Year 5	1462	5.2	2.4	2248	3.9	2.1	1.3	0.1	0.00
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	15817	4.7	2.5	23706	4.8	2.5	0.0	0.0	0.21
FFQ Year 1	14612	5.0	2.6	21685	4.2	2.3	0.8	0.0	0.00
FFQ Year 2	4837	4.8	2.5	6961	4.1	2.2	0.7	0.0	0.00
FFQ Year 3	2639	4.6	2.4	4070	3.9	2.2	0.6	0.1	0.00
FFQ Year 4	2875	4.5	2.4	4515	3.9	2.2	0.5	0.1	0.00
FFQ Year 5	1462	4.4	2.3	2246	3.9	2.1	0.5	0.1	0.00

[1] Intervention group is defined as women randomized to Intervention after 6/15/95 that have revised fat gram goals.
[2] Control group is defined as women randomized to Control after 6/15/95.
[3] Absolute difference.
[4] P-values based on testing in the natural log scale except for % Energy from fat.

Table 3.4
Nutrient Intake Monitoring in American Indian/Alaskan Native Women

Data as of: February 28, 2001

	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	115	40.0	5.2	0.5	0.8	0.54
FFQ Year 1[3]	73	27.5	8.9	97	37.9	8.0	10.4	1.3	0.00
FFQ Year 2[4]	28	26.9	8.8	31	38.5	6.7	11.6	2.0	0.00
FFQ Year 3[5]	15	30.5	9.3	34	37.3	6.9	6.9	2.4	0.02
FFQ Year 4[6]	19	29.6	9.2	21	39.8	8.5	10.2	2.8	0.00
FFQ Year 5[7]	10	29.1	7.4	6	34.4	6.2	5.3	3.6	0.15
FFQ Year 6[8]	3	38.6	2.6	5	37.6	7.3	1.1	4.5	0.78
4DFR Baseline	24	34.0	6.7	45	33.4	7.7	0.6	1.9	0.72
4DFR Year 1	18	20.5	6.2	33	34.3	7.5	13.9	2.1	0.00
Total Energy (kcal)									
FFQ Baseline	88	1717	796	115	1776	716	58	106.5	0.39
FFQ Year 1	73	1631	690	97	1551	751	80	112.4	0.56
FFQ Year 2	28	1508	566	31	1568	714	60	168.9	0.89
FFQ Year 3	15	1517	647	34	1568	674	50	206.5	0.83
FFQ Year 4	19	1443	502	21	1760	499	317	158.4	0.04
FFQ Year 5	10	2002	750	6	1142	491	860	345.5	0.03
FFQ Year 6	3	1008	336	5	2159	540	1151	351.7	0.04
4DFR Baseline	24	1524	426	45	1690	612	166	140.4	0.39
4DFR Year 1	18	1284	419	33	1637	604	353	160.2	0.03
Total Fat (g)									
FFQ Baseline	88	76.5	40.3	115	79.4	35.5	2.8	5.3	0.33
FFQ Year 1	73	50.3	29.6	97	67.1	43.3	16.8	5.9	0.00
FFQ Year 2	28	45.8	29.0	31	69.6	40.2	23.8	9.2	0.00
FFQ Year 3	15	55.5	36.9	34	66.7	34.8	11.2	11.0	0.24
FFQ Year 4	19	47.3	21.0	21	78.9	30.3	31.6	8.3	0.00
FFQ Year 5	10	65.1	29.1	6	45.0	26.7	20.1	14.6	0.18
FFQ Year 6	3	43.6	16.8	5	91.1	30.0	47.5	19.2	0.05
4DFR Baseline	24	57.4	17.5	45	64.4	30.8	7.0	6.8	0.75
4DFR Year 1	18	29.4	12.9	33	64.4	32.6	35.1	8.0	0.00

[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 (7%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 3
[6] 4 (21%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 4.
[7] 1 (10%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 5.
[8] 0 (0%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 6.

Table 3.4 (continued)
Nutrient Intake Monitoring in American Indian/Alaskan Native Women

Data as of: February 28, 2001

	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	115	28.0	14.1	1.1	2.0	0.39
FFQ Year 1[3]	73	17.4	11.0	97	23.7	17.9	6.3	2.4	0.00
FFQ Year 2[4]	28	15.5	9.9	31	23.7	15.0	8.2	3.3	0.01
FFQ Year 3[5]	15	19.5	14.5	34	22.5	11.9	3.0	3.9	0.28
FFQ Year 4[6]	19	16.4	8.2	21	27.2	12.3	10.8	3.3	0.00
FFQ Year 5[7]	10	22.9	13.6	6	15.4	10.5	7.6	6.5	0.25
FFQ Year 6[8]	3	15.7	6.1	5	33.8	16.0	18.1	9.9	0.10
4DFR Baseline	24	19.1	6.9	45	21.7	12.3	2.6	2.7	0.79
4DFR Year 1	18	9.0	4.2	33	20.8	10.8	11.8	2.6	0.00
Polyunsaturated Fat (g)									
FFQ Baseline	88	15.2	9.5	115	15.3	7.6	0.1	1.2	0.48
FFQ Year 1	73	9.4	6.3	97	12.7	8.4	3.3	1.2	0.00
FFQ Year 2	28	8.9	6.6	31	14.2	8.9	5.3	2.1	0.00
FFQ Year 3	15	9.9	6.0	34	12.9	6.9	3.0	2.0	0.16
FFQ Year 4	19	9.2	4.7	21	15.5	6.3	6.3	1.8	0.00
FFQ Year 5	10	12.1	3.4	6	8.0	4.2	4.1	1.9	0.09
FFQ Year 6	3	7.1	4.2	5	16.0	3.9	8.9	2.9	0.09
4DFR Baseline	24	11.5	4.6	45	12.2	6.2	0.8	1.4	0.98
4DFR Year 1	18	6.9	3.8	33	13.4	9.5	6.6	2.3	0.00
Fruits and Vegetables (servings)									
FFQ Baseline	88	3.5	2.0	115	3.1	1.7	0.4	0.3	0.28
FFQ Year 1	73	5.1	2.9	97	3.6	2.2	1.5	0.4	0.00
FFQ Year 2	28	5.2	3.3	31	3.4	1.6	1.9	0.7	0.06
FFQ Year 3	15	5.0	2.2	34	3.7	2.2	1.3	0.7	0.03
FFQ Year 4	19	5.5	3.2	21	4.2	2.2	1.3	0.9	0.27
FFQ Year 5	10	6.3	2.6	6	3.1	1.6	3.2	1.2	0.02
FFQ Year 6	3	1.7	0.5	5	3.8	2.2	2.1	1.3	0.10
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	88	4.5	2.5	115	4.7	2.7	0.2	0.4	0.47
FFQ Year 1	73	5.5	3.4	97	4.2	2.3	1.3	0.4	0.03
FFQ Year 2	28	5.5	3.0	31	4.2	3.0	1.3	0.8	0.14
FFQ Year 3	15	4.3	2.8	34	4.2	2.6	0.1	0.8	0.82
FFQ Year 4	19	4.2	2.5	21	4.2	1.9	0.0	0.7	0.79
FFQ Year 5	10	4.8	3.0	6	3.5	2.2	1.2	1.4	0.41
FFQ Year 6	3	3.6	2.4	5	6.6	2.5	2.9	1.8	0.24

[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 (7%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 3
[6] 4 (21%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 4.
[7] 1 (10%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 5.
[8] 0 (0%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 6.

Table 3.4 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women

Data as of: February 28, 2001

	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]	408	25.8	7.3	628	36.1	6.6	10.3	0.4	0.00
FFQ Year 2[4]	147	27.2	7.4	213	36.1	6.8	8.9	0.8	0.00
FFQ Year 3[5]	96	28.0	7.3	133	36.3	6.5	8.4	0.9	0.00
FFQ Year 4[6]	74	28.9	8.2	126	37.0	6.7	8.0	1.1	0.00
FFQ Year 5[7]	31	26.6	8.4	46	37.4	7.2	10.8	1.8	0.00
FFQ Year 6[8]	3	22.7	1.3	7	41.6	4.2	18.9	2.6	0.00
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	0.00
Total Energy (kcal)									
FFQ Baseline	431	1700	723	674	1675	711	25	44.1	0.50
FFQ Year 1	408	1502	588	628	1524	636	22	39.2	0.94
FFQ Year 2	147	1512	637	213	1500	777	12	77.6	0.24
FFQ Year 3	96	1462	566	133	1418	563	44	75.6	0.48
FFQ Year 4	74	1442	564	126	1479	589	37	85.0	0.90
FFQ Year 5	31	1534	585	46	1514	594	20	137.1	0.80
FFQ Year 6	3	1999	365	7	1708	583	291	370.3	0.27
4DFR Baseline	70	1683	400	104	1732	388	49	60.7	0.38
4DFR Year 1	68	1525	374	88	1620	397	95	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	408	43.5	23.5	628	62.4	31.4	18.9	1.8	0.00
FFQ Year 2	147	46.1	24.7	213	61.1	35.6	15.0	3.4	0.00
FFQ Year 3	96	45.6	23.6	133	57.8	27.2	12.2	3.4	0.00
FFQ Year 4	74	47.1	25.6	126	61.1	27.7	14.0	3.9	0.00
FFQ Year 5	31	47.1	28.8	46	62.1	25.2	15.0	6.2	0.00
FFQ Year 6	3	50.8	11.5	7	79.0	29.7	28.2	18.2	0.07
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	0.00

[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] 15 (16%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 3.
[6] 9 (12%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 4.
[7] 7 (23%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 5.
[8] 0 (0%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 6.

Table 3.4 (continued)
Nutrient Intake Monitoring in Asian/Pacific Islander Women

Data as of: February 28, 2001

	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]	408	13.5	8.0	628	19.6	10.8	6.0	0.6	0.00
FFQ Year 2[4]	147	14.3	8.5	213	19.3	11.9	5.0	1.1	0.00
FFQ Year 3[5]	96	14.1	8.1	133	18.0	9.5	3.9	1.2	0.00
FFQ Year 4[6]	74	14.6	8.7	126	19.2	9.1	4.6	1.3	0.00
FFQ Year 5[7]	31	14.3	8.3	46	20.0	10.0	5.7	2.2	0.01
FFQ Year 6[8]	3	15.1	3.6	7	25.0	12.4	9.9	7.5	0.08
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	0.00
Polyunsaturated Fat (g)									
FFQ Baseline	431	15.6	7.4	674	15.7	7.8	0.0	0.5	0.54
FFQ Year 1	408	9.1	5.0	628	13.6	7.2	4.5	0.4	0.00
FFQ Year 2	147	9.9	5.5	213	13.1	8.0	3.2	0.8	0.00
FFQ Year 3	96	9.8	5.3	133	12.2	5.9	2.5	0.8	0.00
FFQ Year 4	74	10.5	6.2	126	12.8	6.1	2.4	0.9	0.01
FFQ Year 5	31	10.4	10.4	46	13.0	5.3	2.6	1.8	0.01
FFQ Year 6	3	12.2	3.3	7	17.4	4.9	5.2	3.2	0.14
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	0.00
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	406	4.7	2.4	628	3.5	2.0	1.2	0.1	0.00
FFQ Year 2	146	4.8	2.7	213	3.4	1.9	1.4	0.2	0.00
FFQ Year 3	96	4.9	2.5	133	3.4	2.0	1.5	0.3	0.00
FFQ Year 4	73	4.8	2.4	126	3.3	2.1	1.5	0.3	0.00
FFQ Year 5	31	5.0	2.2	46	3.8	2.2	1.2	0.5	0.01
FFQ Year 6	3	7.5	1.0	7	3.5	2.1	4.0	1.3	0.01
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	429	5.0	2.6	674	4.8	2.3	0.2	0.1	0.43
FFQ Year 1	406	5.8	2.7	628	4.5	2.2	1.3	0.2	0.00
FFQ Year 2	146	5.4	2.7	213	4.3	2.5	1.1	0.3	0.00
FFQ Year 3	96	5.1	2.3	133	4.2	2.2	0.8	0.3	0.01
FFQ Year 4	73	5.0	2.4	126	4.4	2.2	0.6	0.3	0.01
FFQ Year 5	31	5.2	2.5	46	4.5	2.2	0.7	0.5	0.12
FFQ Year 6	3	8.5	1.6	7	4.8	2.3	3.7	1.5	0.02

[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] 15 (16%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 3.
[6] 9 (12%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 4.
[7] 7 (23%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 5.
[8] 0 (0%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 6.

Table 3.4 (continued)
Nutrient Intake Monitoring in Black/African American Women

Data as of: February 28, 2001

	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]	1858	28.1	8.4	2622	36.9	7.4	8.8	0.2	0.00
FFQ Year 2[4]	607	29.5	8.0	822	36.4	7.4	7.0	0.4	0.00
FFQ Year 3[5]	312	29.1	7.8	466	38.3	7.2	9.2	0.5	0.00
FFQ Year 4[6]	294	30.1	8.0	460	37.7	7.5	7.7	0.6	0.00
FFQ Year 5[7]	182	30.5	7.9	269	37.1	7.9	6.7	0.8	0.00
FFQ Year 6[8]	104	30.0	8.1	139	36.9	7.8	7.0	1.0	0.00
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	0.00
Total Energy (kcal)									
FFQ Baseline	2135	1745	828	3127	1739	835	6	23.4	0.70
FFQ Year 1	1858	1383	633	2622	1493	775	110	21.8	0.00
FFQ Year 2	607	1390	717	822	1450	726	60	38.6	0.31
FFQ Year 3	312	1396	639	466	1543	800	147	54.1	0.02
FFQ Year 4	294	1323	566	460	1467	773	144	52.2	0.03
FFQ Year 5	182	1381	631	269	1380	667	2	62.6	0.89
FFQ Year 6	104	1275	626	139	1373	709	98	87.5	0.38
4DFR Baseline	243	1704	526	371	1651	478	53	41.1	0.32
4DFR Year 1	219	1346	342	307	1585	482	239	38.0	0.00
Total Fat (g)									
FFQ Baseline	2135	77.8	40.8	3127	77.9	41.3	0.1	1.2	0.90
FFQ Year 1	1858	43.6	26.8	2622	62.3	37.3	18.7	1.0	0.00
FFQ Year 2	607	46.4	32.6	822	60.2	36.0	13.8	1.9	0.00
FFQ Year 3	312	46.0	27.0	466	66.5	39.0	20.5	2.5	0.00
FFQ Year 4	294	44.5	24.0	460	62.5	37.5	18.0	2.5	0.00
FFQ Year 5	182	47.5	28.2	269	57.9	32.1	10.4	2.9	0.00
FFQ Year 6	104	42.5	25.7	139	57.6	34.7	15.2	4.0	0.00
4DFR Baseline	243	65.1	25.7	371	64.0	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	0.00

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 322 (17%) Black/African American Intervention women had <=20% energy from fat at year 1.
[4] 79 (13%) Black/African American Intervention women had <=20% energy from fat at year 2.
[5] 43 (14%) Black/African American Intervention women had <=20% energy from fat at year 3
[6] 35 (12%) Black/African American Intervention women had <=20% energy from fat at year 4.
[7] 17 (9%) Black/African American Intervention women had <=20% energy from fat at year 5.
[8] 12 (12%) Black/African American Intervention women had <=20% energy from fat at year 6.

Table 3.4 (continued)
Nutrient Intake Monitoring in Black/African American Women

Data as of: February 28, 2001

	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	0.89
FFQ Year 1[3]	1858	14.3	9.2	2622	20.5	12.8	6.2	0.3	0.00
FFQ Year 2[4]	607	15.3	11.8	822	19.8	12.3	4.5	0.6	0.00
FFQ Year 3[5]	312	15.0	9.5	466	21.8	13.4	6.8	0.9	0.00
FFQ Year 4[6]	294	14.2	7.9	460	20.6	13.0	6.4	0.8	0.00
FFQ Year 5[7]	182	15.4	9.7	269	19.1	11.4	3.7	1.0	0.00
FFQ Year 6[8]	104	13.6	8.5	139	19.1	12.9	5.6	1.5	0.00
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	0.00
Polyunsaturated Fat (g)									
FFQ Baseline	2135	16.0	8.9	3127	16.0	8.9	0.0	0.3	0.96
FFQ Year 1	1858	8.7	5.6	2622	12.7	8.0	4.0	0.2	0.00
FFQ Year 2	607	9.2	6.2	822	12.1	7.5	3.0	0.4	0.00
FFQ Year 3	312	9.3	5.7	466	13.5	8.0	4.2	0.5	0.00
FFQ Year 4	294	9.1	5.2	460	12.8	7.9	3.6	0.5	0.00
FFQ Year 5	182	9.5	5.9	269	11.9	7.4	2.5	0.7	0.00
FFQ Year 6	104	8.5	6.1	139	11.6	6.7	3.0	0.8	0.00
4DFR Baseline	243	14.5	6.7	371	13.8	6.8	0.7	0.6	0.15
4DFR Year 1	219	7.6	3.2	307	13.7	6.9	6.1	0.5	0.00
Fruits and Vegetables (servings)									
FFQ Baseline	2132	3.3	1.9	3123	3.2	1.9	0.0	0.1	0.72
FFQ Year 1	1852	4.5	2.6	2616	3.4	2.1	1.1	0.1	0.00
FFQ Year 2	606	4.5	2.5	817	3.5	2.2	1.0	0.1	0.00
FFQ Year 3	311	4.8	2.7	466	3.8	2.3	1.0	0.2	0.00
FFQ Year 4	294	4.9	2.9	460	3.4	2.2	1.5	0.2	0.00
FFQ Year 5	181	4.8	2.8	268	3.6	2.3	1.2	0.2	0.00
FFQ Year 6	104	4.6	2.4	139	3.5	2.0	1.1	0.3	0.00
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	2132	4.5	2.8	3122	4.4	2.8	0.1	0.1	0.30
FFQ Year 1	1851	4.4	2.8	2614	3.8	2.5	0.6	0.1	0.00
FFQ Year 2	606	4.2	2.6	816	3.7	2.4	0.5	0.1	0.00
FFQ Year 3	311	4.3	2.8	466	3.8	2.6	0.5	0.2	0.00
FFQ Year 4	294	4.0	2.4	458	3.6	2.3	0.4	0.2	0.02
FFQ Year 5	181	4.0	2.3	267	3.5	2.2	0.5	0.2	0.01
FFQ Year 6	104	3.9	2.4	139	3.4	2.0	0.5	0.3	0.03

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 322 (17%) Black/African American Intervention women had <=20% energy from fat at year 1.
[4] 79 (13%) Black/African American Intervention women had <=20% energy from fat at year 2.
[5] 43 (14%) Black/African American Intervention women had <=20% energy from fat at year 3
[6] 35 (12%) Black/African American Intervention women had <=20% energy from fat at year 4.
[7] 17 (9%) Black/African American Intervention women had <=20% energy from fat at year 5.
[8] 12 (12%) Black/African American Intervention women had <=20% energy from fat at year 6.

Table 3.4 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women

Data as of: February 28, 2001

	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	1095	39.0	5.1	0.4	0.2	0.13
FFQ Year 1[3]	617	27.9	8.0	915	36.1	7.4	8.2	0.4	0.00
FFQ Year 2[4]	226	27.7	8.3	304	36.9	7.6	9.2	0.7	0.00
FFQ Year 3[5]	119	30.0	8.9	170	37.3	7.1	7.3	0.9	0.00
FFQ Year 4[6]	100	30.6	7.8	176	36.3	7.2	5.7	0.9	0.00
FFQ Year 5[7]	53	28.8	9.9	83	37.4	7.6	8.6	1.5	0.00
FFQ Year 6[8]	25	26.0	8.2	36	35.7	6.7	9.7	1.9	0.00
4DFR Baseline	96	32.4	5.7	135	32.4	6.6	0.0	0.8	1.00
4DFR Year 1	82	23.1	7.4	111	32.0	7.3	8.9	1.1	0.00
Total Energy (kcal)									
FFQ Baseline	751	1847	836	1095	1859	870	13	40.6	0.86
FFQ Year 1	617	1419	665	915	1574	866	155	41.2	0.00
FFQ Year 2	226	1411	615	304	1618	768	206	62.1	0.00
FFQ Year 3	119	1572	642	170	1564	737	8	83.6	0.59
FFQ Year 4	100	1464	654	176	1529	730	64	88.1	0.51
FFQ Year 5	53	1446	718	83	1590	688	144	123.0	0.18
FFQ Year 6	25	1090	416	36	1401	758	311	166.9	0.16
4DFR Baseline	96	1643	446	135	1754	463	111	60.9	0.05
4DFR Year 1	82	1400	412	111	1636	457	236	63.8	0.00
Total Fat (g)									
FFQ Baseline	751	81.6	41.0	1095	80.8	40.5	0.7	1.9	0.57
FFQ Year 1	617	44.5	27.3	915	64.5	41.5	20.0	1.9	0.00
FFQ Year 2	226	43.7	24.3	304	67.9	38.5	24.2	2.9	0.00
FFQ Year 3	119	53.9	32.6	170	65.6	35.5	11.8	4.1	0.00
FFQ Year 4	100	49.5	25.2	176	62.6	33.8	13.1	3.9	0.00
FFQ Year 5	53	48.4	35.3	83	68.2	37.6	19.8	6.5	0.00
FFQ Year 6	25	31.1	15.8	36	56.4	35.5	25.3	7.6	0.00
4DFR Baseline	96	59.6	20.1	135	64.4	25.8	4.8	3.2	0.19
4DFR Year 1	82	36.4	17.7	111	59.2	24.7	22.8	3.2	0.00

[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] 13 (11%) Hispanic/Latino Intervention women had <=20% energy from fat at year 3
[6] 10 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 4.
[7] 12 (23%) Hispanic/Latino Intervention women had <=20% energy from fat at year 5.
[8] 6 (24%) Hispanic/Latino Intervention women had <=20% energy from fat at year 6.

Table 3.4 (continued)
Nutrient Intake Monitoring in Hispanic/Latino Women

Data as of: February 28, 2001

	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	1095	27.7	15.1	0.1	0.7	0.65
FFQ Year 1[3]	617	15.0	9.8	915	21.8	14.4	6.8	0.7	0.00
FFQ Year 2[4]	226	14.4	8.4	304	23.0	14.2	8.6	1.1	0.00
FFQ Year 3[5]	119	18.0	12.4	170	22.0	12.8	4.0	1.5	0.00
FFQ Year 4[6]	100	16.2	9.3	176	20.9	12.1	4.7	1.4	0.00
FFQ Year 5[7]	53	16.1	12.2	83	23.8	14.3	7.6	2.4	0.00
FFQ Year 6[8]	25	9.8	5.8	36	19.6	13.0	9.8	2.8	0.00
4DFR Baseline	96	19.8	7.6	135	21.1	10.2	1.3	1.2	0.50
4DFR Year 1	82	11.5	6.8	111	19.5	8.9	8.0	1.2	0.00
Polyunsaturated Fat (g)									
FFQ Baseline	751	15.9	8.4	1095	15.7	8.2	0.2	0.4	0.49
FFQ Year 1	617	8.6	5.5	915	12.8	8.7	4.2	0.4	0.00
FFQ Year 2	226	8.7	5.3	304	13.4	8.2	4.7	0.6	0.00
FFQ Year 3	119	10.6	6.7	170	12.8	7.4	2.2	0.8	0.00
FFQ Year 4	100	9.5	5.5	176	12.3	7.0	2.8	0.8	0.00
FFQ Year 5	53	9.4	7.1	83	12.5	6.7	3.1	1.2	0.00
FFQ Year 6	25	6.5	3.4	36	11.2	8.3	4.7	1.7	0.00
4DFR Baseline	96	11.5	4.6	135	13.4	6.2	1.9	0.7	0.02
4DFR Year 1	82	7.8	4.1	111	12.1	6.3	4.3	0.8	0.00
Fruits and Vegetables (servings)									
FFQ Baseline	748	3.0	1.9	1095	2.9	1.8	0.1	0.1	0.27
FFQ Year 1	614	4.2	2.3	915	3.1	1.9	1.0	0.1	0.00
FFQ Year 2	224	4.4	2.4	304	3.2	1.7	1.2	0.2	0.00
FFQ Year 3	118	4.7	3.0	170	3.3	2.0	1.4	0.3	0.00
FFQ Year 4	100	5.0	2.7	176	3.4	2.3	1.6	0.3	0.00
FFQ Year 5	52	4.8	2.4	83	3.2	2.2	1.6	0.4	0.00
FFQ Year 6	25	5.1	2.6	36	2.8	2.0	2.3	0.6	0.00
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	748	5.5	3.3	1095	5.7	3.5	0.2	0.2	0.53
FFQ Year 1	614	5.1	3.3	915	4.8	3.4	0.3	0.2	0.07
FFQ Year 2	224	5.0	3.5	304	4.9	3.1	0.1	0.3	0.55
FFQ Year 3	118	5.2	3.0	170	4.6	2.8	0.6	0.3	0.14
FFQ Year 4	100	4.5	3.0	176	4.6	2.8	0.1	0.4	0.51
FFQ Year 5	52	4.6	3.0	83	4.7	2.3	0.1	0.5	0.61
FFQ Year 6	25	3.9	1.8	36	4.8	3.6	0.9	0.8	0.68

[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] 13 (11%) Hispanic/Latino Intervention women had <=20% energy from fat at year 3
[6] 10 (10%) Hispanic/Latino Intervention women had <=20% energy from fat at year 4.
[7] 12 (23%) Hispanic/Latino Intervention women had <=20% energy from fat at year 5.
[8] 6 (24%) Hispanic/Latino Intervention women had <=20% energy from fat at year 6.

Table 3.4 (continued)
Nutrient Intake Monitoring in Other/Unspecified Women

Data as of: February 28, 2001

	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	393	39.2	5.1	0.1	0.4	0.77
FFQ Year 1[3]	240	27.7	8.0	353	35.9	7.7	8.3	0.7	0.00
FFQ Year 2[4]	79	27.2	7.9	121	37.3	7.0	10.1	1.1	0.00
FFQ Year 3[5]	45	28.9	7.3	53	38.1	7.6	9.2	1.5	0.00
FFQ Year 4[6]	39	29.4	8.2	72	37.1	7.9	7.7	1.6	0.00
FFQ Year 5[7]	15	27.1	7.8	19	38.1	8.0	11.0	2.7	0.00
FFQ Year 6[8]	5	31.9	3.9	19	38.5	7.6	6.6	3.6	0.02
4DFR Baseline	17	32.2	5.5	28	32.8	5.7	0.6	1.7	0.72
4DFR Year 1	13	22.8	8.9	23	34.0	6.4	11.2	2.6	0.00
Total Energy (kcal)									
FFQ Baseline	265	1796	775	393	1725	770	71	61.4	0.22
FFQ Year 1	240	1506	628	353	1500	639	6	53.1	0.63
FFQ Year 2	79	1464	584	121	1577	688	113	93.9	0.33
FFQ Year 3	45	1488	582	53	1493	733	5	135.4	0.90
FFQ Year 4	39	1405	670	72	1543	605	138	125.0	0.22
FFQ Year 5	15	1498	538	19	1301	623	197	203.0	0.16
FFQ Year 6	5	1971	468	19	1621	900	350	421.2	0.08
4DFR Baseline	17	1504	288	28	1665	381	161	107.4	0.15
4DFR Year 1	13	1334	469	23	1531	338	196	135.1	0.15
Total Fat (g)									
FFQ Baseline	265	79.0	39.4	393	75.9	38.5	3.2	3.1	0.31
FFQ Year 1	240	46.7	28.0	353	60.7	31.6	14.0	2.5	0.00
FFQ Year 2	79	44.9	29.0	121	66.8	35.6	21.9	4.8	0.00
FFQ Year 3	45	46.8	20.8	53	64.2	36.7	17.4	6.2	0.00
FFQ Year 4	39	46.7	33.7	72	64.8	30.9	18.1	6.3	0.00
FFQ Year 5	15	43.4	15.4	19	57.4	33.1	14.0	9.3	0.56
FFQ Year 6	5	70.8	22.6	19	72.5	52.2	1.7	24.2	0.53
4DFR Baseline	17	54.4	16.8	28	60.8	16.8	6.3	5.2	0.24
4DFR Year 1	13	33.7	19.1	23	58.3	17.6	24.6	6.3	0.00

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 38 (16%) Other/Unspecified Intervention women had <=20% energy from fat at year 1.
[4] 16 (20%) Other/Unspecified Intervention women had <=20% energy from fat at year 2.
[5] 5 (11%) Other/Unspecified Intervention women had <=20% energy from fat at year 3
[6] 5 (13%) Other/Unspecified Intervention women had <=20% energy from fat at year 4.
[7] 3 (20%) Other/Unspecified Intervention women had <=20% energy from fat at year 5.
[8] 0 (0%) Other/Unspecified Intervention women had <=20% energy from fat at year 6.

Table 3.4 (continued)
Nutrient Intake Monitoring in Other/Unspecified Women

Data as of: February 28, 2001

	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	393	26.2	14.2	1.0	1.1	0.45
FFQ Year 1[3]	240	15.5	9.4	353	20.9	11.7	5.5	0.9	0.00
FFQ Year 2[4]	79	15.3	10.7	121	23.1	12.7	7.9	1.7	0.00
FFQ Year 3[5]	45	15.6	7.7	53	21.5	13.5	5.9	2.3	0.01
FFQ Year 4[6]	39	15.0	9.9	72	22.7	11.3	7.8	2.2	0.00
FFQ Year 5[7]	15	14.2	5.8	19	19.9	11.9	5.8	3.4	0.48
FFQ Year 6[8]	5	21.5	8.4	19	24.6	19.5	3.1	9.0	0.95
4DFR Baseline	17	17.6	6.7	28	20.6	7.0	3.0	2.1	0.13
4DFR Year 1	13	11.3	8.7	23	19.0	5.8	7.8	2.4	0.00
Polyunsaturated Fat (g)									
FFQ Baseline	265	15.9	8.7	393	15.0	8.6	0.9	0.7	0.19
FFQ Year 1	240	9.1	6.0	353	11.9	6.8	2.8	0.5	0.00
FFQ Year 2	79	8.4	5.6	121	13.0	8.1	4.6	1.0	0.00
FFQ Year 3	45	9.1	4.1	53	13.2	8.1	4.1	1.3	0.00
FFQ Year 4	39	9.6	7.7	72	12.5	7.5	2.8	1.5	0.02
FFQ Year 5	15	8.6	3.1	19	11.0	6.6	2.3	1.8	0.69
FFQ Year 6	5	16.1	5.3	19	14.4	10.3	1.7	4.8	0.20
4DFR Baseline	17	11.7	3.7	28	12.4	4.4	0.7	1.3	0.66
4DFR Year 1	13	6.6	3.1	23	11.9	4.4	5.4	1.4	0.00
Fruits and Vegetables (servings)									
FFQ Baseline	264	3.7	2.0	392	3.4	2.0	0.3	0.2	0.03
FFQ Year 1	239	4.9	2.4	352	3.6	2.0	1.3	0.2	0.00
FFQ Year 2	78	5.0	2.3	121	3.9	2.3	1.1	0.3	0.00
FFQ Year 3	45	5.0	2.6	53	3.7	1.9	1.3	0.5	0.01
FFQ Year 4	38	4.9	3.1	72	4.2	2.4	0.8	0.5	0.46
FFQ Year 5	15	6.3	3.3	19	3.0	1.5	3.3	0.8	0.01
FFQ Year 6	4	6.2	2.7	19	4.5	2.9	1.7	1.6	0.17
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	264	4.8	2.7	392	4.7	2.7	0.1	0.2	0.70
FFQ Year 1	239	5.0	3.0	352	4.2	2.4	0.9	0.2	0.00
FFQ Year 2	78	4.7	2.4	121	4.3	2.4	0.4	0.3	0.39
FFQ Year 3	45	4.8	3.0	53	4.1	2.5	0.7	0.6	0.19
FFQ Year 4	38	4.5	2.6	72	4.0	2.3	0.5	0.5	0.44
FFQ Year 5	15	4.9	2.6	19	3.6	2.5	1.3	0.9	0.09
FFQ Year 6	4	6.3	2.4	19	3.8	2.3	2.5	1.3	0.04

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 38 (16%) Other/Unspecified Intervention women had <=20% energy from fat at year 1.
[4] 16 (20%) Other/Unspecified Intervention women had <=20% energy from fat at year 2.
[5] 5 (11%) Other/Unspecified Intervention women had <=20% energy from fat at year 3
[6] 5 (13%) Other/Unspecified Intervention women had <=20% energy from fat at year 4.
[7] 3 (20%) Other/Unspecified Intervention women had <=20% energy from fat at year 5.
[8] 0 (0%) Other/Unspecified Intervention women had <=20% energy from fat at year 6.

Table 3.5
Control - Intervention Difference in % Energy from Fat in WHI DM Participants
Multivariate Analysis of Study Subject Characteristics and Session Participation
from FFQs Collected in the Last Year[1]

Data as of: February 28, 2001

	Model Including Attendance				Model Including Completion				Model Including Fat Scores			
	N	C - I (%) (Full Model)	R^2	(ΔR^2) for Inclusion	N	C - I (%) (Full Model)	R^2	(ΔR^2) for Inclusion	N	C - I (%) (Full Model)	R^2	(ΔR^2) for Inclusion
Demographics			23.6%				23.6%				23.6%	
Age												
60-69	8818				8818				8818			
50-54 vs. 60-69	2626	0.71 *			2626	0.71 *			2626	0.87 *		
55-59 vs. 60-69	4318	0.21			4318	0.22			4318	0.23		
70-79 vs. 60-69	3123	-0.90 **			3123	-0.82 **			3123	-0.88 **		
Ethnicity												
White	15734				15734				15734			
American Indian vs. White	93	-0.14			93	0.03			93	0.74		
Asian/Pacific Islander vs. White	435	-0.66			435	-0.64			435	-0.86		
Black vs. White	1785	-0.45			1785	-0.55			1785	-0.30		
Hispanic vs. White	619	-0.88			619	-0.85			619	-0.56		
Other Minority vs. White	219	-0.36			219	-0.20			219	-0.23		
Education												
Post H.S.	14809				14809				14809			
0-8 Years vs. Post H.S.	175	-0.89			175	-0.48			175	-1.00		
Some H.S. or Diploma vs. Post H.S.	3901	0.49			3901	0.53			3901	0.42		
Family Income												
≥75K	3303				3303				3303			
<20K vs. ≥75K	3244	-0.81 *			3244	-0.70			3244	-0.49		
20-35K vs. ≥75K	4517	-0.46			4517	-0.33			4517	-0.23		
35-50K vs. ≥75K	3972	-0.52			3972	-0.39			3972	-0.31		
50-75K vs. ≥75K	3849	0.01			3849	0.05			3849	0.12		
HRT Randomized												
No	15915				15915				15915			
Yes vs. No	2970	0.74 *			2970	0.89 **			2970	0.73 *		
Visit			26.0%	(2.4%)			26.0%	(2.4%)			26.0%	(2.4%)
Visit Year												
AV-2	952				952				952			
AV-3 vs. AV-2	4463	-0.55			4463	-1.09 **			4463	-0.79		
AV-4 vs. AV-2	6527	-0.38			6527	-0.91 *			6527	-0.65		
AV-5 vs. AV-2	4173	-0.49			4173	-1.03 *			4173	-0.72		
AV-6 vs. AV-2	2770	-0.80			2770	-1.43 **			2770	-1.06 *		
Clinic Effect			29.2%	(3.2%)			29.2%	(3.2%)			29.2%	(3.2%)
Intervention Participation												
# Sessions Attended in Previous 12 Months			32.6%	(3.4%)								
None	13280											
1 vs. None	1297	4.48 **										
2 vs. None	1704	5.70 **										
3 vs. None	1700	6.68 **										
4+ vs. None	904	7.00 **										
# Sessions Completed in Previous 12 Months							33.1%	(4.0%)				
None					12526							
1 vs. None					501	3.12 **						
2 vs. None					1340	6.77 **						
3 vs. None					2143	7.45 **						
4+ vs. None					2375	8.54 **						
# Fat Scores Provided in Previous 12 Months											33.9%	(4.7%)
None									13354			
1 vs. None									842	4.04 **		
2 vs. None									1287	6.10 **		
3 vs. None									1682	7.23 **		
4+ vs. None									1720	8.20 **		

[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 3.6
Body Weight

Data as of: February 28, 2001

Body Weight (kg)[1]	Intervention			Control			Difference		
	N	Mean	S.D.	N	Mean	S.D.	Mean[2]	S.E.	p-value
All Participants									
Baseline	19524	76.8	16.7	29272	76.7	16.6	-0.1	0.2	0.36
Year 1	18135	74.4	16.8	26669	76.4	16.8	1.9	0.2	0.00
Year 2	16681	75.4	17.2	25018	76.7	16.9	1.3	0.2	0.00
Year 3	15582	75.7	17.1	23740	76.7	16.8	1.1	0.2	0.00
Year 4	10485	75.9	17.0	16130	76.6	16.7	0.8	0.2	0.00
Year 5	5423	76.1	16.7	8316	76.4	16.4	0.4	0.3	0.21
Year 6	2206	75.7	16.0	3414	75.7	15.6	0.0	0.4	0.92
Participants Aged 70-79									
Baseline	3246	73.0	14.7	4870	72.9	14.5	-0.1	0.3	0.82
Year 1	3008	70.7	15.2	4482	72.7	15.4	2.0	0.4	0.00
Year 2	2779	71.1	15.1	4166	72.6	15.3	1.5	0.4	0.00
Year 3	2512	71.0	15.4	3828	72.0	14.7	1.0	0.4	0.01
Year 4	1514	70.4	14.5	2293	71.2	14.3	0.8	0.5	0.10
Year 5	666	70.2	14.0	1046	71.2	14.5	1.0	0.7	0.17
Year 6	269	70.6	15.6	453	70.2	13.3	-0.4	1.1	0.72
Participants with Revised Fat Gram Goals[3]									
Baseline	15846	77.0	17.0	23739	77.0	16.9	0.0	0.2	0.79
Year 1	14678	74.6	17.1	21601	76.6	17.1	2.0	0.2	0.00
Year 2	13419	75.5	17.4	20175	77.0	17.2	1.5	0.2	0.00
Year 3	12383	75.8	17.4	18909	77.0	17.0	1.2	0.2	0.00
Year 4	7414	75.9	17.1	11426	76.9	16.9	0.9	0.3	0.00
Year 5	2450	76.4	17.2	3727	76.8	16.6	0.5	0.4	0.29
Year 6	27	75.9	21.8	2	76.8	1.1	0.8	15.6	0.85

[1] Shown for 30 <= weight (kg) <= 220
[2] Control - Intervention
[3] For revised fat gram goals:
Intervention group is defined as women randomized to Intervention after 6/15/95 that have revised fat gram goals.
Control group is defined as women randomized to Control after 6/15/95.

Table 3.6 (continued)
Body Weight by Race/Ethnicity

Data as of: February 28, 2001

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	115	80.8	16.9	3.0	2.3	0.18
Year 1	74	75.6	15.0	94	81.1	16.8	5.6	2.5	0.02
Year 2	66	76.9	18.7	91	83.5	18.1	6.6	3.0	0.03
Year 3	66	75.5	15.6	89	84.2	17.8	8.7	2.8	0.00
Year 4	49	77.7	16.4	56	87.2	19.3	9.5	3.5	0.01
Year 5	24	78.6	17.0	27	85.4	19.8	6.8	5.2	0.20
Year 6	9	77.2	18.2	7	80.8	14.7	3.6	8.5	0.67
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	356	63.1	13.6	556	64.0	15.1	0.8	1.0	0.39
Year 4	212	61.9	11.6	364	63.3	13.5	1.4	1.1	0.19
Year 5	67	61.3	10.6	108	61.5	11.0	0.2	1.7	0.91
Year 6	14	65.1	12.1	17	61.3	9.2	-3.7	3.8	0.35
Black/African American									
Baseline	2133	85.3	18.2	3126	85.1	18.5	-0.1	0.5	0.79
Year 1	1891	84.3	19.3	2663	84.9	19.0	0.6	0.6	0.28
Year 2	1711	84.9	18.8	2500	85.2	19.0	0.3	0.6	0.56
Year 3	1550	85.2	19.4	2305	85.2	18.8	0.0	0.6	1.00
Year 4	1045	85.2	19.0	1567	85.8	18.4	0.7	0.7	0.38
Year 5	521	85.0	19.1	768	84.6	18.3	-0.4	1.1	0.69
Year 6	173	85.0	16.8	258	84.0	17.3	-1.0	1.7	0.56
Hispanic/Latino									
Baseline	750	75.2	16.0	1095	73.7	15.2	-1.5	0.7	0.05
Year 1	637	74.2	16.6	935	73.2	15.5	-1.0	0.8	0.24
Year 2	570	74.4	16.1	864	73.9	15.8	-0.5	0.9	0.59
Year 3	513	75.4	17.1	802	74.4	16.6	-1.0	0.9	0.31
Year 4	326	76.2	18.2	512	73.7	13.8	-2.4	1.1	0.04
Year 5	147	74.8	16.9	234	73.5	14.1	-1.4	1.6	0.41
Year 6	49	73.8	14.1	70	68.2	13.3	-5.6	2.5	0.03
Other/Unspecified									
Baseline	265	78.3	18.4	393	76.5	16.8	-1.9	1.4	0.18
Year 1	239	77.6	20.4	344	77.0	18.0	-0.6	1.6	0.72
Year 2	205	76.3	18.6	324	77.3	18.6	1.0	1.7	0.56
Year 3	186	76.5	17.4	286	77.1	18.4	0.6	1.7	0.70
Year 4	107	75.7	16.9	183	75.8	16.1	0.1	2.0	0.96
Year 5	46	79.7	17.6	65	75.5	16.2	-4.2	3.2	0.20
Year 6	11	84.8	18.3	30	74.9	16.0	-9.9	5.9	0.13
White									
Baseline	15858	76.1	16.1	23869	76.1	15.9	0.0	0.2	0.87
Year 1	14880	73.5	15.9	21997	75.8	16.2	2.4	0.2	0.00
Year 2	13737	74.6	16.6	20624	76.2	16.3	1.6	0.2	0.00
Year 3	12911	74.9	16.5	19702	76.1	16.2	1.3	0.2	0.00
Year 4	8746	75.1	16.4	13448	76.0	16.1	0.9	0.2	0.00
Year 5	4618	75.3	16.1	7114	75.9	16.0	0.6	0.3	0.05
Year 6	1950	74.9	15.6	3032	75.3	15.2	0.4	0.5	0.43

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

Table 3.7
Reasons for Stopping DM

Data as of: February 28, 2001

Reasons[1]	(N = 2093)	
Personal/family		
Demands of work	267	(12.8%)
Family illness, emergency, or other family demands	306	(14.6%)
Financial problems	10	(0.5%)
Lack of cooperation/support from family/friends	39	(1.9%)
Living in nursing home	14	(0.7%)
Issues of interest in study	223	(10.7%)
Travel		
Too far to CC	136	(6.5%)
Moved out of area or refuses to be followed at another CC	11	(0.5%)
Other Travel Issues	64	(3.1%)
Visits & Procendures		
Doesn't like visits/calls	46	(2.2%)
Doesn't like required forms or safety procedures	45	(2.2%)
Problems with other procedures	14	(0.7%)
Worried about health effects of medical tests/procedures	4	(0.2%)
Wants test results	0	(0.0%)
Problems with the CC	25	(1.2%)

[1] Multiple reasons may be reported for a woman.

Table 3.7 (continued)
Reasons for Stopping DM

Data as of: February 28, 2001

Reasons[1]	(N = 2093)	
Symptoms		
GI Problems	0	(0.0%)
Hair/Skin Changes	1	(<0.1%)
Weight loss/gain	5	(0.2%)
HRT Related Symptoms	4	(0.2%)
Other	6	(0.3%)
Health Conditions		
Disease and/or health conditions	47	(2.2%)
Communication difficulties	27	(1.3%)
Intervention		
Doesn't like randomized nature of intervention	10	(0.5%)
Expected some benefit from intervention	38	(1.8%)
Feels guilty/unhappy or like a failure for not meeting study goals of intervention	9	(0.4%)
Pill Issues	5	(0.2%)
CaD Issues	1	(<0.1%)
HRT Issues	1	(<0.1%)
Problem with DM group nutritionist or group members	33	(1.6%)
Doesn't like attending DM intervention classes	42	(2.0%)
Doesn't like self-monitoring	34	(1.6%)
Doesn't like budgeting fat grams	1	(<0.1%)
Health concerns regarding long-term risk/benefits of low fat diet	11	(0.5%)
Unhappy that not losing weight	13	(0.6%)
Not in control of meal preparation	10	(0.5%)
Too difficult to meet or maintain dietary goals	30	(1.4%)
Doesn't like eating low fat diet	18	(0.9%)
Doesn't like eating 5 vegetables/fruits per day	2	(0.1%)
Doesn't like eating 6 grains per day	6	(0.3%)
Feels fat gram goal is unrealistic	5	(0.2%)
Eating pattern conflicts with personal health beliefs	19	(0.9%)
Other Health Issues		
Worried about costs if adverse effects occur	1	(<0.1%)
Expected more health care	11	(0.5%)
Advised not to participate by health care provider	25	(1.2%)
Study conflicts with other health issues	29	(1.4%)
Other		
Other reasons not listed above	466	(22.3%)
Refuses to give a reason	96	(4.6%)

[1] Multiple reasons may be reported for a woman.

Table 3.8
Blood Specimen Analysis: DM Participants

Data as of: February 28, 2001

	N	Mean[1]	S.D.[1]
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	2396	0.08	0.08
AV-1	2398	0.08	0.07
AV-1 – Baseline	2393	0.00	0.06
Beta-Carotene (µg/ml)			
Baseline	2396	0.30	0.29
AV-1	2398	0.31	0.29
AV-1 – Baseline	2393	0.00	0.22
Alpha-tocopherol (µg/ml)			
Baseline	2396	16.19	6.97
AV-1	2398	16.95	7.52
AV-1 – Baseline	2393	0.75	5.45
Gamma-tocopherol (µg/ml)			
Baseline	2396	2.20	1.42
AV-1	2397	1.84	1.30
AV-1 – Baseline	2392	-0.36	0.93
Beta-Cryptoxanthine (µg/ml)			
Baseline	2396	0.09	0.07
AV-1	2397	0.09	0.07
AV-1 - Baseline	2392	0.00	0.06
Lycopene (µg/ml)			
Baseline	2396	0.41	0.19
AV-1	2398	0.41	0.19
AV-1 – Baseline	2393	-0.01	0.16
Lutein and Zeaxanthin (µg/ml)			
Baseline	2396	0.22	0.11
AV-1	2398	0.22	0.10
AV-1 – Baseline	2393	0.00	0.07
Retinol (µg/ml)			
Baseline	2396	0.61	0.15
AV-1	2398	0.62	0.15
AV-1 – Baseline	2393	0.00	0.10

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

Table 3.8 (continued)
Blood Specimen Analysis: DM Participants

Data as of: February 28, 2001

	N	Mean[1]	S.D.[1]
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	2323	130.86	32.76
AV-1	2304	130.69	32.81
AV-1 - Baseline	2248	-0.24	22.37
Factor VII C (%)			
Baseline	2280	129.48	30.69
AV-1	2273	127.07	30.22
AV-1 - Baseline	2184	-2.83	22.32
Fibrinogen (mg/dl)			
Baseline	2317	300.17	61.25
AV-1	2298	297.80	60.57
AV-1 - Baseline	2237	-2.32	49.75
Hormones/Other			
Glucose (mg/dl)			
Baseline	2396	100.21	26.69
AV-1	2390	98.94	26.43
AV-1 - Baseline	2385	-1.26	19.04
Insulin (μIU/ml)			
Baseline	2344	11.51	7.41
AV-1	2338	11.23	10.41
AV-1 - Baseline	2290	-0.29	8.57

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

Table 3.8 (continued)
Blood Specimen Analysis: DM Participants

Data as of: February 28, 2001

	N	Mean[1]	S.D.[1]
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	2395	156.02	85.74
AV-1	2396	158.55	86.46
AV-1 – Baseline	2391	2.34	55.06
Total Cholesterol (mg/dl)			
Baseline	2395	224.27	37.88
AV-1	2396	217.74	37.49
AV-1 – Baseline	2391	-6.58	26.73
LDL-C (mg/dl)			
Baseline	2352	133.63	34.81
AV-1	2354	126.71	34.21
AV-1 – Baseline	2328	-6.81	23.83
HDL-C (mg/dl)			
Baseline	2389	59.60	15.71
AV-1	2394	59.46	15.32
AV-1 – Baseline	2384	-0.10	8.81
HDL-2 (mg/dl)			
Baseline	2335	18.74	8.26
AV-1	2353	19.03	8.40
AV-1 – Baseline	2299	0.30	4.99
HDL-3 (mg/dl)			
Baseline	2337	41.00	9.05
AV-1	2354	40.48	8.58
AV-1 – Baseline	2302	-0.52	5.56
Lp(a) (mg/dl)			
Baseline	2364	25.72	26.57
AV-1	2365	25.13	26.22
AV-1 – Baseline	2335	-0.57	10.11

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

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

Data as of: February 28, 2001

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	58	0.06	0.04
AV-1	58	0.07	0.06
AV-1 – Baseline	58	0.01	0.04
Beta-Carotene (µg/ml)			
Baseline	58	0.28	0.26
AV-1	58	0.28	0.31
AV-1 – Baseline	58	0.00	0.20
Alpha-tocopherol (µg/ml)			
Baseline	58	17.17	8.17
AV-1	58	18.19	9.54
AV-1 – Baseline	58	1.02	5.53
Gamma-tocopherol (µg/ml)			
Baseline	58	2.19	1.25
AV-1	58	1.79	1.22
AV-1 – Baseline	58	-0.40	0.84
Beta-Cryptoxanthine (µg/ml)			
Baseline	58	0.06	0.04
AV-1	58	0.07	0.04
AV-1 - Baseline	58	0.01	0.04
Lycopene (µg/ml)			
Baseline	58	0.36	0.15
AV-1	58	0.36	0.16
AV-1 – Baseline	58	0.00	0.13
Lutein and Zeaxanthin (µg/ml)			
Baseline	58	0.20	0.09
AV-1	58	0.20	0.10
AV-1 – Baseline	58	0.00	0.06
Retinol (µg/ml)			
Baseline	58	0.61	0.15
AV-1	58	0.60	0.15
AV-1 – Baseline	58	-0.01	0.08

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

Data as of: February 28, 2001

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	56	136.93	32.88
AV-1	56	137.82	31.01
AV-1 - Baseline	55	0.93	18.31
Factor VII C (%)			
Baseline	56	128.36	28.02
AV-1	56	126.63	26.45
AV-1 - Baseline	55	-1.82	14.59
Fibrinogen (mg/dl)			
Baseline	56	307.23	67.02
AV-1	56	312.30	75.69
AV-1 - Baseline	55	5.11	54.50
Hormones/Other			
Glucose (mg/dl)			
Baseline	58	105.12	27.42
AV-1	58	102.09	21.15
AV-1 - Baseline	58	-3.03	17.51
Insulin (µIU/ml)			
Baseline	55	13.14	7.66
AV-1	56	12.07	6.17
AV-1 - Baseline	53	-1.07	4.66

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

Data as of: February 28, 2001

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	57	171.37	78.56
AV-1	57	171.88	88.15
AV-1 – Baseline	56	-1.00	52.10
Total Cholesterol (mg/dl)			
Baseline	57	219.81	36.74
AV-1	57	212.00	36.94
AV-1 – Baseline	56	-7.14	23.98
LDL-C (mg/dl)			
Baseline	56	129.00	34.37
AV-1	54	124.54	33.35
AV-1 – Baseline	53	-4.72	20.87
HDL-C (mg/dl)			
Baseline	57	56.32	16.26
AV-1	57	55.56	15.22
AV-1 – Baseline	56	-0.27	7.59
HDL-2 (mg/dl)			
Baseline	55	18.02	8.33
AV-1	56	17.16	7.84
AV-1 – Baseline	53	0.02	4.73
HDL-3 (mg/dl)			
Baseline	56	38.91	8.40
AV-1	56	37.96	8.26
AV-1 – Baseline	54	-0.20	4.97
Lp(a) (mg/dl)			
Baseline	56	19.29	20.21
AV-1	56	19.89	19.95
AV-1 – Baseline	55	0.67	9.60

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

Data as of: February 28, 2001

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	173	0.10	0.10
AV-1	173	0.10	0.10
AV-1 – Baseline	173	0.00	0.10
Beta-Carotene (µg/ml)			
Baseline	173	0.44	0.41
AV-1	173	0.48	0.53
AV-1 – Baseline	173	0.05	0.40
Alpha-tocopherol (µg/ml)			
Baseline	173	19.19	9.77
AV-1	173	19.43	11.00
AV-1 – Baseline	173	0.24	6.70
Gamma-tocopherol (µg/ml)			
Baseline	173	1.69	1.19
AV-1	173	1.31	0.98
AV-1 – Baseline	173	-0.38	0.85
Beta-Cryptoxanthine (µg/ml)			
Baseline	173	0.18	0.17
AV-1	173	0.19	0.18
AV-1 - Baseline	173	0.01	0.14
Lycopene (µg/ml)			
Baseline	173	0.38	0.20
AV-1	173	0.36	0.19
AV-1 – Baseline	173	-0.02	0.18
Lutein and Zeaxanthin (µg/ml)			
Baseline	173	0.27	0.12
AV-1	173	0.28	0.12
AV-1 – Baseline	173	0.01	0.09
Retinol (µg/ml)			
Baseline	173	0.61	0.15
AV-1	173	0.62	0.15
AV-1 – Baseline	173	0.01	0.09

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

Data as of: February 28, 2001

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	168	131.68	30.48
AV-1	165	130.78	29.41
AV-1 - Baseline	160	-0.90	20.53
Factor VII C (%)			
Baseline	168	126.55	24.81
AV-1	165	125.51	25.75
AV-1 - Baseline	160	-1.48	17.75
Fibrinogen (mg/dl)			
Baseline	169	292.37	57.49
AV-1	165	285.18	57.29
AV-1 - Baseline	161	-6.73	53.28
Hormones/Other			
Glucose (mg/dl)			
Baseline	173	100.50	18.39
AV-1	173	100.83	23.90
AV-1 - Baseline	173	0.32	19.33
Insulin (μIU/ml)			
Baseline	169	10.28	5.76
AV-1	167	10.03	5.93
AV-1 - Baseline	163	-0.28	3.79

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

Data as of: February 28, 2001

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	172	172.98	93.78
AV-1	173	173.16	94.65
AV-1 – Baseline	172	0.03	60.28
Total Cholesterol (mg/dl)			
Baseline	172	220.86	36.28
AV-1	173	213.32	33.53
AV-1 – Baseline	172	-7.55	24.43
LDL-C (mg/dl)			
Baseline	166	128.52	35.31
AV-1	167	120.96	30.35
AV-1 – Baseline	163	-8.54	25.14
HDL-C (mg/dl)			
Baseline	172	58.33	13.84
AV-1	173	59.65	13.97
AV-1 – Baseline	172	1.26	8.41
HDL-2 (mg/dl)			
Baseline	168	18.40	7.42
AV-1	171	19.38	7.30
AV-1 – Baseline	167	1.05	4.51
HDL-3 (mg/dl)			
Baseline	168	40.17	8.10
AV-1	171	40.36	8.29
AV-1 – Baseline	167	0.22	5.35
Lp(a) (mg/dl)			
Baseline	169	18.46	16.87
AV-1	172	16.12	13.83
AV-1 – Baseline	169	-2.16	12.82

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

Data as of: February 28, 2001

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	662	0.06	0.06
AV-1	661	0.07	0.07
AV-1 – Baseline	661	0.00	0.06
Beta-Carotene (µg/ml)			
Baseline	662	0.32	0.35
AV-1	661	0.32	0.30
AV-1 – Baseline	661	0.00	0.22
Alpha-tocopherol (µg/ml)			
Baseline	662	14.05	6.14
AV-1	661	14.53	6.09
AV-1 – Baseline	661	0.49	4.74
Gamma-tocopherol (µg/ml)			
Baseline	662	2.47	1.32
AV-1	661	2.26	1.32
AV-1 – Baseline	661	-0.20	0.91
Beta-Cryptoxanthine (µg/ml)			
Baseline	662	0.09	0.06
AV-1	661	0.09	0.06
AV-1 - Baseline	661	0.00	0.06
Lycopene (µg/ml)			
Baseline	662	0.39	0.21
AV-1	661	0.38	0.20
AV-1 – Baseline	661	-0.01	0.19
Lutein and Zeaxanthin (µg/ml)			
Baseline	662	0.24	0.11
AV-1	661	0.25	0.11
AV-1 – Baseline	661	0.01	0.08
Retinol (µg/ml)			
Baseline	662	0.55	0.15
AV-1	661	0.55	0.14
AV-1 – Baseline	661	0.01	0.09

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

Data as of: February 28, 2001

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	641	114.56	27.16
AV-1	645	115.55	27.80
AV-1 - Baseline	625	1.01	20.67
Factor VII C (%)			
Baseline	623	117.84	29.76
AV-1	633	115.92	26.50
AV-1 - Baseline	600	-2.17	20.92
Fibrinogen (mg/dl)			
Baseline	641	322.81	67.49
AV-1	646	320.36	67.18
AV-1 - Baseline	626	-3.27	49.35
Hormones/Other			
Glucose (mg/dl)			
Baseline	662	106.13	34.86
AV-1	658	106.85	38.21
AV-1 - Baseline	658	0.78	26.73
Insulin (μIU/ml)			
Baseline	654	13.90	10.08
AV-1	652	13.91	11.05
AV-1 - Baseline	645	-0.21	6.18

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

Data as of: February 28, 2001

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	662	117.39	51.60
AV-1	661	117.93	47.71
AV-1 – Baseline	661	0.59	36.51
Total Cholesterol (mg/dl)			
Baseline	662	220.05	40.23
AV-1	661	216.80	41.72
AV-1 – Baseline	661	-3.28	26.06
LDL-C (mg/dl)			
Baseline	662	137.68	37.91
AV-1	660	133.37	39.46
AV-1 – Baseline	660	-4.39	24.32
HDL-C (mg/dl)			
Baseline	662	58.87	14.66
AV-1	661	59.90	14.99
AV-1 – Baseline	661	1.00	8.21
HDL-2 (mg/dl)			
Baseline	653	18.70	7.75
AV-1	654	19.51	8.67
AV-1 – Baseline	646	0.78	5.00
HDL-3 (mg/dl)			
Baseline	653	40.14	8.36
AV-1	654	40.33	7.97
AV-1 – Baseline	646	0.14	5.18
Lp(a) (mg/dl)			
Baseline	652	37.62	27.74
AV-1	657	37.83	28.27
AV-1 – Baseline	648	0.01	11.67

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

Data as of: February 28, 2001

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	259	0.09	0.10
AV-1	259	0.09	0.07
AV-1 – Baseline	259	0.00	0.10
Beta-Carotene (µg/ml)			
Baseline	259	0.30	0.42
AV-1	259	0.29	0.28
AV-1 – Baseline	259	-0.02	0.35
Alpha-tocopherol (µg/ml)			
Baseline	259	15.82	6.83
AV-1	259	17.07	7.72
AV-1 – Baseline	259	1.25	5.96
Gamma-tocopherol (µg/ml)			
Baseline	259	2.10	1.34
AV-1	259	1.84	1.33
AV-1 – Baseline	259	-0.26	0.94
Beta-Cryptoxanthine (µg/ml)			
Baseline	259	0.11	0.10
AV-1	259	0.11	0.10
AV-1 - Baseline	259	-0.01	0.09
Lycopene (µg/ml)			
Baseline	259	0.42	0.20
AV-1	259	0.40	0.18
AV-1 – Baseline	259	-0.02	0.16
Lutein and Zeaxanthin (µg/ml)			
Baseline	259	0.20	0.10
AV-1	259	0.20	0.10
AV-1 – Baseline	259	0.00	0.08
Retinol (µg/ml)			
Baseline	259	0.55	0.13
AV-1	259	0.56	0.13
AV-1 – Baseline	259	0.02	0.09

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

Data as of: February 28, 2001

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	251	122.21	27.55
AV-1	247	124.00	28.68
AV-1 - Baseline	240	1.82	21.39
Factor VII C (%)			
Baseline	244	121.06	27.22
AV-1	237	121.63	27.39
AV-1 - Baseline	228	0.28	21.13
Fibrinogen (mg/dl)			
Baseline	251	307.49	63.65
AV-1	246	307.33	67.35
AV-1 - Baseline	239	-0.21	55.94
Hormones/Other			
Glucose (mg/dl)			
Baseline	258	102.58	32.47
AV-1	258	104.22	34.85
AV-1 - Baseline	257	1.54	21.05
Insulin (μIU/ml)			
Baseline	253	13.73	8.87
AV-1	256	13.33	11.94
AV-1 - Baseline	250	-0.44	8.86

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

Data as of: February 28, 2001

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	259	163.03	75.44
AV-1	259	165.46	77.05
AV-1 – Baseline	259	2.43	54.62
Total Cholesterol (mg/dl)			
Baseline	259	216.49	35.95
AV-1	259	212.15	35.84
AV-1 – Baseline	259	-4.34	25.16
LDL-C (mg/dl)			
Baseline	255	129.87	32.98
AV-1	254	124.56	33.61
AV-1 – Baseline	252	-5.70	22.53
HDL-C (mg/dl)			
Baseline	259	54.18	12.37
AV-1	259	55.54	12.60
AV-1 – Baseline	259	1.37	7.86
HDL-2 (mg/dl)			
Baseline	256	16.17	6.60
AV-1	256	16.93	6.85
AV-1 – Baseline	254	0.78	4.83
HDL-3 (mg/dl)			
Baseline	256	37.94	7.53
AV-1	256	38.61	7.57
AV-1 – Baseline	254	0.67	5.13
Lp(a) (mg/dl)			
Baseline	259	20.31	23.07
AV-1	255	19.15	20.12
AV-1 – Baseline	255	-0.98	7.89

Table 3.9 (continued)
Blood Specimen Analysis: White Women

Data as of: February 28, 2001

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (μg/ml)			
Baseline	1198	0.08	0.08
AV-1	1201	0.08	0.07
AV-1 – Baseline	1196	0.00	0.06
Beta-Carotene (μg/ml)			
Baseline	1198	0.30	0.27
AV-1	1201	0.30	0.27
AV-1 – Baseline	1196	0.01	0.21
Alpha-tocopherol (μg/ml)			
Baseline	1198	16.36	6.87
AV-1	1201	17.16	7.43
AV-1 – Baseline	1196	0.78	5.45
Gamma-tocopherol (μg/ml)			
Baseline	1198	2.19	1.44
AV-1	1200	1.80	1.29
AV-1 – Baseline	1195	-0.39	0.93
Beta-Cryptoxanthine (μg/ml)			
Baseline	1198	0.08	0.06
AV-1	1200	0.09	0.07
AV-1 - Baseline	1195	0.00	0.05
Lycopene (μg/ml)			
Baseline	1198	0.42	0.19
AV-1	1201	0.41	0.19
AV-1 – Baseline	1196	-0.01	0.16
Lutein and Zeaxanthin (μg/ml)			
Baseline	1198	0.21	0.10
AV-1	1201	0.21	0.10
AV-1 – Baseline	1196	0.00	0.07
Retinol (μg/ml)			
Baseline	1198	0.63	0.15
AV-1	1201	0.63	0.15
AV-1 – Baseline	1196	0.00	0.10

Table 3.9 (continued)
Blood Specimen Analysis: White Women

Data as of: February 28, 2001

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	1161	133.34	33.08
AV-1	1147	132.97	33.16
AV-1 - Baseline	1124	-0.48	22.68
Factor VII C (%)			
Baseline	1143	131.53	30.76
AV-1	1139	128.86	30.66
AV-1 - Baseline	1098	-3.15	22.73
Fibrinogen (mg/dl)			
Baseline	1154	297.04	59.63
AV-1	1141	294.70	58.47
AV-1 - Baseline	1112	-2.20	49.35
Hormones/Other			
Glucose (mg/dl)			
Baseline	1199	99.28	25.24
AV-1	1197	97.56	23.91
AV-1 - Baseline	1193	-1.71	17.74
Insulin (μIU/ml)			
Baseline	1167	11.12	6.88
AV-1	1161	10.82	10.35
AV-1 - Baseline	1133	-0.30	8.97

Table 3.9 (continued)
Blood Specimen Analysis: White Women

Data as of: February 28, 2001

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	1200	159.77	88.05
AV-1	1201	162.71	89.09
AV-1 – Baseline	1198	2.73	56.80
Total Cholesterol (mg/dl)			
Baseline	1200	225.30	37.65
AV-1	1201	218.26	37.10
AV-1 – Baseline	1198	-7.10	26.95
LDL-C (mg/dl)			
Baseline	1170	133.48	34.42
AV-1	1174	126.11	33.53
AV-1 – Baseline	1157	-7.18	23.80
HDL-C (mg/dl)			
Baseline	1194	60.04	15.97
AV-1	1199	59.63	15.50
AV-1 – Baseline	1191	-0.37	8.92
HDL-2 (mg/dl)			
Baseline	1158	18.88	8.37
AV-1	1171	19.07	8.44
AV-1 – Baseline	1134	0.19	4.99
HDL-3 (mg/dl)			
Baseline	1159	41.32	9.21
AV-1	1172	40.63	8.71
AV-1 – Baseline	1136	-0.70	5.62
Lp(a) (mg/dl)			
Baseline	1182	24.79	26.44
AV-1	1181	24.21	26.13
AV-1 – Baseline	1164	-0.59	9.91

Table 3.9 (continued)
Blood Specimen Analysis: Other/Unspecified Women

Data as of: February 28, 2001

	N	Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	46	0.08	0.08
AV-1	46	0.08	0.08
AV-1 – Baseline	46	0.00	0.06
Beta-Carotene (µg/ml)			
Baseline	46	0.26	0.22
AV-1	46	0.27	0.21
AV-1 – Baseline	46	0.01	0.13
Alpha-tocopherol (µg/ml)			
Baseline	46	17.50	9.60
AV-1	46	17.17	9.60
AV-1 – Baseline	46	-0.33	6.67
Gamma-tocopherol (µg/ml)			
Baseline	46	2.16	1.17
AV-1	46	2.03	1.07
AV-1 – Baseline	46	-0.13	0.77
Beta-Cryptoxanthine (µg/ml)			
Baseline	46	0.11	0.12
AV-1	46	0.10	0.06
AV-1 - Baseline	46	-0.01	0.08
Lycopene (µg/ml)			
Baseline	46	0.40	0.19
AV-1	46	0.40	0.20
AV-1 – Baseline	46	0.00	0.18
Lutein and Zeaxanthin (µg/ml)			
Baseline	46	0.22	0.12
AV-1	46	0.23	0.16
AV-1 – Baseline	46	0.01	0.10
Retinol (µg/ml)			
Baseline	46	0.58	0.18
AV-1	46	0.58	0.16
AV-1 – Baseline	46	0.00	0.11

Table 3.9 (continued)
Blood Specimen Analysis: Other/Unspecified Women

Data as of: February 28, 2001

	N	Mean	S.D.
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	46	122.74	28.68
AV-1	44	117.86	27.92
AV-1 - Baseline	44	-2.73	24.99
Factor VII C (%)			
Baseline	46	124.30	30.16
AV-1	43	120.81	25.01
AV-1 - Baseline	43	-0.07	22.21
Fibrinogen (mg/dl)			
Baseline	46	308.20	67.60
AV-1	44	298.70	65.46
AV-1 - Baseline	44	-9.45	40.42
Hormones/Other			
Glucose (mg/dl)			
Baseline	46	100.41	25.86
AV-1	46	101.07	25.92
AV-1 - Baseline	46	0.65	12.11
Insulin (μIU/ml)			
Baseline	46	10.32	6.16
AV-1	46	10.80	5.71
AV-1 - Baseline	46	0.49	3.35

Table 3.9 (continued)
Blood Specimen Analysis: Other/Unspecified Women

Data as of: February 28, 2001

	N	Mean	S.D.
Lipoproteins			
Triglyceride (mg/dl)			
Baseline	45	163.67	104.17
AV-1	45	158.40	78.08
AV-1 – Baseline	45	-5.27	60.74
Total Cholesterol (mg/dl)			
Baseline	45	231.47	37.47
AV-1	45	228.58	35.36
AV-1 – Baseline	45	-2.89	26.47
LDL-C (mg/dl)			
Baseline	43	139.28	35.65
AV-1	45	135.71	34.86
AV-1 – Baseline	43	-1.79	24.40
HDL-C (mg/dl)			
Baseline	45	59.96	17.37
AV-1	45	61.11	15.91
AV-1 – Baseline	45	1.16	9.92
HDL-2 (mg/dl)			
Baseline	45	20.09	11.10
AV-1	45	20.64	10.40
AV-1 – Baseline	45	0.56	6.23
HDL-3 (mg/dl)			
Baseline	45	39.87	7.70
AV-1	45	40.47	7.13
AV-1 – Baseline	45	0.60	6.05
Lp(a) (mg/dl)			
Baseline	46	25.09	31.03
AV-1	44	21.82	21.01
AV-1 – Baseline	44	-0.64	9.28

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

Data as of: February 28, 2001

	N	Mean	S.D.
Whole Body Scan			
Baseline	3621	1.03	0.11
AV1	3277	1.03	0.11
AV3	3075	1.04	0.11
AV6	979	1.05	0.12
AV1 % Change from baseline BMD[2]	3249	0.18	2.49
AV3 % Change from baseline BMD[3]	3049	1.32	3.62
AV6 % Change from baseline BMD[4]	968	2.32	4.99
Spine Scan			
Baseline	3538	0.99	0.17
AV1	3207	1.00	0.17
AV3	3009	1.01	0.17
AV6	976	1.01	0.17
AV1 % Change from baseline BMD	3184	0.72	3.84
AV3 % Change from baseline BMD	2986	2.14	5.23
AV6 % Change from baseline BMD	964	3.10	6.69
Hip Scan			
Baseline	3620	0.87	0.14
AV1	3276	0.87	0.14
AV3	3076	0.88	0.14
AV6	999	0.88	0.14
AV1 % Change from baseline BMD	3258	-0.04	2.77
AV3 % Change from baseline BMD	3059	1.01	4.18
AV6 % Change from baseline BMD	992	1.03	5.04

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

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

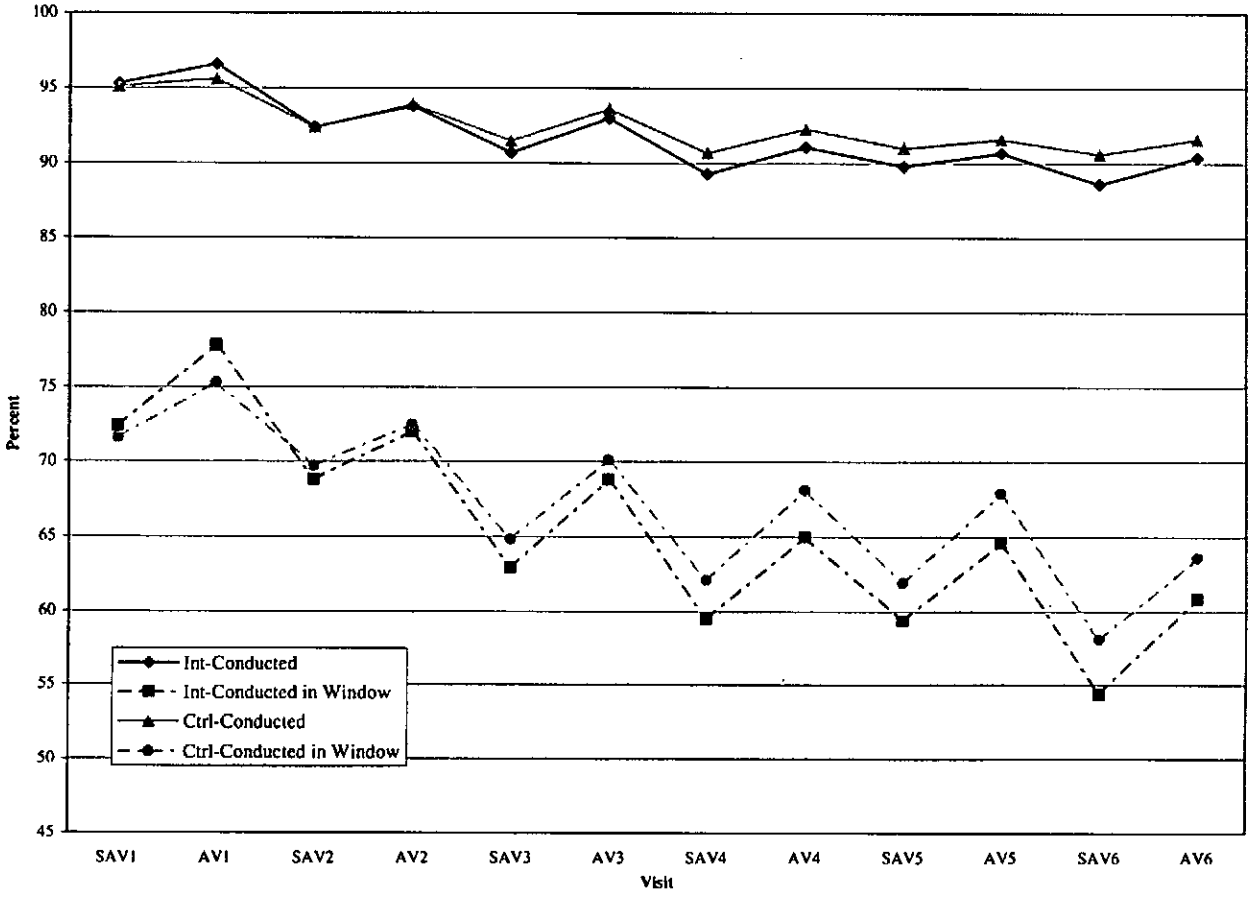
Data as of: February 28, 2001

	Black/African American			Hispanic/Latino			White		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan									
Baseline	582	1.07	0.11	195	1.05	0.11	2787	1.01	0.11
AV1	512	1.09	0.11	152	1.05	0.11	2570	1.01	0.10
AV3	487	1.10	0.12	152	1.05	0.12	2394	1.03	0.11
AV6	90	1.09	0.11	38	1.10	0.14	840	1.05	0.12
AV1 % Change from baseline BMD[2]	506	0.99	2.96	151	-0.33	2.24	2550	0.06	2.37
AV3 % Change from baseline BMD[3]	482	2.08	2.92	151	0.65	4.45	2375	1.21	3.68
AV6 % Change from baseline BMD[4]	90	0.07	3.31	38	4.00	5.70	829	2.49	5.05
Spine Scan									
Baseline	577	1.07	0.18	190	0.98	0.16	2714	0.98	0.16
AV1	507	1.08	0.18	148	0.98	0.16	2509	0.98	0.16
AV3	481	1.09	0.19	149	0.96	0.15	2337	1.00	0.17
AV6	95	1.11	0.19	38	0.97	0.15	832	1.00	0.17
AV1 % Change from baseline BMD	502	0.81	4.31	147	0.15	4.36	2493	0.74	3.69
AV3 % Change from baseline BMD	477	2.13	5.22	148	-0.11	6.24	2320	2.30	5.13
AV6 % Change from baseline BMD	95	1.46	7.39	37	1.41	5.58	821	3.38	6.65
Hip Scan									
Baseline	584	0.97	0.15	195	0.88	0.14	2784	0.85	0.13
AV1	514	0.98	0.15	152	0.88	0.14	2567	0.85	0.13
AV3	487	0.99	0.15	152	0.88	0.15	2395	0.86	0.13
AV6	95	0.98	0.14	38	0.90	0.16	855	0.87	0.13
AV1 % Change from baseline BMD	510	0.85	2.87	151	-0.62	2.94	2555	-0.19	2.67
AV3 % Change from baseline BMD	483	1.48	3.77	151	0.89	5.85	2384	0.92	4.10
AV6 % Change from baseline BMD	95	-1.44	4.86	38	2.26	4.41	848	1.26	5.01

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

Table 3.12
Adherence to Follow-up Contacts

Data as of: February 28, 2001



Contact		Due N	Conducted N	Conducted %	Conducted in window N	Conducted in window %
Semi-Annual Contact 1	Intervention	19542	18628	95.3%	14151	72.4%
	Control	29295	27862	95.1%	20987	71.6%
Annual Visit 1	Intervention	19542	18887	96.6%	15198	77.8%
	Control	29295	28019	95.6%	22054	75.3%
Semi-Annual Contact 2	Intervention	19542	18064	92.4%	13447	68.8%
	Control	29295	27080	92.4%	20431	69.7%
Annual Visit 2	Intervention	19542	18334	93.8%	14063	72.0%
	Control	29295	27507	93.9%	21239	72.5%
Semi-Annual Contact 3	Intervention	19539	17731	90.7%	12291	62.9%
	Control	29290	26786	91.5%	18972	64.8%
Annual Visit 3	Intervention	18088	16822	93.0%	12445	68.8%
	Control	27135	25400	93.6%	19010	70.1%
Semi-Annual Contact 4	Intervention	15609	13940	89.3%	9286	59.5%
	Control	23422	21234	90.7%	14548	62.1%
Annual Visit 4	Intervention	12668	11543	91.1%	8233	65.0%
	Control	18980	17528	92.3%	12928	68.1%
Semi-Annual Contact 5	Intervention	9448	8489	89.8%	5616	59.4%
	Control	14188	12907	91.0%	8781	61.9%
Annual Visit 5	Intervention	6598	5983	90.7%	4265	64.6%
	Control	9863	9031	91.6%	6700	67.9%
Semi-Annual Visit 6	Intervention	4337	3841	88.6%	2359	54.4%
	Control	6472	5863	90.6%	3760	58.1%
Annual Visit 6	Intervention	2667	2412	90.4%	1623	60.9%
	Control	3977	3642	91.6%	2530	63.6%

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

Data as of: February 28, 2001

	DM Participants (N = 48837)	
	N	%
Vital Status/Participation		
Deceased	812	1.7
Alive: Current Participation[1]	45166	92.5
Alive: Recent Participation[2]	1245	2.5
Alive: Past/Unknown Participation[3]	44	0.1
Stopped Follow-Up[4]	867	1.8
Lost to Follow-Up[5]	703	1.4

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

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

Data as of: February 28, 2001

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	48837		6961		11044		22714		8118	
Mean follow-up (months)	50.7		57.0		52.9		48.6		48.2	
Cancer										
Breast cancer[1]	931	(0.45%)	97	(0.29%)	210	(0.43%)	450	(0.49%)	174	(0.53%)
Invasive breast cancer	733	(0.36%)	65	(0.20%)	168	(0.34%)	360	(0.39%)	140	(0.43%)
Non-invasive breast cancer	209	(0.10%)	32	(0.10%)	46	(0.09%)	95	(0.10%)	36	(0.11%)
Ovary cancer	92	(0.04%)	15	(0.05%)	18	(0.04%)	36	(0.04%)	23	(0.07%)
Endometrial cancer[2]	130	(0.11%)	18	(0.10%)	31	(0.10%)	55	(0.11%)	26	(0.15%)
Colorectal cancer	244	(0.12%)	15	(0.05%)	44	(0.09%)	124	(0.13%)	61	(0.19%)
Other cancer[3]	900	(0.44%)	79	(0.24%)	149	(0.31%)	453	(0.49%)	219	(0.67%)
Total cancer	2242	(1.09%)	218	(0.66%)	437	(0.90%)	1095	(1.19%)	492	(1.51%)
Cardiovascular										
CHD[4]	604	(0.29%)	36	(0.11%)	64	(0.13%)	294	(0.32%)	210	(0.64%)
CHD death[5]	162	(0.08%)	8	(0.02%)	11	(0.02%)	81	(0.09%)	62	(0.19%)
Total MI[6]	483	(0.23%)	29	(0.09%)	57	(0.12%)	232	(0.25%)	165	(0.51%)
Clinical MI	464	(0.22%)	25	(0.08%)	57	(0.12%)	221	(0.24%)	161	(0.49%)
Definite Silent MI	30	(0.01%)	5	(0.02%)	1	(0.00%)	17	(0.02%)	7	(0.02%)
Possible Silent MI	105	(0.05%)	10	(0.03%)	21	(0.04%)	45	(0.05%)	29	(0.09%)
Angina	806	(0.39%)	50	(0.15%)	102	(0.21%)	414	(0.45%)	240	(0.74%)
CABG/PTCA	714	(0.35%)	35	(0.11%)	90	(0.18%)	366	(0.40%)	223	(0.68%)
Carotid artery disease	139	(0.07%)	5	(0.02%)	13	(0.03%)	70	(0.08%)	51	(0.16%)
Congestive heart failure	397	(0.19%)	21	(0.06%)	40	(0.08%)	179	(0.19%)	157	(0.48%)
Stroke	408	(0.20%)	18	(0.05%)	40	(0.08%)	190	(0.21%)	160	(0.49%)
PVD	98	(0.05%)	3	(0.01%)	11	(0.02%)	46	(0.05%)	38	(0.12%)
CHD[4]/Possible Silent MI	693	(0.34%)	46	(0.14%)	80	(0.16%)	332	(0.36%)	235	(0.72%)
Coronary disease[7]	1701	(0.82%)	105	(0.32%)	204	(0.42%)	846	(0.92%)	546	(1.67%)
Total CVD	2191	(1.06%)	124	(0.38%)	255	(0.52%)	1082	(1.18%)	730	(2.24%)
Fractures										
Hip fracture	169	(0.08%)	6	(0.02%)	15	(0.03%)	70	(0.08%)	78	(0.24%)
Vertebral fracture	190	(0.09%)	10	(0.03%)	19	(0.04%)	78	(0.08%)	83	(0.25%)
Other fracture[3]	2589	(1.26%)	323	(0.98%)	515	(1.06%)	1218	(1.33%)	533	(1.63%)
Total fracture	2869	(1.39%)	336	(1.02%)	545	(1.12%)	1332	(1.45%)	656	(2.01%)
Deaths										
Cardiovascular deaths	215	(0.10%)	9	(0.03%)	16	(0.03%)	102	(0.11%)	88	(0.27%)
Cancer deaths	366	(0.18%)	24	(0.07%)	46	(0.09%)	183	(0.20%)	113	(0.35%)
Deaths: other known cause	97	(0.05%)	6	(0.02%)	13	(0.03%)	40	(0.04%)	38	(0.12%)
Deaths: unknown cause	33	(0.02%)	4	(0.01%)	2	(0.00%)	15	(0.02%)	12	(0.04%)
Deaths: not yet adjudicated	101	(0.05%)	5	(0.02%)	11	(0.02%)	45	(0.05%)	40	(0.12%)
Total death	812	(0.39%)	48	(0.15%)	88	(0.18%)	385	(0.42%)	291	(0.89%)

[1] Excludes four 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, definite silent MI, and CHD death.
[5] "CHD death" includes definite and possible CHD death and "other" and "unknown" cardiovascular death.
[6] "Total MI" includes clinical MI and definite silent MI.
[7] "Coronary disease" includes clinical MI, definite silent MI, possible silent MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

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

Data as of: February 28, 2001

Outcome	Race/Ethnicity: American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	203	1105	5262	1846	39763	658
Mean follow-up (months)	50.3	46.8	49.1	48.0	51.2	46.6
Cancer						
Breast cancer[1]	2 (0.24%)	18 (0.42%)	58 (0.27%)	22 (0.30%)	824 (0.49%)	7 (0.27%)
Invasive breast cancer	2 (0.24%)	16 (0.37%)	43 (0.20%)	16 (0.22%)	653 (0.39%)	3 (0.12%)
Non-invasive breast cancer	0 (0.00%)	2 (0.05%)	17 (0.08%)	6 (0.08%)	180 (0.11%)	4 (0.16%)
Ovary cancer	1 (0.12%)	0 (0.00%)	8 (0.04%)	2 (0.03%)	80 (0.05%)	1 (0.04%)
Endometrial cancer[2]	0 (0.00%)	1 (0.04%)	9 (0.09%)	7 (0.18%)	111 (0.11%)	2 (0.14%)
Colorectal cancer	2 (0.24%)	5 (0.12%)	30 (0.14%)	11 (0.15%)	192 (0.11%)	4 (0.16%)
Other cancer[3]	2 (0.24%)	9 (0.21%)	67 (0.31%)	18 (0.24%)	794 (0.47%)	10 (0.39%)
Total cancer	7 (0.82%)	33 (0.77%)	168 (0.78%)	57 (0.77%)	1955 (1.15%)	22 (0.86%)
Cardiovascular						
CHD[4]	1 (0.12%)	1 (0.02%)	61 (0.28%)	8 (0.11%)	527 (0.31%)	6 (0.23%)
CHD death[5]	1 (0.12%)	0 (0.00%)	21 (0.10%)	1 (0.01%)	136 (0.08%)	3 (0.12%)
Total MI[6]	0 (0.00%)	1 (0.02%)	49 (0.23%)	7 (0.09%)	421 (0.25%)	5 (0.20%)
Clinical MI	0 (0.00%)	1 (0.02%)	45 (0.21%)	7 (0.09%)	407 (0.24%)	4 (0.16%)
Definite Silent MI	0 (0.00%)	0 (0.00%)	4 (0.02%)	0 (0.00%)	25 (0.01%)	1 (0.04%)
Possible Silent MI	0 (0.00%)	3 (0.07%)	11 (0.05%)	2 (0.03%)	89 (0.05%)	0 (0.00%)
Angina	2 (0.24%)	9 (0.21%)	109 (0.51%)	22 (0.30%)	654 (0.39%)	10 (0.39%)
CABG/PTCA	0 (0.00%)	5 (0.12%)	66 (0.31%)	13 (0.18%)	625 (0.37%)	5 (0.20%)
Carotid artery disease	2 (0.24%)	3 (0.07%)	13 (0.06%)	1 (0.01%)	118 (0.07%)	2 (0.08%)
Congestive heart failure	0 (0.00%)	0 (0.00%)	70 (0.32%)	5 (0.07%)	317 (0.19%)	5 (0.20%)
Stroke	3 (0.35%)	9 (0.21%)	49 (0.23%)	8 (0.11%)	332 (0.20%)	7 (0.27%)
PVD	1 (0.12%)	0 (0.00%)	19 (0.09%)	1 (0.01%)	76 (0.04%)	1 (0.04%)
CHD[4]/Possible Silent MI	1 (0.12%)	4 (0.09%)	71 (0.33%)	10 (0.14%)	601 (0.35%)	6 (0.23%)
Coronary disease[7]	3 (0.35%)	14 (0.33%)	226 (1.05%)	34 (0.46%)	1405 (0.83%)	19 (0.74%)
Total CVD	8 (0.94%)	24 (0.56%)	277 (1.29%)	43 (0.58%)	1812 (1.07%)	27 (1.06%)
Fractures						
Hip fracture	0 (0.00%)	0 (0.00%)	7 (0.03%)	1 (0.01%)	159 (0.09%)	2 (0.08%)
Vertebral fracture	0 (0.00%)	4 (0.09%)	1 (0.00%)	4 (0.05%)	180 (0.11%)	1 (0.04%)
Other fracture[3]	10 (1.18%)	39 (0.91%)	140 (0.65%)	57 (0.77%)	2316 (1.37%)	27 (1.06%)
Total fracture	10 (1.18%)	43 (1.00%)	147 (0.68%)	61 (0.83%)	2578 (1.52%)	30 (1.17%)
Deaths						
Cardiovascular deaths	1 (0.12%)	2 (0.05%)	28 (0.13%)	1 (0.01%)	179 (0.11%)	4 (0.16%)
Cancer deaths	1 (0.12%)	1 (0.02%)	30 (0.14%)	7 (0.09%)	321 (0.19%)	6 (0.23%)
Deaths: other known cause	3 (0.35%)	0 (0.00%)	13 (0.06%)	2 (0.03%)	78 (0.05%)	1 (0.04%)
Deaths: unknown cause	0 (0.00%)	0 (0.00%)	5 (0.02%)	1 (0.01%)	27 (0.02%)	0 (0.00%)
Deaths: not yet adjudicated	0 (0.00%)	2 (0.05%)	13 (0.06%)	2 (0.03%)	83 (0.05%)	1 (0.04%)
Total death	5 (0.59%)	5 (0.12%)	89 (0.41%)	13 (0.18%)	688 (0.41%)	12 (0.47%)

[1] Excludes four 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, definite silent MI, and CHD death.
[5] "CHD death" includes definite and possible CHD death and "other" and "unknown" cardiovascular death.
[6] "Total MI" includes clinical MI and definite silent MI.
[7] "Coronary disease" includes clinical MI, definite silent MI, possible silent MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

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

Data as of: February 28, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48837	6961	11044	22714	8118
Mean follow-up (months)	50.7	57.0	52.9	48.6	48.2
Hospitalizations					
Ever	14848 (7.20%)	1602 (4.85%)	2794 (5.74%)	7140 (7.77%)	3312 (10.15%)
Two or more	5946 (2.88%)	568 (1.72%)	1010 (2.07%)	2806 (3.05%)	1562 (4.79%)
Other					
DVT[1]	260 (0.13%)	20 (0.06%)	43 (0.09%)	118 (0.13%)	79 (0.25%)
PE	151 (0.07%)	10 (0.03%)	25 (0.05%)	76 (0.08%)	40 (0.12%)
Diabetes (treated)	1749 (0.89%)	244 (0.76%)	399 (0.85%)	806 (0.92%)	300 (0.97%)
Gallbladder disease[2]	2073 (1.20%)	332 (1.13%)	483 (1.16%)	951 (1.26%)	307 (1.17%)
Hysterectomy	936 (0.80%)	144 (0.77%)	211 (0.71%)	424 (0.83%)	157 (0.88%)
Glaucoma	2532 (1.27%)	252 (0.77%)	467 (0.98%)	1261 (1.43%)	552 (1.83%)
Osteoporosis	5353 (2.75%)	524 (1.62%)	932 (1.98%)	2684 (3.12%)	1213 (4.16%)
Osteoarthritis[3]	5179 (4.16%)	713 (3.01%)	1179 (3.65%)	2407 (4.60%)	880 (5.49%)
Rheumatoid arthritis	1556 (0.78%)	221 (0.69%)	366 (0.77%)	690 (0.78%)	279 (0.90%)
Intestinal polyps	3517 (1.83%)	437 (1.36%)	754 (1.63%)	1727 (2.04%)	599 (2.06%)
Lupus	256 (0.12%)	44 (0.13%)	53 (0.11%)	125 (0.14%)	34 (0.10%)
Kidney Stones[3]	574 (0.38%)	82 (0.37%)	127 (0.37%)	278 (0.41%)	87 (0.36%)
Cataracts[3]	7509 (5.52%)	388 (1.71%)	1128 (3.29%)	4194 (6.79%)	1799 (10.49%)
Pills for hypertension	6323 (4.38%)	856 (3.21%)	1434 (3.89%)	2910 (4.72%)	1123 (5.80%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African Am	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	203	1105	5262	1846	39763	658
Mean follow-up (months)	50.3	46.8	49.1	48.0	51.2	46.6
Hospitalizations						
Ever	55 (6.46%)	188 (4.37%)	1578 (7.32%)	447 (6.06%)	12405 (7.31%)	175 (6.85%)
Two or more	32 (3.76%)	61 (1.42%)	641 (2.97%)	155 (2.10%)	4996 (2.95%)	61 (2.39%)
Other						
DVT[1]	0 (0.00%)	0 (0.00%)	23 (0.11%)	3 (0.04%)	231 (0.14%)	3 (0.12%)
PE	1 (0.12%)	1 (0.02%)	11 (0.05%)	2 (0.03%)	132 (0.08%)	4 (0.16%)
Diabetes (treated)	13 (1.64%)	52 (1.28%)	348 (1.82%)	98 (1.42%)	1214 (0.74%)	24 (0.99%)
Gallbladder disease[2]	9 (1.48%)	35 (0.90%)	167 (0.87%)	75 (1.34%)	1757 (1.24%)	30 (1.38%)
Hysterectomy	4 (1.00%)	20 (0.73%)	65 (0.68%)	33 (0.84%)	810 (0.82%)	4 (0.28%)
Glaucoma	10 (1.23%)	53 (1.28%)	362 (1.80%)	83 (1.16%)	1995 (1.22%)	29 (1.20%)
Osteoporosis	22 (2.72%)	118 (2.90%)	258 (1.24%)	186 (2.71%)	4694 (2.94%)	75 (3.17%)
Osteoarthritis[3]	24 (5.05%)	103 (3.35%)	532 (4.20%)	222 (4.52%)	4233 (4.16%)	65 (4.22%)
Rheumatoid arthritis	13 (1.70%)	27 (0.65%)	288 (1.43%)	130 (1.85%)	1076 (0.66%)	22 (0.91%)
Intestinal polyps	19 (2.42%)	70 (1.77%)	381 (1.89%)	113 (1.60%)	2876 (1.82%)	58 (2.47%)
Lupus	3 (0.36%)	4 (0.09%)	34 (0.16%)	6 (0.08%)	206 (0.12%)	3 (0.12%)
Kidney Stones[3]	4 (0.68%)	12 (0.38%)	53 (0.34%)	29 (0.53%)	467 (0.38%)	9 (0.48%)
Cataracts[3]	34 (6.27%)	154 (5.30%)	713 (5.02%)	254 (4.86%)	6244 (5.61%)	110 (6.43%)
Pills for hypertension	23 (4.24%)	140 (4.85%)	731 (6.75%)	264 (4.80%)	5091 (4.14%)	74 (4.26%)

[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 3.16
Sensitivity of DM Study Power to Adherence Assumptions[1]

Outcome	Year	Intervention Effect[1] (%)	Percentage of Cases[2]		Power (%)		
			Control	Intervention	Design[3]	Revised Adherence[4]	Revised Goal[5]
Breast Cancer							
	2001	11	1.98	1.86	28	18	19
		12	1.99	1.85	35	22	23
		14	1.99	1.83	44	27	29
	2004	11	2.86	2.61	63	46	50
		12	2.86	2.57	75	56	62
		14	2.86	2.54	85[5]	67	73
Colorectal Cancer							
	2001	18	1.08	0.97	37	24	25
		20	1.08	0.96	45	28	30
		22	1.09	0.95	52	34	36
	2004	18	1.64	1.40	83	65	70
		20	1.63	1.37	90	75	80
		22	1.63	1.24	95	83	87

[1] Analysis has not been updated from that of February 29, 2000.
[2] Intervention Effects and Percentage of Cases are shown for original Design assumptions. The other adherence patterns would produce greater incidence rates in Intervention women and a corresponding reduction in the estimated treatment effect.
[3] C-1 % Energy from fat: 13% at AV-1, 11% at year 10
[4] C-1 % Energy from fat: 11% at AV-1, 9% at year 10. 8.5 follow-up years.
[5] Design values
[5] C-1 % Energy from fat: 11% at AV-1, 10% at year 10. 8.5 follow-up years.

4. CaD Component

4.1 Recruitment

Table 4.1 presents the final sample size for number of women randomized in the Calcium and Vitamin D component of the WHI Clinical Trial. A total of 36,283 women have been randomized which is 80.6% of the overall goal of 45,000. The age distribution of the CaD trial participants is somewhat younger than anticipated in the design assumptions for the trial. Seventeen percent of women randomized are aged 70-79 years compared with the design assumption of 25%.

4.2 Adherence

Table 4.2 presents rates of follow-up, stopping intervention and pill collection, and adherence to pill taking by visit schedule for all CaD participants. The adherence pattern among women with pill collections is generally stable over time. The adherence summary for all CaD participants, defined as those women known to be consuming 80% or more of the prescribed dose, has improved slightly since the last report (see *Figure 4.1*) and is now about 58%-63% (adherence summary was 55%-63% in the last progress report). Adherence to CaD, however, remains somewhat low, primarily because of a significant proportion of women stopping the intervention entirely, and because of lower than expected pill-taking rates among women staying on the intervention.

Table 4.3 summarizes interval and cumulative drop-out rates in comparison to the original design assumptions. The original power calculations for CaD assumed a 6% drop-out rate in year 1 and a 3% per year drop-out rate thereafter. An independent lost-to-follow-up rate of 3% per year was also incorporated, resulting in approximately 8.8% stopping intervention in year 1 and 5.9% in subsequent years. Our current data suggest the drop-out rates are somewhat higher than projected at AV-2 and AV-3, and then slightly lower (absolute difference of 1%) than projected at AV-4 through AV-6. By AV-5, the observed and design-specified cumulative drop-out rates are very similar overall. At AV-6 the observed cumulative drop-out rate is actually less than projected (26.1% vs. 28.5%).

Figure 4.1 shows the CaD adherence summary over six month periods from the present period ending February 28, 2001 back to September 1997-February 1998. The graph shows that CaD adherence has improved over this three-year period. In the most recent interval, small improvement was noted at AV-4 and AV-5.

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 8.2% have indicated that they were advised by their physician to discontinue these supplements. 499 women (6.8%) reported health problems or diseases, 2332 women (31.7%) reported symptoms not known to be related to the intervention, and 449 women (6.1%) reported that the study conflicts with other health issues. "Other pill issues" was the most frequently reported intervention-related reason (11.4%) followed by not liking the randomized nature of the intervention (4.4%). Miscellaneous reasons grouped together as "other reasons not listed above" were reported by 24.1% of women.

We also monitor the number of women who have begun alternative anti-osteoporosis therapies within the CaD trial. As of February 28, 2001, 1429 (3.9%) women were taking alendronate, 211 (0.6%) were taking calcitonin, and 429 (1.2%) were taking raloxifene.

4.3 Bone Mineral Density

Table 4.5 presents the mean bone mineral density levels at AV-1 and AV-3 and percent change in BMD during this interval 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 1.5-2 times as large as those observed at AV-3 ranging from 1.9% at the hip to 3.3% at the whole body. *Table 4.6* presents the mean bone mineral density levels and percent change according to race/ethnicity. The number of women who have data available at AV-6 is too small to yield reliable estimates. However, at AV-3 the rates of change relative to AV-1 were generally in the range of 1-2% gains for all skeletal sites.

4.4 Vital Status

Table 4.7 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*. For operational purposes, we define CT participants to have an "unknown" participation status if there is no outcomes information from the participant for 18 months and no other contacts for 6 months. Currently, 1.5% of the participants are lost-to-follow-up or have stopped follow-up, and 1.3% 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 3.1 years, suggesting that approximately 9.0% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

4.5 Outcomes

Table 4.8 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. The category CHD death (corrected) and CHD (corrected) do not include death from "other cardiovascular" and "unknown cardiovascular" causes. These corrected categories are the ones that we plan to use for further reporting. The (uncorrected) CHD and CHD death categories are provided for comparison with previous reports. See also *Section 2.8 – HRT-Outcomes*. Approximately 6% 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 96 cases of hip fracture locally verified, we have observed only about 35% of the number of hip fractures that were projected by the assumptions underlying the power calculations. The number of observed colorectal cancer cases (132 cases) is approximately 75%, the number of invasive breast cancer cases (403 cases) is approximately 100%, and the number of CHD cases is about 70% of what was expected (354 cases).

Table 4.9 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 Power Considerations

Since observed adherence, drop-out, and lost-to-follow-up rates have changed little over the last year, we include the previous power calculations for reference in this report. We have calculated the power for CaD using the type of adherence model employed for the DM component. This approach incorporates total calcium intake from diet and supplements. To make within-model comparisons, we determined the calcium intake assumptions that would reproduce the original power calculations based on a model that dichotomized adherence to pills, holding constant all other parameters (e.g., treatment effect, lag time, control group incidence rates, and average follow-up time). Average total calcium consumption (in mg) of 920, 950, 1000 at baseline, year 1 and year 9, respectively in controls and similarly 1920, 1850, 1800 in the intervention arm produces powers within 1%-2% of the protocol-specified values with n=45,000 for all outcomes of interest. The value of 920 mg/day in controls at baseline was determined from the median total calcium intake in the CaD participants at AV-1 who are also DM participants, and who therefore provide FFQ data.

With recruitment ongoing we have conducted power sensitivity analyses using a projected sample size of 36,000, an adherence pattern suggested by the current data, and revised incidence rates, reflecting the low early rates of hip fractures (healthy volunteer effect starting at 0.2 in year 1 and rising to 0.8 by year 7). *Table 4.10* shows the power for hip fractures, other fractures and colorectal cancer under both adherence patterns and all other parameters held constant. Note that power is low for hip fracture and colorectal cancer in scenarios based on poor adherence. Power for combined fractures is high under most scenarios, especially if moderate adherence is achieved.

4.7 Issues

The Serum Vitamin D Analyte Study has been completed and reported to the WHI DSMB. Briefly, this study was conducted to determine if participants who take CaD supplements absorb Vitamin D from the CaD supplement in measurable amounts compared to those who take placebo. Absorption is determined by comparing the AV-3 serum levels of 25(OH)D in active and control arm CaD participants. AV-3 serum samples of all WHI participants meeting the following criteria were measured for 25(OH)D: 1) participant in the CaD trial, 2) had an AV-3 blood draw in November, December, January or February, and 3) had at least 2 serum aliquots available. A total of 448 women, 227 active arm and 221 placebo arm, were included. Another purpose of this study is to investigate regional and seasonal differences in serum Vitamin D levels. Once the DSMB approves release of these data to WHI investigators for analysis, Dr. Cedric Garland will lead a writing group to complete the analysis and report the study.

Smith-Kline Beecham has requested approval to increase the amount of calcium in the WHI CaD supplement from 500 mg to 600 mg in each pill. The CaD Advisory Committee considered this request and recommends against changing the dose of CaD midway through the trial.

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

Data as of: February 28, 2001

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**36,283**			
50-54	5158	118%	14%	10
55-59	8264	94%	23%	20
60-69	16521	84%	46%	45
70-79	6340	58%	17%	25
Race/Ethnicity	**36,283**			
American Indian	149		<1%	
Asian	721		2%	
Black	3316		9%	
Hispanic	1502		4%	
White	30156		83%	
Other/Unspecified	439		1%	

Table 4.2
CaD Adherence Summary
All CaD Participants

Data as of: February 28, 2001

	Due	Conducted		Conducted in Window		Stopped CaD		Missed Pill Collection		Total with Collections		Medication Rate[1] <50%		Medication Rate[1] 50%-80%		Medication Rate[1] 80% +		Adherence Summary[2]
	N	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	%
Semi-Annual Contact-2	33048	32205	97	26169	79	2054	6	4171	13	28849	87	4084	14	5783	20	18982	66	58
Annual Visit-2	33048	32265	98	25849	78	1419	4	2179	7	28147	93	2930	10	4834	17	20383	72	62
Annual Visit -3	33453	32338	97	24763	74	2119	6	2718	9	27070	91	2315	9	4629	17	20126	74	61
Annual Visit -4	22581	21431	95	16000	71	1101	5	1581	9	17037	92	1286	8	2594	15	13157	77	59
Annual Visit -5	11342	10688	94	8000	71	505	5	687	8	8172	92	548	7	1170	14	6454	79	58
Annual Visit -6	4326	4061	94	2835	66	131	3	203	6	3063	94	206	7	383	13	2474	81	58

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

Table 4.3
CaD Drop-Out Rates by Follow-Up Time
(Design-specified values in parentheses)

Data as of: February 28, 2001

	Total			
	Interval[1]		Cumulative[2]	
Drop-Outs[3]				
AV-2	10.2%	(8.8)	10.2%	(8.8)
AV-3	6.4%	(5.9)	16.0%	(14.2)
AV-4	4.9%	(5.9)	20.1%	(19.2)
AV-5	4.5%	(5.9)	23.7%	(24.0)
AV-6	3.1%	(5.9)	26.1%	(28.5)

[1] Estimates of stopping or starting supplements in the Interval
[2] Estimates of cumulative rates.
[3] Drop-out rates derived from Form 7 by date. Cumulative rates calculated as life-table estimates.

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

Data as of: February 28, 2001

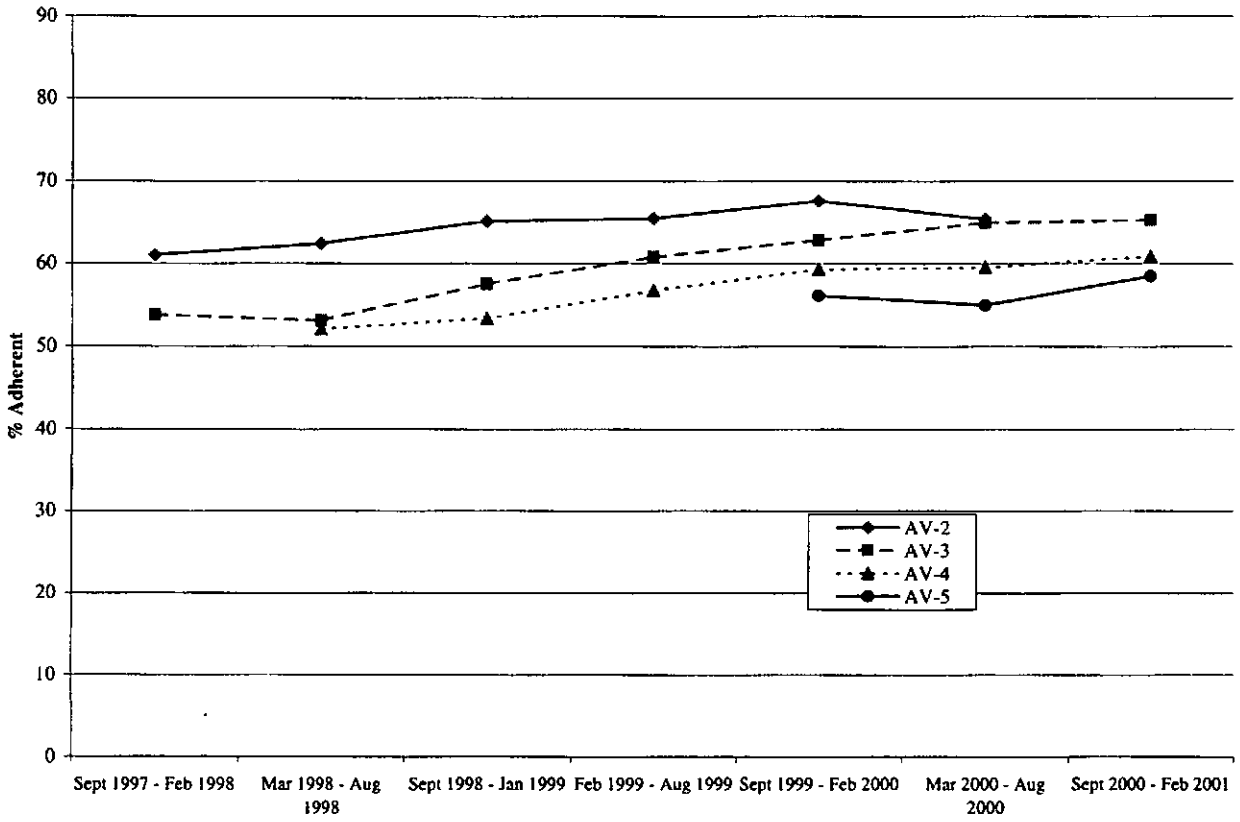


Table 4.4
Reasons for Stopping CaD

Data as of: February 28, 2001

Reasons[1]	(N = 7359)	
Personal/family		
Demands of work	156	(2.1%)
Family illness, emergency or other family demands	262	(3.6%)
Financial problems	9	(0.1%)
Lack of cooperation/support from family/friends	36	(0.5%)
Living in nursing home	15	(0.2%)
Issues of interest in study	171	(2.3%)
Travel		
Too far to CC	154	(2.1%)
Moved out of area or refuses to be followed at another CC	39	(0.5%)
Other travel issues	67	(0.9%)
Visits & Procendures		
Doesn't like visits, calls	69	(0.9%)
Doesn't like required forms or safety procedures	67	(0.9%)
Problems with other procedures	25	(0.3%)
Worried about health effects of medical tests/procedures	31	(0.4%)
Wants results of blood analyses	2	(<0.1%)
Wants results of bone mineral density	0	(0.0%)
Problems with CC	42	(0.6%)

[1] Multiple reasons may be reported for a woman.

Table 4.4 (continued)
Reasons for Stopping CaD

Data as of: February 28, 2001

Reasons[1]	(N = 7359)	
Symptoms		
Bloating/gas	105	(1.4%)
Constipation	133	(1.8%)
Other gastrointestinal problems	137	(1.9%)
HRT Related Symptoms	37	(0.5%)
Other	2332	(31.7%)
Health Conditions		
Hypercalcemia	60	(0.8%)
Renal calculi	62	(0.8%)
Osteoporosis	38	(0.5%)
Other Diseases/Health Conditions	499	(6.8%)
Communication difficulties	38	(0.5%)
Intervention		
Doesn't like randomized nature of intervention	321	(4.4%)
Expected some benefit from intervention	48	(0.7%)
Feels guilty, unhappy, or like a failure for not meeting study goals of intervention	12	(0.2%)
Takes too many pills	123	(1.7%)
Other pill issues	840	(11.4%)
HRT Issues	61	(0.8%)
DM Issues	17	(0.2%)
Wants to take her own calcium	162	(2.2%)
Feels diet is already sufficient in calcium/Vit D	20	(0.3%)
Taking more than the max allowable IU of Vit D	16	(0.2%)
Taking Calcitrol	10	(0.1%)
Other Health Issues		
Worried about cost if adverse effects occur	9	(0.1%)
Expected more health care	18	(0.2%)
Advised not to participate by health care provider	606	(8.2%)
Study conflicts with other health issues	449	(6.1%)
Other		
Other reasons not listed above	1773	(24.1%)
Refuses to give a reason	117	(1.6%)

[1] Multiple reasons may be reported for a woman.

Table 4.5
Bone Mineral Density[1] Analysis: CaD Participants

Data as of: February 28, 2001

	N	Mean	S.D.
Whole Body Scan			
AV1	2440	1.02	0.11
AV3	2260	1.03	0.11
AV6	727	1.05	0.12
AV3 % Change from AV1 BMD[2]	2188	1.49	3.39
AV6 % Change from AV1 BMD[3]	705	3.26	4.73
Spine Scan			
AV1	2371	0.99	0.17
AV3	2221	1.01	0.17
AV6	729	1.01	0.17
AV3 % Change from AV1 BMD[2]	2151	1.59	4.27
AV6 % Change from AV1 BMD[3]	706	2.90	5.79
Hip Scan			
AV1	2432	0.86	0.14
AV3	2268	0.87	0.14
AV6	744	0.88	0.14
AV3 % Change from AV1 BMD[2]	2199	1.31	3.56
AV6 % Change from AV1 BMD[3]	724	1.94	4.87

[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 4.6
Bone Mineral Density[1] Analysis: CaD Participants by Race/Ethnicity

Data as of: February 28, 2001

	Black/African American			Hispanic/Latino			White		
	N	Mean	S.D.	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan									
AV1	278	1.08	0.11	123	1.04	0.12	2002	1.01	0.10
AV3	256	1.10	0.11	116	1.05	0.12	1851	1.03	0.11
AV6	55	1.10	0.13	31	1.14	0.17	634	1.04	0.11
AV3 % Change from AV1 BMD[2]	252	1.34	2.96	104	2.20	4.36	1798	1.47	3.39
AV6 % Change from AV1 BMD[3]	54	1.96	3.90	23	6.29	4.34	622	3.27	4.78
Spine Scan									
AV1	274	1.07	0.18	120	0.98	0.17	1940	0.98	0.16
AV3	254	1.08	0.18	115	0.97	0.15	1815	1.00	0.17
AV6	58	1.10	0.18	31	1.00	0.17	633	1.00	0.17
AV3 % Change from AV1 BMD	250	1.21	4.39	102	0.07	4.88	1765	1.76	4.18
AV6 % Change from AV1 BMD	57	0.60	5.39	23	2.19	5.12	620	3.11	5.81
Hip Scan									
AV1	279	0.98	0.14	123	0.87	0.14	1993	0.85	0.13
AV3	258	0.98	0.15	116	0.88	0.13	1857	0.86	0.13
AV6	60	1.00	0.15	31	0.91	0.17	646	0.87	0.13
AV3 % Change from AV1 BMD	254	0.96	3.07	104	1.80	4.78	1807	1.33	3.53
AV6 % Change from AV1 BMD	59	-0.02	4.62	23	4.15	3.78	636	2.03	4.87

[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
Lost-to-Follow-up and Vital Status: CaD Participants

Data as of: February 28, 2001

	CaD Participants (N=36283)	
	N	%
Vital Status/Participation		
Deceased	467	1.3
Alive: Current Participation[1]	34590	95.3
Alive: Recent Participation[2]	676	1.9
Alive: Past/Unknown Participation[3]	13	0.0
Stopped Follow-Up[4]	278	0.8
Lost to Follow-Up[5]	259	0.7

[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] Participiants 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 4.8
Locally Verified Outcomes (Annualized Percentages) by Age for Calcium and Vitamin D

Data as of: February 28, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number of participants	36283	5158	8264	16521	6340
Mean follow-up (months)	37.5	43.1	39.5	35.7	34.9
Fractures					
Hip fracture	96 (0.08%)	3 (0.02%)	9 (0.03%)	39 (0.08%)	45 (0.24%)
Vertebral fracture	104 (0.09%)	4 (0.02%)	11 (0.04%)	40 (0.08%)	49 (0.27%)
Other fracture[3]	1502 (1.33%)	196 (1.06%)	309 (1.14%)	679 (1.38%)	318 (1.72%)
Total fracture	1659 (1.46%)	202 (1.09%)	328 (1.21%)	738 (1.50%)	391 (2.12%)
Cancer					
Colorectal cancer	132 (0.12%)	10 (0.05%)	23 (0.08%)	62 (0.13%)	37 (0.20%)
Breast cancer[1]	510 (0.45%)	60 (0.32%)	118 (0.43%)	243 (0.49%)	89 (0.48%)
Invasive breast cancer	403 (0.36%)	46 (0.25%)	96 (0.35%)	189 (0.38%)	72 (0.39%)
Non-invasive breast cancer	109 (0.10%)	14 (0.08%)	22 (0.08%)	55 (0.11%)	18 (0.10%)
Ovary cancer	49 (0.04%)	7 (0.04%)	12 (0.04%)	18 (0.04%)	12 (0.07%)
Endometrial cancer[2]	70 (0.11%)	11 (0.10%)	16 (0.10%)	32 (0.11%)	11 (0.11%)
Other cancer[3]	496 (0.44%)	44 (0.24%)	90 (0.33%)	234 (0.48%)	128 (0.69%)
Total cancer	1236 (1.09%)	131 (0.71%)	253 (0.93%)	581 (1.18%)	271 (1.47%)
Cardiovascular					
CHD[4]	354 (0.31%)	24 (0.13%)	35 (0.13%)	170 (0.35%)	125 (0.68%)
CHD death[5]	101 (0.09%)	7 (0.04%)	9 (0.03%)	46 (0.09%)	39 (0.21%)
Total MI[6]	279 (0.25%)	19 (0.10%)	28 (0.10%)	136 (0.28%)	96 (0.52%)
Clinical MI	261 (0.23%)	16 (0.09%)	28 (0.10%)	125 (0.25%)	92 (0.50%)
Silent MI	26 (0.02%)	4 (0.02%)	0 (0.00%)	16 (0.03%)	6 (0.03%)
Possible Silent MI	87 (0.08%)	9 (0.05%)	18 (0.07%)	34 (0.07%)	26 (0.14%)
Angina	436 (0.38%)	24 (0.13%)	54 (0.20%)	209 (0.43%)	149 (0.81%)
CABG/PTCA	410 (0.36%)	23 (0.12%)	49 (0.18%)	196 (0.40%)	142 (0.77%)
Carotid artery disease	77 (0.07%)	2 (0.01%)	6 (0.02%)	36 (0.07%)	33 (0.18%)
Congestive heart failure	236 (0.21%)	9 (0.05%)	30 (0.11%)	106 (0.22%)	91 (0.49%)
Stroke	225 (0.20%)	9 (0.05%)	30 (0.11%)	97 (0.20%)	89 (0.48%)
PVD	57 (0.05%)	2 (0.01%)	7 (0.03%)	23 (0.05%)	25 (0.14%)
CHD[4]/Possible Silent MI	432 (0.38%)	33 (0.18%)	51 (0.19%)	202 (0.41%)	146 (0.79%)
Coronary disease[7]	1006 (0.89%)	61 (0.33%)	128 (0.47%)	474 (0.97%)	343 (1.86%)
Total CVD	1273 (1.12%)	70 (0.38%)	163 (0.60%)	600 (1.22%)	440 (2.38%)
Deaths					
Cardiovascular deaths	127 (0.11%)	8 (0.04%)	10 (0.04%)	55 (0.11%)	54 (0.29%)
Cancer deaths	206 (0.18%)	16 (0.09%)	28 (0.10%)	91 (0.19%)	71 (0.38%)
Deaths: other known cause	53 (0.05%)	3 (0.02%)	9 (0.03%)	22 (0.04%)	19 (0.10%)
Deaths: unknown cause	21 (0.02%)	1 (0.01%)	1 (0.00%)	9 (0.02%)	10 (0.05%)
Deaths: not yet adjudicated	60 (0.05%)	4 (0.02%)	5 (0.02%)	25 (0.05%)	26 (0.14%)
Total death	467 (0.41%)	32 (0.17%)	53 (0.19%)	202 (0.41%)	180 (0.98%)

[1] Excludes four 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, definite silent MI, and CHD death.
[5] "CHD death" includes definite and possible CHD death and "other" and "unknown" cardiovascular death.
[6] "Total MI" includes clinical MI and definite silent MI.
[7] "Coronary disease" includes clinical MI, definite silent MI, possible silent MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 4.8 (Continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Calcium and Vitamin D

Data as of: February 28, 2001

Outcome	Race/Ethnicity: American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Other/ Unspecified
Number of participants	149	721	3316	1502	30156	439
Mean follow-up (months)	37.5	33.8	36.3	36.2	37.8	33.7
Fractures						
Hip fracture	0 (0.00%)	1 (0.05%)	3 (0.03%)	1 (0.02%)	91 (0.10%)	0 (0.00%)
Vertebral fracture	0 (0.00%)	2 (0.10%)	0 (0.00%)	3 (0.07%)	98 (0.10%)	1 (0.08%)
Other fracture[1]	7 (1.50%)	20 (0.98%)	73 (0.73%)	38 (0.84%)	1355 (1.43%)	9 (0.73%)
Total fracture	7 (1.50%)	22 (1.08%)	76 (0.76%)	42 (0.93%)	1502 (1.58%)	10 (0.81%)
Cancer						
Colorectal cancer	2 (0.43%)	3 (0.15%)	13 (0.13%)	6 (0.13%)	107 (0.11%)	1 (0.08%)
Breast cancer[2]	1 (0.21%)	8 (0.39%)	26 (0.26%)	14 (0.31%)	459 (0.48%)	2 (0.16%)
Invasive breast cancer	1 (0.21%)	8 (0.39%)	20 (0.20%)	11 (0.24%)	361 (0.38%)	2 (0.16%)
Non-invasive breast cancer	0 (0.00%)	0 (0.00%)	6 (0.06%)	3 (0.07%)	100 (0.11%)	0 (0.00%)
Ovary cancer	0 (0.00%)	0 (0.00%)	4 (0.04%)	0 (0.00%)	45 (0.05%)	0 (0.00%)
Endometrial cancer[3]	1 (0.52%)	0 (0.00%)	2 (0.05%)	2 (0.08%)	64 (0.11%)	1 (0.14%)
Other cancer[1]	2 (0.43%)	7 (0.34%)	28 (0.28%)	9 (0.20%)	446 (0.47%)	4 (0.32%)
Total cancer	6 (1.29%)	18 (0.89%)	73 (0.73%)	30 (0.66%)	1101 (1.16%)	8 (0.65%)
Cardiovascular						
CHD[4]	0 (0.00%)	0 (0.00%)	36 (0.36%)	9 (0.20%)	308 (0.32%)	1 (0.08%)
CHD death[5]	0 (0.00%)	0 (0.00%)	16 (0.16%)	2 (0.04%)	82 (0.09%)	1 (0.08%)
Total MI[6]	0 (0.00%)	0 (0.00%)	23 (0.23%)	7 (0.15%)	248 (0.26%)	1 (0.08%)
Clinical MI	0 (0.00%)	0 (0.00%)	20 (0.20%)	7 (0.15%)	233 (0.25%)	1 (0.08%)
Silent MI	0 (0.00%)	0 (0.00%)	3 (0.03%)	0 (0.00%)	23 (0.02%)	0 (0.00%)
Possible Silent MI	0 (0.00%)	3 (0.15%)	10 (0.10%)	3 (0.07%)	71 (0.07%)	0 (0.00%)
Angina	1 (0.21%)	3 (0.15%)	41 (0.41%)	18 (0.40%)	369 (0.39%)	4 (0.32%)
CABG/PTCA	0 (0.00%)	2 (0.10%)	33 (0.33%)	16 (0.35%)	354 (0.37%)	5 (0.41%)
Carotid artery disease	1 (0.21%)	2 (0.10%)	4 (0.04%)	0 (0.00%)	70 (0.07%)	0 (0.00%)
Congestive heart failure	0 (0.00%)	0 (0.00%)	33 (0.33%)	7 (0.15%)	193 (0.20%)	3 (0.24%)
Stroke	3 (0.64%)	6 (0.30%)	22 (0.22%)	6 (0.13%)	184 (0.19%)	4 (0.32%)
PVD	1 (0.21%)	0 (0.00%)	12 (0.12%)	0 (0.00%)	43 (0.05%)	1 (0.08%)
CHD[4]/Possible Silent MI	0 (0.00%)	3 (0.15%)	44 (0.44%)	12 (0.26%)	372 (0.39%)	1 (0.08%)
Coronary disease[7]	1 (0.21%)	8 (0.39%)	108 (1.08%)	31 (0.68%)	850 (0.89%)	8 (0.65%)
Total CVD	5 (1.07%)	15 (0.74%)	133 (1.33%)	36 (0.79%)	1071 (1.13%)	13 (1.05%)
Deaths						
Cardiovascular deaths	0 (0.00%)	1 (0.05%)	21 (0.21%)	2 (0.04%)	102 (0.11%)	1 (0.08%)
Cancer deaths	0 (0.00%)	6 (0.30%)	17 (0.17%)	2 (0.04%)	178 (0.19%)	3 (0.24%)
Deaths: other known cause	1 (0.21%)	0 (0.00%)	4 (0.04%)	0 (0.00%)	47 (0.05%)	1 (0.08%)
Deaths: unknown cause	1 (0.21%)	0 (0.00%)	4 (0.04%)	0 (0.00%)	16 (0.02%)	0 (0.00%)
Deaths: not yet adjudicated	0 (0.00%)	3 (0.15%)	7 (0.07%)	1 (0.02%)	49 (0.05%)	0 (0.00%)
Total death	2 (0.43%)	10 (0.49%)	53 (0.53%)	5 (0.11%)	392 (0.41%)	5 (0.41%)

[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 four 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, definite silent MI, and CHD death.

[5] "CHD death" includes definite and possible CHD death and "other" and "unknown" cardiovascular death.

[6] "Total MI" includes clinical MI and definite silent MI.

[7] "Coronary disease" includes clinical MI, definite silent MI, possible silent MI, CHD death, angina, congestive heart failure, and CABG/PTCA.

Table 4.9
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for Calcium and Vitamin D who did not report a prevalent condition at baseline

Data as of: February 28, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	36283	5158	8264	16521	6340
Mean follow-up (months)	37.5	43.1	39.5	35.7	34.9
Hospitalizations					
Ever	8719 (7.70%)	960 (5.18%)	1667 (6.13%)	4098 (8.34%)	1994 (10.80%)
Two or more	2999 (2.65%)	297 (1.60%)	509 (1.87%)	1382 (2.81%)	811 (4.39%)
Other					
DVT[1]	174 (0.16%)	12 (0.07%)	36 (0.14%)	71 (0.15%)	55 (0.31%)
PE	87 (0.08%)	6 (0.03%)	20 (0.07%)	43 (0.09%)	18 (0.10%)
Diabetes (treated)	1175 (1.08%)	186 (1.03%)	276 (1.05%)	518 (1.10%)	195 (1.11%)
Gallbladder disease[2]	1169 (1.22%)	185 (1.13%)	298 (1.27%)	525 (1.29%)	161 (1.07%)
Hysterectomy	463 (0.70%)	71 (0.67%)	109 (0.65%)	213 (0.75%)	70 (0.68%)
Glaucoma	1496 (1.37%)	156 (0.85%)	282 (1.06%)	717 (1.52%)	341 (1.98%)
Osteoporosis	3102 (2.87%)	279 (1.53%)	544 (2.06%)	1518 (3.26%)	761 (4.54%)
Osteoarthritis[3]	3200 (3.05%)	451 (2.66%)	746 (2.96%)	1459 (3.19%)	544 (3.16%)
Rheumatoid arthritis	848 (0.78%)	127 (0.71%)	213 (0.81%)	349 (0.74%)	159 (0.91%)
Intestinal polyps	1996 (1.88%)	245 (1.36%)	427 (1.64%)	976 (2.14%)	348 (2.11%)
Lupus	156 (0.14%)	30 (0.16%)	33 (0.12%)	68 (0.14%)	25 (0.14%)
Kidney Stones[3]	280 (0.22%)	37 (0.23%)	71 (0.26%)	129 (0.21%)	43 (0.16%)
Cataracts[3]	4923 (4.34%)	275 (1.70%)	782 (2.94%)	2649 (5.00%)	1217 (6.75%)
Pills for hypertension	4343 (5.34%)	577 (3.81%)	980 (4.67%)	1937 (5.73%)	849 (7.47%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African Am	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	149	721	3316	1502	30156	439
Mean follow-up (months)	37.5	33.8	36.3	36.2	37.8	33.7
Hospitalizations						
Ever	38 (8.15%)	98 (4.82%)	820 (8.18%)	282 (6.23%)	7389 (7.78%)	92 (7.46%)
Two or more	19 (4.08%)	30 (1.48%)	279 (2.78%)	89 (1.96%)	2557 (2.69%)	25 (2.03%)
Other						
DVT[1]	2 (0.44%)	0 (0.00%)	12 (0.12%)	3 (0.07%)	156 (0.17%)	1 (0.08%)
PE	2 (0.43%)	0 (0.00%)	7 (0.07%)	2 (0.04%)	74 (0.08%)	2 (0.16%)
Diabetes (treated)	7 (1.63%)	35 (1.83%)	210 (2.34%)	87 (2.04%)	823 (0.89%)	13 (1.12%)
Gallbladder disease[2]	6 (1.73%)	23 (1.24%)	80 (0.88%)	56 (1.60%)	990 (1.24%)	14 (1.36%)
Hysterectomy	1 (0.52%)	5 (0.38%)	23 (0.53%)	12 (0.48%)	418 (0.73%)	4 (0.58%)
Glaucoma	7 (1.57%)	28 (1.43%)	191 (2.03%)	77 (1.75%)	1182 (1.28%)	11 (0.93%)
Osteoporosis	8 (1.81%)	56 (2.85%)	129 (1.33%)	116 (2.73%)	2752 (3.04%)	41 (3.58%)
Osteoarthritis[3]	16 (3.68%)	62 (3.14%)	289 (3.07%)	167 (3.93%)	2627 (2.99%)	39 (3.35%)
Rheumatoid arthritis	9 (2.19%)	14 (0.72%)	152 (1.64%)	78 (1.80%)	585 (0.64%)	10 (0.86%)
Intestinal polyps	11 (2.56%)	31 (1.65%)	188 (2.00%)	67 (1.54%)	1677 (1.89%)	22 (1.94%)
Lupus	3 (0.65%)	2 (0.10%)	14 (0.14%)	5 (0.11%)	131 (0.14%)	1 (0.08%)
Kidney Stones[3]	2 (0.39%)	5 (0.23%)	14 (0.12%)	22 (0.46%)	233 (0.22%)	4 (0.29%)
Cataracts[3]	26 (5.52%)	81 (4.37%)	402 (3.87%)	203 (4.57%)	4158 (4.38%)	53 (4.29%)
Pills for hypertension	18 (6.09%)	84 (6.04%)	451 (8.60%)	204 (5.82%)	3539 (5.05%)	47 (5.89%)

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

Table 4.10
Sensitivity of CaD Study Power to Adherence and Incidence Rate Assumptions[1]
Revised Sample Size of 36,000

	Year	Intervention Effect[1] (%)	Percentage of Cases[2]		Design[3]	Revised Assumptions[4]
			Control	Intervention		
Hip Fractures						
	2001	20	1.61	1.36	57	29
		27	1.62	1.31	74	40
		33	1.62	1.26	86	52
	2004	20	2.84	2.35	86	58
		27	2.85	2.25	96	75
		33	2.85	2.15	99	88
Combined Fractures[5]						
	2001	19	6.48	5.54	98	91
		23	6.50	5.36	>99	98
		28	6.51	5.18	>99	>99
	2004	19	10.22	8.62	>99	99
		23	10.24	8.30	>99	>99
		28	10.25	7.98	>99	>99
Colorectal Cancer						
	2001	18	0.90	0.80	22	15
		20	0.90	0.79	26	18
		22	0.90	0.78	30	20
	2004	18	1.48	1.22	68	47
		20	1.49	1.20	77	54
		22	1.49	1.18	84	62

[1] Analysis has not been updated from that of February 29, 2000.

[2] Intervention Effects and Percentage of Cases are shown for original Design assumptions. The other adherence patterns would produce greater incidence rates in Intervention women and a corresponding reduction in the estimated treatment effect.

[3] For design, the calculations were based on n = 35,000.

[4] For revised assumption, calculations were based on n = 36,000 and 7.5 years of follow-up for years 1 though 9. For hip fractures, healthy volunteer factors of (.20, .30, .40, .50, .60, .70, .80, .80, .80) were applied to the incidence rates for follow-up years 1 through 9.

[5] Proximal femur, distal forearm, proximal humerus, pelvis, vertebra.

5. Observational Study

5.1 Recruitment

Recruitment into the OS component, completed in December of 1998, reached 93,721, approximately 94% of the expected sample size. *Table 5.1* documents the age distribution and the racial/ethnic composition of this cohort.

5.2 Overview of Follow-up

OS follow-up is conducted by annual mailed self-administered questionnaires except for year 3, when participants attend a clinic follow-up visit. Approximately 2 months prior to the anniversary of the participants' enrollment, the CCC mails the Medical History Update and the OS Exposure Update questionnaires. 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 must attempt to complete follow-up of non-responders by local contacts, usually telephone reminders or interviews.

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

5.3 Completeness of Annual Mail Follow-up

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

The overall response of 95.7% for year 1 data collection, which includes mailings plus CC follow-up of non-responders, slightly exceeds the 95% goal for completion of the OS Exposure Update (*Form 48*), but falls short of the optimal goal (98%) for completion of the Medical History Update (*Form 33*). For years 2, 4, and 5, the rates of 93.5% (Y2), 92.8% (Y4), and 96.4% (Y5) nearly meet or exceed the 94% (Y2), 92% (Y4), and 91% (Y5) goals for the Exposure Update.

5.4 Completeness of Year 3 Clinic Visit

Table 5.3 shows completeness of activities conducted at the year 3 clinic visit. Of those participants due for the year 3 visit through 4/30/00, 95.6% overall completed medical history updates (*Form 33*) and 82.7% provided blood samples (*Form 100*).

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.

Tables 5.4 (overall) and *Table 5.5* (by race and ethnicity) show the OS component-specific BMD means and standard deviations for baseline AV-3 along with % change from baseline for the three types of scans available: whole body, spine, and hip. Baseline and % change is also given using

only those women who have an AV-3 bone scan, as nearly 3,000 of the women with a baseline do not have an AV-3 measure. The current data suggest overall a small increase in bone density over three years in this group of women. In general, we would have expected a small decrease in BMD over time. As with the corresponding DM results, this increase could be related to some selection of health conscious women who may be taking hormone replacement therapy or calcium supplements of their own. Alternatively, there may be some bias introduced by missing data (currently 33% of OS women at these 3 sites are missing BMD data) or there may possibly be a measurement problem.

5.6 Vital Status

Table 5.6 presents data on the vital status and the participation status of participants in the OS. A detailed description of CC and CCC activities to actively locate participants who do not complete their periodic visits is given in *Section 6 – Outcomes.* 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 1.8% of the participants are lost-to-follow-up, and an additional 1.0% of the participants have stopped follow-up. About 1.9% of the OS participants are deceased. Compared to six months ago, the percentage of participants who either are lost-to-follow-up or have stopped follow-up has decreased by 0.1%. Over that period, the participation of alive participants has gotten slightly worse, as now 92.0% of the participants are current, while 3.0% have either recent or past participation. In contrast, six months ago 92.2% were current and 3.4% had recent or past participation.

5.7 Outcomes

Table 5.7 contains counts of the number of locally verified major WHI outcomes for OS participants by age and race/ethnicity. The category CHD death (corrected) and CHD (corrected) do not include death from "other cardiovascular" and "unknown cardiovascular" causes. These corrected categories are the ones that we plan to use for further reporting. The (uncorrected) CHD and CHD death categories are provided for comparison with previous reports. See also *Section 2.8 – HRT-Outcomes.* As approximately 7% 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 115% of the expected number of breast cancers, 65% of the expected number of colorectal cancers, about 55% of the expected number of CHD events, and about 35% of the expected number hip fractures. For most outcomes categories there are now hundreds of events, which should make it possible to do interesting etiological analyses.

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

Table 5.1
Observational Study Age and Race/Ethnicity Specific Recruitment

Data as of: February 28, 2001

	Total Enrolled	Distribution
Age	**93,717**	
50-54	12387	13%
55-59	17323	18%
60-69	41214	44%
70-79	22793	24%
Race/Ethnicity	**93,717**	
American Indian	422	<1%
Asian	2671	3%
Black	7636	8%
Hispanic	3642	4%
White	78025	83%
Other/Unspecified	1321	1%

Table 5.2
Response Rates to OS Follow-up Procedures

Data as of: February 28, 2001

	# Due[1]	Mailings Initiated[2] N	Mailings Initiated[2] %	Response to Mailings N	Response to Mailings %[3]	Response to CC follow-up N	Response to CC follow-up %[4]	Total Responses N	Total Responses %[5]
Year 1	93,518	93,333	99.8%	86,666	92.9%	2,830	42.4%	89,496	95.7%
VCC	41,632	41,599	99.9%	38,415	92.3%	1,689	53.0%	40,104	96.3%
NCC	51,886	51,734	99.7%	48,251	93.3%	1,141	32.8%	49,392	95.2%
Year 2	75,674	74,117	97.9%	69,796	94.2%	N/A		70,785	93.5%
VCC	34,199	33,474	97.9%	31,593	94.4%	N/A		32,074	93.8%
NCC	41,475	40,643	98.0%	38,203	94.0%	N/A		38,711	93.3%
Year 4	26,922	26,267	97.6%	24,384	92.8%	N/A		24,984	92.8%
VCC	13,854	13,431	96.9%	12,486	93.0%	N/A		12,742	92.0%
NCC	13,068	12,836	98.2%	11,898	92.7%	N/A		12,242	93.7%
Year 5	2,610	2,587	99.1%	2,462	95.2%	53	42.4%	2,515	96.4%
VCC	2,579	2,557	99.1%	2,433	95.2%	53	42.7%	2,486	96.4%
NCC	31	30	96.8%	29	96.7%	0	0.0%	29	93.5%

[1] Includes annual contacts due through 2/28/2000. 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.

Table 5.3
OS Annual Visit 3 Task Completeness

Data as of: February 28, 2001

Task	# Due[1]	# Done[2]	% Done
Form 33 - Medical History Update	58,398	55,806	95.6%
Form 38 - Daily Life	58,398	51,628	88.4%
Form 44 - Current Medications	58,398	49,747	85.2%
Form 45 - Current Supplements	58,398	49,678	85.1%
Form 60 - Food Frequency Quest	58,398	51,662	88.5%
Form 80 - Physical Measures	58,398	48,735	83.5%
Form 100 - Blood Collection	58,398	48,281	82.7%
Form 143 - Follow-up	58,398	51,397	88.0%

[1] Includes all Year 3 contacts due through 4/30/2000. Excludes women who are deceased.
[2] Tasks completed within the -6/+15 months window.

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

Data as of: February 28, 2001

	N	Mean	S.D.
Whole Body Scan			
Baseline	6416	1.01	0.11
Baseline (for ppts. with an AV3 scan)	4739	1.01	0.11
Baseline (for ppts. with an AV6 scan)	389	1.01	0.10
AV3	4788	1.02	0.11
AV6	391	1.02	0.11
AV3 % Change from baseline BMD[2]	4739	1.09	3.69
AV6 % Change from baseline BMD[3]	389	0.93	4.62
Spine Scan			
Baseline	6306	0.98	0.17
Baseline (for ppts. with an AV3 scan)	4677	0.97	0.17
Baseline (for ppts. with an AV6 scan)	376	0.97	0.15
AV3	4713	0.99	0.18
AV6	378	1.00	0.17
AV3 % Change from baseline BMD	4677	1.70	5.15
AV6 % Change from baseline BMD	376	3.16	6.61
Hip Scan			
Baseline	6418	0.84	0.14
Baseline (for ppts. with an AV3 scan)	4778	0.84	0.14
Baseline (for ppts. with an AV6 scan)	391	0.84	0.13
AV3	4812	0.85	0.14
AV6	393	0.84	0.14
AV3 % Change from baseline BMD	4778	0.73	4.31
AV6 % Change from baseline BMD	391	-0.57	5.37

[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, 2001

	American Indian/ Alaskan Native			Asian/Pacific Islander			Black/African American			Hispanic/Latino			White			Other/Unspecified		
	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	828	1.05	0.11	464	1.01	0.11	4945	1.01	0.10	46	1.01	0.12
Baseline (for ppts. with an AV3 scan)	56	1.02	0.12	22	1.03	0.09	547	1.05	0.11	309	1.02	0.10	3775	1.01	0.10	30	1.01	0.12
Baseline (for ppts. with an AV6 scan)	1	1.27	N/A	3	0.98	0.07	21	1.06	0.09	6	1.04	0.08	354	1.01	0.10	4	0.97	0.08
AV3	57	1.02	0.13	22	1.03	0.11	554	1.07	0.12	322	1.03	0.11	3802	1.02	0.11	31	1.01	0.11
AV6	1	1.32	N/A	3	0.98	0.07	21	1.07	0.09	6	1.05	0.11	356	1.02	0.11	4	0.98	0.08
AV3 % Change from baseline BMD[2]	56	-0.05	4.07	22	-0.03	5.44	547	1.68	3.20	309	1.46	4.52	3775	1.01	3.66	30	0.46	2.94
AV6 % Change from baseline BMD[3]	1	3.55	N/A	3	-0.13	2.29	21	0.13	2.10	6	1.38	5.45	354	0.97	4.74	4	0.65	4.14
Spine Scan																		
Baseline	109	0.99	0.17	25	0.95	0.12	823	1.04	0.18	457	0.95	0.16	4846	0.97	0.17	46	0.99	0.19
Baseline (for ppts. with an AV3 scan)	56	1.00	0.16	22	0.96	0.12	554	1.04	0.18	304	0.95	0.16	3711	0.97	0.17	30	0.95	0.18
Baseline (for ppts. with an AV6 scan)	1	1.22	N/A	3	0.93	0.12	20	1.03	0.14	6	0.97	0.14	342	0.96	0.15	4	0.89	0.20
AV3	57	1.00	0.16	22	0.96	0.12	556	1.05	0.19	315	0.95	0.16	3732	0.98	0.17	31	0.96	0.17
AV6	1	1.17	N/A	3	0.91	0.08	20	1.08	0.12	6	0.96	0.13	344	0.99	0.17	4	0.95	0.20
AV3 % Change from baseline BMD	56	-0.15	5.83	22	0.22	4.62	554	1.15	5.53	304	0.20	5.32	3711	1.95	5.04	30	0.85	4.90
AV6 % Change from baseline BMD	1	-3.77	N/A	3	-1.54	3.55	20	4.74	6.01	6	-0.57	6.71	342	3.15	6.65	4	7.19	4.48
Hip Scan																		
Baseline	109	0.87	0.15	25	0.82	0.10	827	0.93	0.15	464	0.83	0.13	4947	0.83	0.13	46	0.85	0.14
Baseline (for ppts. with an AV3 scan)	56	0.89	0.16	22	0.82	0.10	556	0.94	0.15	310	0.84	0.12	3804	0.83	0.13	30	0.82	0.13
Baseline (for ppts. with an AV6 scan)	1	1.09	N/A	3	0.82	0.04	21	0.93	0.14	6	0.84	0.07	355	0.84	0.13	5	0.79	0.12
AV3	57	0.89	0.16	22	0.82	0.09	561	0.94	0.15	322	0.85	0.12	3819	0.83	0.13	31	0.82	0.13
AV6	1	1.14	N/A	3	0.82	0.04	21	0.91	0.13	6	0.84	0.09	357	0.83	0.14	5	0.79	0.10
AV3 % Change from baseline BMD	56	-0.54	5.45	22	0.81	4.42	556	0.58	3.88	310	1.61	5.05	3804	0.71	4.27	30	-0.18	4.63
AV6 % Change from baseline BMD	1	4.84	N/A	3	-0.20	1.07	21	-1.61	4.14	6	0.80	3.64	355	-0.56	5.47	5	0.50	6.26

[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, 2001

	OS Participants (N=93717)	
	N	%
Vital Status/Participation		
Deceased	1783	1.9
Alive: Current Participation[1]	86262	92.0
Alive: Recent Participation[2]	2809	3.0
Alive: Past/Unknown Participation[3]	231	0.2
Stopped Follow-Up[4]	959	1.0
Lost to Follow-Up[5]	1673	1.8

[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] Participiants 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 5.7
Locally Verified Outcomes (Annualized Percentages) by Age for Observational Study

Data as of: February 28, 2001

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number enrolled	93717		12387		17323		41214		22793	
Mean follow-up (months)	43.3		47.1		45.5		42.1		41.9	
Cardiovascular										
CHD[1]	940	(0.28%)	28	(0.06%)	80	(0.12%)	361	(0.25%)	471	(0.59%)
CHD death[2]	318	(0.09%)	4	(0.01%)	17	(0.03%)	108	(0.07%)	189	(0.24%)
Clinical MI	684	(0.20%)	24	(0.05%)	68	(0.10%)	268	(0.19%)	324	(0.41%)
Angina	1369	(0.40%)	63	(0.13%)	130	(0.20%)	620	(0.43%)	556	(0.70%)
CABG/PTCA	1203	(0.36%)	33	(0.07%)	115	(0.18%)	544	(0.38%)	511	(0.64%)
Carotid artery disease	270	(0.08%)	17	(0.04%)	20	(0.03%)	110	(0.08%)	123	(0.15%)
Congestive heart failure	753	(0.22%)	26	(0.05%)	62	(0.09%)	295	(0.20%)	370	(0.47%)
Stroke	629	(0.19%)	15	(0.03%)	48	(0.07%)	239	(0.17%)	327	(0.41%)
PVD	187	(0.06%)	7	(0.01%)	16	(0.02%)	66	(0.05%)	98	(0.12%)
Coronary disease[3]	2752	(0.81%)	109	(0.22%)	250	(0.38%)	1161	(0.80%)	1232	(1.55%)
Total CVD	3559	(1.05%)	139	(0.29%)	313	(0.48%)	1471	(1.02%)	1636	(2.06%)
Cancer										
Breast cancer[4]	1715	(0.51%)	185	(0.38%)	314	(0.48%)	766	(0.53%)	450	(0.57%)
Invasive breast cancer	1413	(0.42%)	154	(0.32%)	260	(0.40%)	620	(0.43%)	379	(0.48%)
Non-invasive breast cancer	316	(0.09%)	34	(0.07%)	58	(0.09%)	151	(0.10%)	73	(0.09%)
Ovary cancer	156	(0.05%)	12	(0.02%)	27	(0.04%)	66	(0.05%)	51	(0.06%)
Endometrial cancer[5]	225	(0.11%)	21	(0.07%)	30	(0.07%)	105	(0.13%)	69	(0.15%)
Colorectal cancer	372	(0.11%)	19	(0.04%)	43	(0.07%)	160	(0.11%)	150	(0.19%)
Other cancer[6]	1542	(0.46%)	110	(0.23%)	198	(0.30%)	709	(0.49%)	525	(0.66%)
Total cancer	3929	(1.16%)	342	(0.70%)	602	(0.92%)	1769	(1.22%)	1216	(1.53%)
Fractures										
Hip fracture	321	(0.09%)	8	(0.02%)	28	(0.04%)	105	(0.07%)	180	(0.23%)
Vertebral fracture[7]	47	(0.16%)	2	(0.05%)	4	(0.08%)	13	(0.10%)	28	(0.39%)
Other fracture[6,7]	387	(1.32%)	48	(1.16%)	64	(1.20%)	157	(1.24%)	118	(1.66%)
Total fracture[8]	738	(0.22%)	57	(0.12%)	94	(0.14%)	269	(0.19%)	318	(0.40%)
Deaths										
Cardiovascular deaths	428	(0.13%)	8	(0.02%)	21	(0.03%)	144	(0.10%)	255	(0.32%)
Cancer deaths	726	(0.21%)	40	(0.08%)	85	(0.13%)	301	(0.21%)	300	(0.38%)
Deaths: other known cause	254	(0.08%)	12	(0.02%)	29	(0.04%)	102	(0.07%)	111	(0.14%)
Deaths: unknown cause	104	(0.03%)	7	(0.01%)	6	(0.01%)	42	(0.03%)	49	(0.06%)
Deaths: not yet adjudicated	271	(0.08%)	11	(0.02%)	27	(0.04%)	112	(0.08%)	121	(0.15%)
Total death	1783	(0.53%)	78	(0.16%)	168	(0.26%)	701	(0.49%)	836	(1.05%)

[1] "CHD" includes clinical MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death and "other" and "unknown" cardiovascular death.
[3] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[4] Excludes six 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] Only women from three bone density clinics.
[8] Hip fractures are adjudicated at all clinics, while other fractures 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 Observational Study

Data as of: February 28, 2001

Outcomes	Ethnicity: American Indian/Alaskan Native		Asian/Pacific Islander		Black/African American		Hispanic/ Latino		White		Other/ Unspecified	
Number enrolled	422		2671		7636		3642		78025		1321	
Mean follow-up (months)	40.8		42.3		40.8		38.3		43.8		41.5	
Cardiovascular												
CHD[1]	6	(0.42%)	19	(0.20%)	74	(0.29%)	17	(0.15%)	805	(0.28%)	19	(0.42%)
CHD death[2]	1	(0.07%)	5	(0.05%)	37	(0.14%)	1	(0.01%)	267	(0.09%)	7	(0.15%)
Clinical MI	5	(0.35%)	15	(0.16%)	45	(0.17%)	16	(0.14%)	590	(0.21%)	13	(0.28%)
Angina	8	(0.56%)	27	(0.29%)	109	(0.42%)	33	(0.28%)	1179	(0.41%)	13	(0.28%)
CABG/PTCA	5	(0.35%)	23	(0.24%)	71	(0.27%)	30	(0.26%)	1056	(0.37%)	18	(0.39%)
Carotid artery disease	1	(0.07%)	3	(0.03%)	15	(0.06%)	8	(0.07%)	236	(0.08%)	7	(0.15%)
Congestive heart failure	6	(0.42%)	12	(0.13%)	84	(0.32%)	17	(0.15%)	623	(0.22%)	11	(0.24%)
Stroke	5	(0.35%)	21	(0.22%)	62	(0.24%)	8	(0.07%)	520	(0.18%)	13	(0.28%)
PVD	2	(0.14%)	1	(0.01%)	20	(0.08%)	2	(0.02%)	159	(0.06%)	3	(0.07%)
Coronary disease[3]	15	(1.04%)	49	(0.52%)	235	(0.91%)	60	(0.52%)	2357	(0.83%)	36	(0.79%)
Total CVD	21	(1.46%)	70	(0.74%)	312	(1.20%)	73	(0.63%)	3029	(1.06%)	54	(1.18%)
Cancer												
Breast cancer[4]	2	(0.14%)	31	(0.33%)	105	(0.40%)	46	(0.40%)	1514	(0.53%)	17	(0.37%)
Invasive breast cancer	2	(0.14%)	23	(0.24%)	84	(0.32%)	35	(0.30%)	1255	(0.44%)	14	(0.31%)
Non-invasive breast cancer	0	(0.00%)	8	(0.08%)	22	(0.08%)	11	(0.09%)	272	(0.10%)	3	(0.07%)
Ovary cancer	0	(0.00%)	2	(0.02%)	7	(0.03%)	5	(0.04%)	142	(0.05%)	0	(0.00%)
Endometrial cancer[5]	0	(0.00%)	5	(0.08%)	4	(0.03%)	4	(0.06%)	207	(0.12%)	5	(0.19%)
Colorectal cancer	1	(0.07%)	8	(0.08%)	46	(0.18%)	7	(0.06%)	308	(0.11%)	2	(0.04%)
Other cancer[6]	7	(0.49%)	26	(0.28%)	87	(0.34%)	34	(0.29%)	1370	(0.48%)	18	(0.39%)
Total cancer	10	(0.70%)	70	(0.74%)	241	(0.93%)	95	(0.82%)	3471	(1.22%)	42	(0.92%)
Fractures												
Hip fracture	1	(0.07%)	5	(0.05%)	2	(0.01%)	4	(0.03%)	306	(0.11%)	3	(0.07%)
Vertebral fracture[7]	1	(0.24%)	0	(0.00%)	0	(0.00%)	2	(0.10%)	44	(0.19%)	0	(0.00%)
Other fracture[6,7]	5	(1.22%)	2	(1.64%)	19	(0.52%)	18	(0.87%)	340	(1.49%)	3	(1.58%)
Total fracture[8]	7	(0.49%)	7	(0.07%)	21	(0.08%)	23	(0.20%)	674	(0.24%)	6	(0.13%)
Deaths												
Cardiovascular deaths	3	(0.21%)	7	(0.07%)	45	(0.17%)	2	(0.02%)	362	(0.13%)	9	(0.20%)
Cancer deaths	3	(0.21%)	11	(0.12%)	51	(0.20%)	18	(0.16%)	635	(0.22%)	8	(0.18%)
Deaths: other known cause	5	(0.35%)	3	(0.03%)	17	(0.07%)	9	(0.08%)	215	(0.08%)	5	(0.11%)
Deaths: unknown cause	0	(0.00%)	2	(0.02%)	14	(0.05%)	7	(0.06%)	80	(0.03%)	1	(0.02%)
Deaths: not yet adjudicated	3	(0.21%)	9	(0.10%)	34	(0.13%)	9	(0.08%)	214	(0.08%)	2	(0.04%)
Total death	14	(0.98%)	32	(0.34%)	161	(0.62%)	45	(0.39%)	1506	(0.53%)	25	(0.55%)

[1] "CHD" includes clinical MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death and "other" and "unknown" cardiovascular death.
[3] "Coronary disease" includes clinical MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[4] Excludes six 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] Only women from three bone density clinics.
[8] Hip fractures are adjudicated at all clinics, while other fractures 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, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	93717	12387	17323	41214	22793
Mean follow-up (months)	43.3	47.1	45.5	42.1	41.9
Hospitalizations					
Ever	23919 (7.07%)	2242 (4.62%)	3433 (5.23%)	10530 (7.29%)	7714 (9.70%)
Two or more	8548 (2.53%)	689 (1.42%)	1046 (1.59%)	3701 (2.56%)	3112 (3.91%)
Other					
DVT[1]	289 (0.09%)	26 (0.05%)	30 (0.05%)	126 (0.09%)	107 (0.14%)
PE	176 (0.05%)	20 (0.04%)	18 (0.03%)	74 (0.05%)	64 (0.08%)
Diabetes (treated)	2186 (0.67%)	251 (0.53%)	391 (0.62%)	997 (0.72%)	547 (0.72%)
Gallbladder disease[2]	2793 (0.98%)	447 (1.04%)	541 (0.95%)	1232 (1.02%)	573 (0.88%)
Hysterectomy	1753 (0.89%)	251 (0.87%)	345 (0.84%)	776 (0.93%)	381 (0.85%)
Glaucoma	3597 (1.12%)	357 (0.75%)	531 (0.83%)	1637 (1.19%)	1072 (1.47%)
Osteoporosis	11054 (3.56%)	1030 (2.20%)	1664 (2.66%)	5117 (3.88%)	3243 (4.71%)
Osteoarthritis[3]	7835 (2.32%)	928 (1.91%)	1364 (2.08%)	3494 (2.42%)	2049 (2.58%)
Rheumatoid arthritis	2253 (0.70%)	332 (0.71%)	439 (0.70%)	896 (0.66%)	586 (0.79%)
Intestinal polyps	5584 (1.82%)	642 (1.39%)	986 (1.60%)	2591 (1.99%)	1365 (1.99%)
Lupus	514 (0.15%)	87 (0.18%)	103 (0.16%)	221 (0.15%)	103 (0.13%)
Kidney Stones[3]	946 (0.23%)	127 (0.28%)	181 (0.26%)	394 (0.21%)	244 (0.20%)
Cataracts[3]	12248 (3.47%)	579 (1.27%)	1417 (2.08%)	6356 (3.90%)	3896 (5.07%)
Pills for hypertension	10014 (4.14%)	1114 (2.77%)	1735 (3.39%)	4291 (4.27%)	2874 (5.78%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African Am	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	422	2671	7636	3642	78025	1321
Mean follow-up (months)	40.8	42.3	40.8	38.3	43.8	41.5
Hospitalizations						
Ever	120 (8.36%)	415 (4.41%)	1860 (7.17%)	649 (5.59%)	20578 (7.22%)	297 (6.50%)
Two or more	51 (3.55%)	136 (1.44%)	658 (2.54%)	187 (1.61%)	7408 (2.60%)	108 (2.37%)
Other						
DVT[1]	2 (0.15%)	2 (0.02%)	21 (0.08%)	3 (0.03%)	259 (0.09%)	2 (0.05%)
PE	1 (0.07%)	3 (0.03%)	12 (0.05%)	1 (0.01%)	158 (0.06%)	1 (0.02%)
Diabetes (treated)	24 (1.97%)	74 (0.83%)	351 (1.54%)	143 (1.32%)	1566 (0.57%)	28 (0.64%)
Gallbladder disease[2]	14 (1.23%)	37 (0.43%)	188 (0.82%)	109 (1.20%)	2407 (1.00%)	38 (0.99%)
Hysterectomy	7 (0.98%)	33 (0.54%)	116 (0.98%)	73 (1.14%)	1493 (0.88%)	31 (1.17%)
Glaucoma	20 (1.51%)	125 (1.39%)	446 (1.87%)	125 (1.14%)	2828 (1.04%)	53 (1.22%)
Osteoporosis	41 (3.09%)	338 (3.74%)	442 (1.86%)	334 (3.03%)	9718 (3.54%)	181 (4.14%)
Osteoarthritis[3]	33 (2.30%)	228 (2.42%)	657 (2.53%)	366 (3.16%)	6427 (2.25%)	124 (2.72%)
Rheumatoid arthritis	20 (1.51%)	50 (0.56%)	346 (1.46%)	197 (1.79%)	1592 (0.58%)	48 (1.10%)
Intestinal polyps	23 (1.73%)	140 (1.56%)	465 (1.95%)	162 (1.47%)	4724 (1.73%)	70 (1.61%)
Lupus	7 (0.53%)	11 (0.12%)	52 (0.22%)	22 (0.20%)	413 (0.15%)	9 (0.21%)
Kidney Stones[3]	10 (0.54%)	14 (0.14%)	104 (0.32%)	51 (0.38%)	750 (0.21%)	17 (0.31%)
Cataracts[3]	45 (2.81%)	321 (3.93%)	877 (3.10%)	390 (3.18%)	10428 (3.50%)	187 (4.06%)
Pills for hypertension	42 (3.12%)	291 (3.20%)	870 (3.61%)	417 (3.76%)	8255 (3.00%)	139 (3.14%)

[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.

6. Outcomes Processing

6.1 Overview

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

After these forms are completed and entered into the database, the CCs identify adjudication cases based on the *Form 33D* information. CCs then request hospital and related records. Once the cases are documented, clinic staff send 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 93% 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 94% of self-reported outcomes in the CT and 93% of the self-reported outcomes in the OS requiring adjudication have been closed. In particular, 50% of the outcomes in the CT and 53% of the outcomes in the OS have been closed within 90 days of self-report and 69% (CT) and 75% (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 almost 70%, and the percentage of forms that were adjudicated within 180 days has increased from about 60% to over 85%. 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 1.1%. Currently, 32 of the 40 clinics have ten or fewer outstanding *Forms 33D* that are more than a year old.

Figures 6.1-6.2 – Timeliness per Period of Self-Report display Kaplan-Meier curves for the time period from reporting an outcome on *Form 33D* until the adjudication case is closed per year of self-report and, for recent data, per half 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. The two current areas of emphasis of the OPMC are assisting clinics in closing out the few really old cases, and assisting the remaining clinics that are lagging behind in the timeliness of outcomes processing.

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 78% agreement rate between self-reports and locally confirmed outcomes (84% if we exclude angina, which is probably the softest cardiovascular outcome), cancer outcomes have an agreement rate of 87% (92% for the primary cancers), and fracture outcomes have an agreement rate of 79% 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).

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.

Table 6.7-6.8 – Agreement of Locally and Centrally Adjudicated Cause of Death are new tables in this report. 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 6.9 – Locally Verified Outcomes (Annualized Percentages) by Age and Ethnicity for CT contains the number of locally verified outcomes for the major WHI outcomes categories. Since about 7% 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 90% of the invasive breast cancer, 70% of the colorectal cancer and 30% of the hip fracture cases of what was assumed for the power calculations. The observed rate of CHD is approximately 80-85% of what was assumed for the 55-59 and 60-69 age categories. The rate in the youngest age category, 50-54 at baseline, is actually higher than what was assumed. Only in the oldest age category, 70-79 at baseline, are the current observed rates considerably lower (about 55%) than design assumptions. When we combine the four age categories, the observed CHD rate is about 70% of what was assumed in the design. Note that DVT and PE, which are only adjudicated for HRT participants, are not included in this table.

Table 6.10 – Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Ethnicity for CT 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.

Tables 6.11 – Locally Confirmed Other Cancers and *6.12 – Locally Confirmed Other Fractures* split out the other cancers and other fractures for the locally verified outcomes by event type and by study. Since for OS participants other fractures are only locally verified at the three bone mineral density clinics, we provide the number of self-reported fractures for these participants. In the CT, approximately 80% of self-reported fractures are confirmed, though the location of the fracture is misreported in approximately 25-30% of cases.

6.5 ECG Data

Electrocardiograms (ECGs) are given to all CT participants at baseline and in years 3, 6, and 9. The ECGs are sent to EPICARE (Pentti Rauthaharju, PI), which subcontracts to the CCC. EPICARE provides the CCC with a comprehensive analysis of each individual ECG, as well as with a serial analysis of the follow-up ECGs of a participant relative to that participant's baseline ECG. This serial analysis is intended to identify silent MIs: MIs that are detected by this ECG analysis, but were not reported by the participant. As of February 28, 2001, the CCC had received serial analysis on 49,554 CT participants whose year 3 ECGs and/or their year 6 ECGs had been analyzed by EPICARE.

Table 6.13 – Cross-tabulation of ECG Codes Suggesting an MI and Locally Confirmed and Self-Reported MI for All CT Participants shows the relation between MIs that have been identified prior to the follow-up ECG and incident MIs as identified by the ECG analysis. A total of 40 evolving Q-wave MIs have been identified. We note that 15 of these MIs were also identified by the regular outcomes reporting process. The remaining 25 evolving Q-wave MIs are thus the "definite silent MIs." *Table 6.9* also gives the number of possible silent MIs.

6.6 Vital Status

Table 6.14 – Cause of Death: CT and OS Participants (Annualized Percentages) presents the cause of death for CT and OS participants. To reduce the time that it takes before cause of death information is available on WHI participants who have passed away, clinics are encouraged to report a "temporary" cause of death for those participants for whom some, but not all, documentation related to the death has been collected. The goal is that a temporary cause is entered in the database as soon as possible, preferably within eight weeks. The cause based on the complete documentation should be entered as soon as all documents are collected. Cases for which reported unsuccessful requests for documentation have been made over a one year period can be closed out with incomplete documentation.

As of the February 28, 2001 database, there were 1,193 deaths in the CT and 1,783 in the OS. Of the 1,193 CT deaths, there were 972 (81%) for which a final adjudication was available, and an additional 88 (7%) for which a temporary adjudication was available. These 1,193 CT deaths include 71 that were first reported after January 1 of this year. Of the 1,122 that were first reported before January 1, 2001, 965 have a final adjudication and 78 have a temporary one, giving us cause of death information on 93% of the CT deaths. For the OS there is cause of death information on 85% of all deaths, and 89% of all deaths that were reported before January 1, 2000.

Table 6.15 – 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 when WHI conducts a National Death Index (NDI) search.

About 1.8% of the CT participants are deceased, we do not know the vital status of about 1.4% of the CT participants, and 1.7% 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 4.2 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 0.0 to 6.9% per clinic. The percentage of participants who stopped follow-up ranges from less than 0.0 to 10.8%.

Table 6.16 – Lost-to-Follow-up and Vital Status by Clinic: OS Participants contains the same information as *Table 6.15* 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 2.8% 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[1]

Data as of: February 28, 2001

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	3916	267	7%	777	20%	3893	99%	23	1%
1996 July - December	1382	309	22%	720	52%	1377	100%	5	0%
1997 January-June	2175	766	35%	1335	61%	2169	100%	6	0%
1997 July-December	2542	977	38%	1514	60%	2536	100%	6	0%
1998 January-June	3576	1667	47%	2786	78%	3570	100%	6	0%
1998 July-December	4158	2368	57%	3344	80%	4139	100%	19	0%
1999 January-June	4601	2836	62%	3812	83%	4559	99%	42	1%
1999 July-December	4457	2875	65%	3707	83%	4369	98%	88	2%
2000 January	784	526	67%	645	82%	753	96%	31	4%
2000 February	736	492	67%	625	85%	695	94%	41	6%
2000 March	822	531	65%	693	84%	779	95%	43	5%
2000 April	755	485	64%	648	86%	714	95%	41	5%
2000 May	795	542	68%	687	86%	745	94%	50	6%
2000 June	804	542	67%	690	86%	738	92%	66	8%
2000 July	650	473	73%	568	87%	597	92%	53	8%
2000 August	844	591	70%	728	86%	748	89%	96	11%
2000 September	671	450	67%	578	86%	578	86%	93	14%
2000 October	850	579	68%	693	82%	693	82%	157	18%
2000 November	739	506	68%	559	76%	559	76%	180	24%
2000 December	621	420	68%	420	68%	420	68%	201	32%
2001 January	890	344	39%	344	39%	344	39%	546	61%
2001 February	580	54	9%	54	9%	54	9%	526	91%
Total	37348	18600	50%	25927	69%	35029	94%	2319	6%

[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[1]

Data as of: February 28, 2001

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	237	85	36%	128	54%	236	100%	1	0%
1996 July - December	1309	309	24%	703	54%	1303	100%	6	0%
1997 January-June	2151	849	39%	1406	65%	2140	99%	11	1%
1997 July-December	2295	712	31%	1362	59%	2286	100%	9	0%
1998 January-June	2832	1273	45%	2042	72%	2820	100%	12	0%
1998 July-December	3798	2014	53%	2913	77%	3774	99%	24	1%
1999 January-June	4751	2859	60%	3949	83%	4699	99%	52	1%
1999 July-December	4213	2544	60%	3445	82%	4126	98%	87	2%
2000 January	685	423	62%	539	79%	649	95%	36	5%
2000 February	789	486	62%	634	80%	751	95%	38	5%
2000 March	1279	862	67%	1102	86%	1223	96%	56	4%
2000 April	1055	672	64%	889	84%	997	95%	58	5%
2000 May	1089	703	65%	916	84%	1003	92%	86	8%
2000 June	1021	666	65%	880	86%	936	92%	85	8%
2000 July	802	528	66%	668	83%	718	90%	84	10%
2000 August	911	629	69%	797	87%	819	90%	92	10%
2000 September	687	458	67%	583	85%	583	85%	104	15%
2000 October	709	482	68%	584	82%	584	82%	125	18%
2000 November	593	377	64%	420	71%	420	71%	173	29%
2000 December	591	385	65%	385	65%	385	65%	206	35%
2001 January	841	351	42%	351	42%	351	42%	490	58%
2001 February	566	60	11%	60	11%	60	11%	506	89%
Total	33204	17727	53%	24756	75%	30863	93%	2341	7%

[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

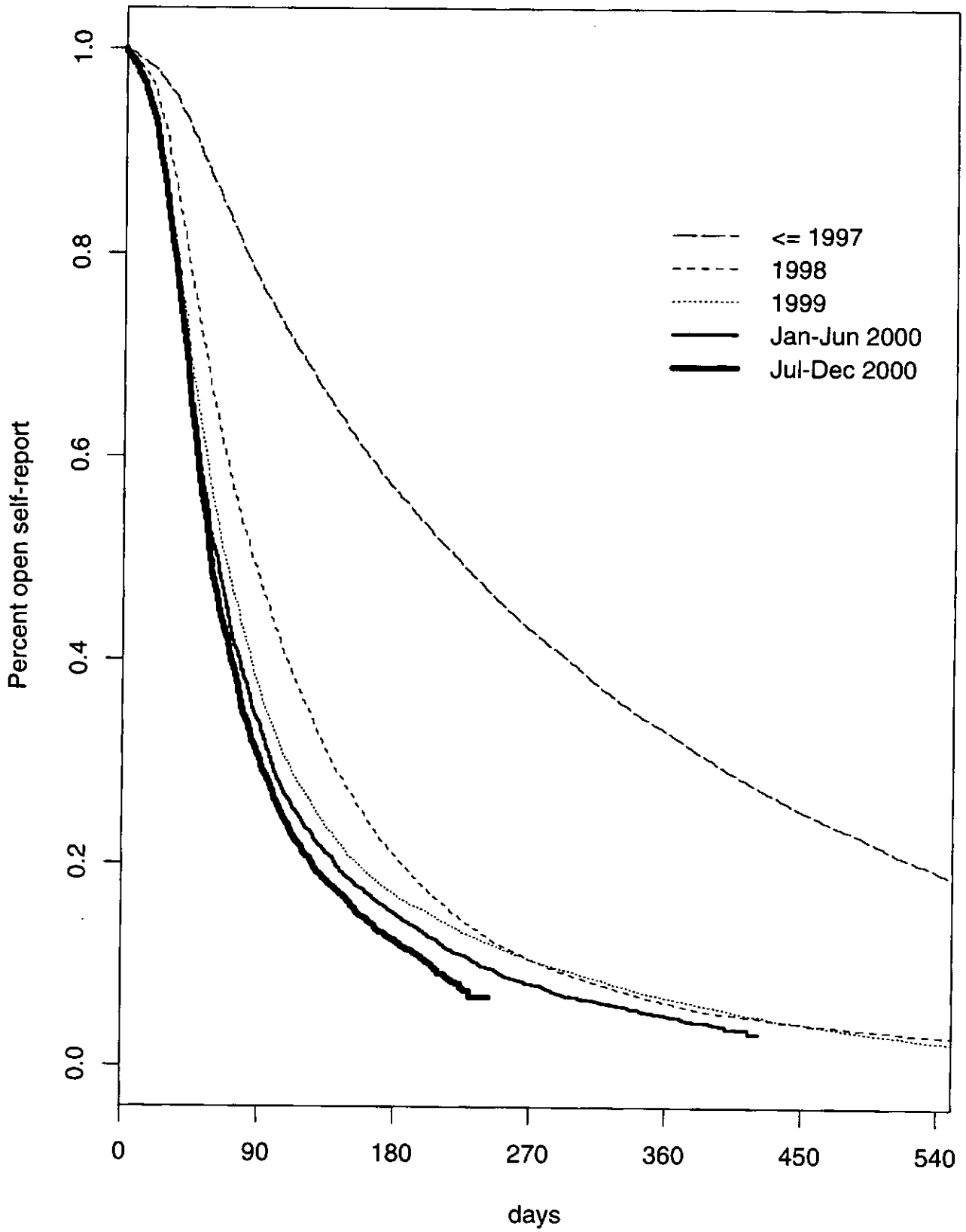


Figure 6.2 Observational Study Timeliness per Period of Self-Report

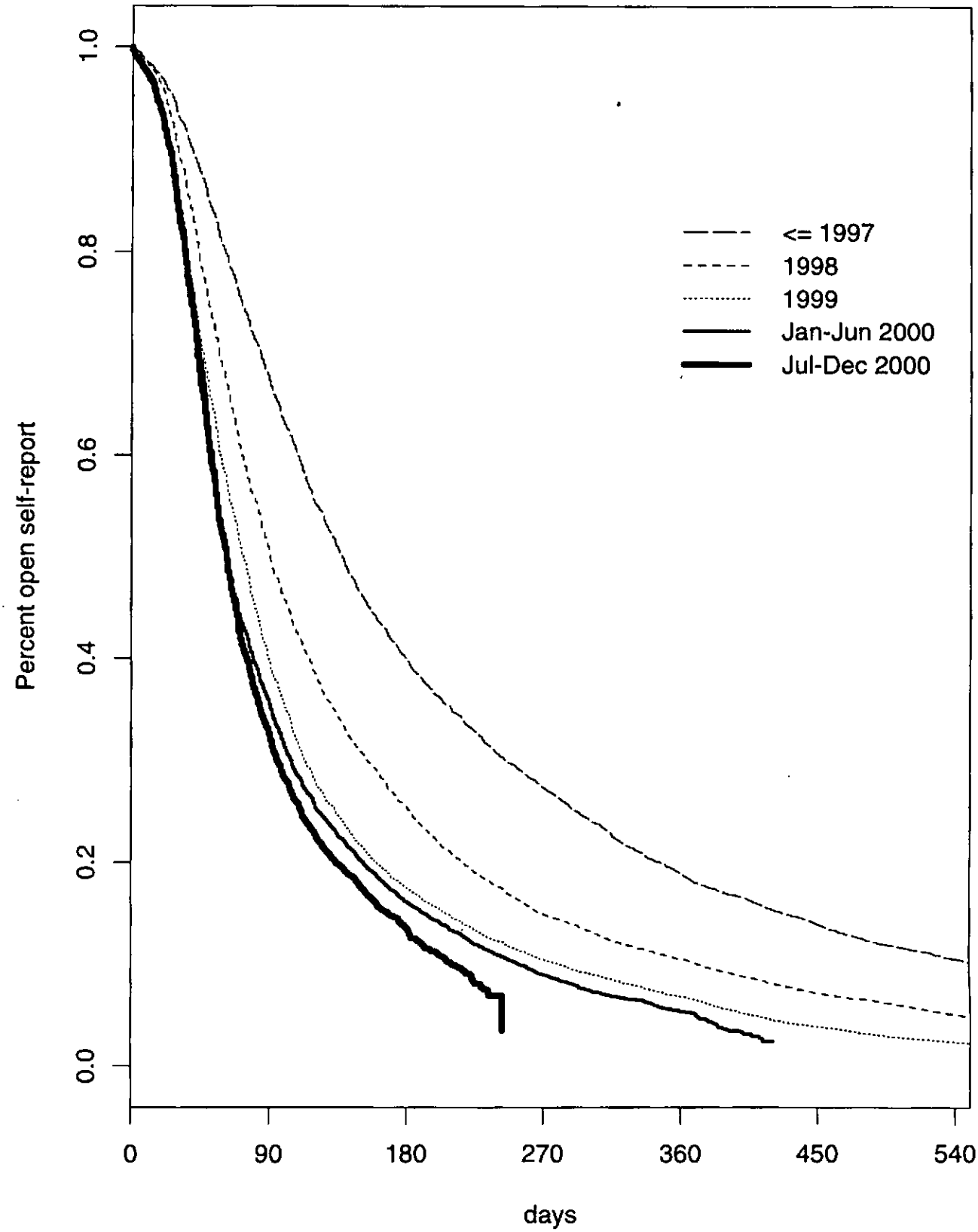


Table 6.3
Agreement of the Local Adjudications with Self-Reports — CT

Data as of: February 28, 2001

	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											
MI	693	624	(90%)	452	(72%)	91	(15%)	73	(12%)	8	(1%)
Angina[2]	1381	1247	(90%)	585	(47%)	58	(5%)	576	(46%)	28	(2%)
Congestive heart failure	430	386	(90%)	274	(71%)	27	(7%)	79	(20%)	6	(2%)
CABG/PTCA	1420	1248	(88%)	1001	(80%)	108	(9%)	121	(10%)	18	(1%)
Carotid artery disease[3]	206	184	(89%)	152	(83%)	19	(10%)	9	(5%)	4	(2%)
Stroke/TIA[4]	1056	960	(91%)	734	(76%)	43	(4%)	169	(18%)	14	(1%)
PVD	139	121	(87%)	73	(60%)	15	(12%)	30	(25%)	3	(2%)
DVT[5]	209	192	(92%)	132	(69%)	30	(16%)	25	(13%)	5	(3%)
PE[5]	102	91	(89%)	79	(87%)	5	(5%)	7	(8%)	0	(0%)
Cancers											
Breast cancer	1329	1215	(91%)	1158[6]	(95%)	1	(0%)	50	(4%)	6	(0%)
Ovary cancer	141	129	(91%)	94	(73%)	27	(21%)	6	(5%)	2	(2%)
Endometrial cancer	179	160	(89%)	121	(76%)	22	(14%)	16	(10%)	1	(1%)
Colorectal	383	349	(91%)	306	(88%)	20	(6%)	21	(6%)	2	(1%)
Other cancer[7]	1527	1384	(91%)	1051	(76%)	77	(6%)	227	(16%)	29	(2%)
Fractures											
Hip fracture	278	260	(94%)	210	(81%)	16	(6%)	31	(12%)	3	(1%)
Vertebral fracture	504	449	(89%)	232	(52%)	14	(3%)	187	(42%)	16	(4%)
Other fracture	4788	4452	(93%)	3607	(81%)	38	(1%)	683	(15%)	124	(3%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI, is not adjudicated. In particular, 157 such self-reports of angina are excluded from this table.
[3] Carotid artery disease that is self-reported after a confirmed Stroke, is not adjudicated. In particular, 4 such self-reports of Carotid artery disease are excluded from this table.
[4] Stroke and TIA have a combined self-report. Only stroke is monitored. There were 215 participants who reported stroke/TIA for whom only TIA was confirmed.
[5] HRT Participants only
[6] There were 909 cases of invasive breast cancer and 249 cases of non-invasive breast cancer.
[7] Excludes non-melanoma skin cancer

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

Data as of: February 28, 2001

	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											
MI	612	543	(89%)	361	(66%)	98	(18%)	76	(14%)	8	(1%)
Angina[2]	1580	1106	(70%)	638	(58%)	84	(8%)	691	(62%)	30	(3%)
Congestive heart failure	487	430	(88%)	306	(71%)	31	(7%)	85	(20%)	8	(2%)
CABG/PTCA	1599	1414	(88%)	1082	(77%)	137	(10%)	169	(12%)	26	(2%)
Carotid artery disease[3]	239	184	(77%)	173	(94%)	25	(14%)	17	(9%)	3	(2%)
Stroke/TIA[4]	1200	1070	(89%)	791	(74%)	48	(4%)	203	(19%)	28	(3%)
PVD	194	165	(85%)	96	(58%)	21	(13%)	43	(26%)	5	(3%)
Cancers											
Breast cancer	1954	1763	(90%)	1607[5]	(91%)	10	(1%)	129	(7%)	17	(1%)
Ovary cancer	180	158	(88%)	108	(68%)	23	(15%)	26	(16%)	1	(1%)
Endometrial cancer	217	189	(87%)	148	(78%)	24	(13%)	13	(7%)	4	(2%)
Colorectal	415	377	(91%)	314	(83%)	24	(6%)	32	(8%)	7	(2%)
Other cancer[6]	1998	1781	(89%)	1235	(69%)	131	(7%)	363	(20%)	52	(3%)
Fractures											
Hip fracture	367	338	(92%)	262	(78%)	2	(1%)	63	(19%)	11	(3%)
Vertebral fracture	68	60	(88%)	37	(62%)	6	(10%)	14	(23%)	3	(5%)
Other fracture	520	486	(93%)	357	(73%)	10	(2%)	105	(22%)	14	(3%)

[1] Percentages between parentheses are relative to "closed."

[2] Angina that is self-reported after a confirmed MI, is not adjudicated. In particular, 109 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, 7 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 263 participants who reported stroke/TIA for whom only TIA was confirmed.

[5] There were 1320 cases of invasive breast cancer and 287 cases of non-invasive breast cancer.

[6] Excludes non-melanoma skin cancer

Table 6.5
Agreement of Central Adjudications with Local Adjudications — CT

Data as of: February 28, 2001

	Locally confirmed N	Centrally adjudicated N	%	In agreement N	%[1]
Cardiovascular					
MI	686	454	66%	382	84%
Angina[2]	1265	896	71%	666	74%
Congestive heart failure	594	398	67%	299	75%
CABG/PTCA	1093	739	68%	716	97%
DVT[3]	173	120	69%	101	84%
PE[3]	102	64	63%	56	88%
Cancers					
Breast cancer	1177	972	83%	968	100%
Invasive	922	753	82%	740	98%
Non Invasive	255	215	84%	187	87%
Ovary cancer	114	87	76%	69	79%
Endometrial cancer	152	128	84%	122	95%
Colorectal cancer	341	274	80%	269	98%
Fractures					
Hip fracture	256	208	81%	197	95%

[1] Percentage is relative to centrally adjudicated cases
[2]Participants with a confirmed MI no longer require adjudication of angina
[3]HRT only; DVT and PE are centrally adjudicated since May of 1997

Table 6.6
Agreement of Central Adjudications with Local Adjudications — OS

Data as of: February 28, 2001

	Locally confirmed N	Centrally adjudicated N	%	In agreement N	%[1]
Cardiovascular					
MI	684	407	60%	330	81%
Angina[2]	1434	973	68%	757	78%
Congestive heart failure	753	482	64%	385	80%
CABG/PTCA	1203	776	65%	744	96%
Cancers					
Breast cancer	1660	1303	78%	1276	98%
Invasive	1358	1036	76%	1006	97%
Non Invasive	302	240	79%	195	81%
Ovary cancer	140	103	74%	82	80%
Endometrial cancer	215	166	77%	152	92%
Colorectal cancer	352	268	76%	252	94%
Fractures					
Hip fracture	321	244	76%	237	97%

[1] Percentage is relative to centrally adjudicated cases
[2]Participants with a confirmed MI no longer require adjudication of angina

Table 6.7
Agreement of Locally and Centrally Adjudicated Cause of Death for <u>All CT Participants</u>

Data as of: February 28, 2001

	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	972	468	(48%)	387	(83%)	37	(8%)	44	(9%)
Cardiovascular									
Artheroslerotic cardiac[3]	159	76	(48%)	66	(87%)	4	(5%)	6	(8%)
Cerebrovascular	70	32	(46%)	29	(91%)	0	(0%)	3	(9%)
Pulminary embolism	3	1	(33%)	0	(0%)	0	(0%)	1	(100%)
Other cardiovascular	69	34	(49%)	18	(53%)	9	(26%)	7	(21%)
Unknown cardiovascular	17	8	(47%)	0	(0%)	4	(50%)	4	(50%)
Total cardiovascular deaths	318	151	(47%)	113	(75%)	17	(11%)	21	(14%)
Cancer									
Breast cancer	13	8	(62%)	8	(100%)	0	(0%)	0	(0%)
Ovarian cancer	31	15	(48%)	14	(93%)	1	(7%)	0	(0%)
Endometrial cancer	3	2	(67%)	1	(50%)	1	(50%)	0	(0%)
Colorectal cancer	51	23	(45%)	21	(91%)	1	(4%)	1	(4%)
Other cancer	360	182	(51%)	169	(93%)	9	(5%)	4	(2%)
Unknown cancer site	25	10	(40%)	6	(60%)	4	(40%)	0	(0%)
Total cancer deaths	483	240	(50%)	219	(91%)	16	(7%)	5	(2%)
Accident/injury									
Homicide	4	4	(100%)	3	(75%)	1	(25%)	0	(0%)
Accident	29	16	(55%)	13	(81%)	1	(6%)	2	(13%)
Suicide	5	4	(80%)	4	(100%)	0	(0%)	0	(0%)
Other injury	3	1	(33%)	0	(0%)	0	(0%)	1	(100%)
Total Accidental deaths	41	25	(61%)	20	(80%)	2	(8%)	3	(12%)
Other									
Other known cause	94	44	(47%)	32	(73%)	1	(2%)	11	(25%)
Unknown cause	36	8	(22%)	3	(38%)	1	(13%)	4	(50%)
Total deaths - other causes	130	52	(40%)	35	(67%)	2	(4%)	15	(29%)

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

Table 6.8
Agreement of Locally and Centrally Adjudicated Cause of Death for All OS Participants

Data as of: February 28, 2001

	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	1343	648	(48%)	516	(80%)	65	(10%)	67	(10%)
Cardiovascular									
Artherosclerotic cardiac[3]	182	81	(45%)	62	(77%)	8	(10%)	11	(14%)
Cerebrovascular	92	51	(55%)	45	(88%)	3	(6%)	3	(6%)
Pulminary embolism	7	2	(29%)	1	(50%)	0	(0%)	1	(50%)
Other cardiovascular	91	42	(46%)	21	(50%)	13	(31%)	8	(19%)
Unknown cardiovascular	17	11	(65%)	0	(0%)	9	(82%)	2	(18%)
Total cardiovascular deaths	389	187	(48%)	129	(69%)	33	(18%)	25	(13%)
Cancer									
Breast cancer	78	40	(51%)	36	(90%)	3	(8%)	1	(3%)
Ovarian cancer	42	20	(48%)	19	(95%)	0	(0%)	1	(5%)
Endometrial cancer	10	4	(40%)	2	(50%)	2	(50%)	0	(0%)
Colorectal cancer	59	26	(44%)	25	(96%)	0	(0%)	1	(4%)
Other cancer	439	3	(1%)	1	(33%)	2	(67%)	0	(0%)
Uterus cancer	0	208	N/A	195	(94%)	9	(4%)	4	(2%)
Unknown cancer site	42	23	(55%)	16	(70%)	7	(30%)	0	(0%)
Total cancer deaths	670	324	(48%)	294	(91%)	23	(7%)	7	(2%)
Accident/injury									
Homicide	4	3	(75%)	3	(100%)	0	(0%)	0	(0%)
Accident	36	21	(58%)	16	(76%)	2	(10%)	3	(14%)
Suicide	14	6	(43%)	5	(83%)	0	(0%)	1	(17%)
Other injury	1	1	(100%)	0	(0%)	1	(100%)	0	(0%)
Total accidental deaths	55	31	(56%)	24	(77%)	3	(10%)	4	(13%)
Other									
Other known cause	179	84	(47%)	62	(74%)	2	(2%)	20	(24%)
Unknown cause	50	22	(44%)	7	(32%)	4	(18%)	11	(50%)
Total deaths - other causes	229	106	(46%)	69	(65%)	6	(6%)	31	(29%)

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

Table 6.9
Locally Verified Outcomes (Annualized Percentages) by Age for Clinical Trial

Data as of: February 28, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68135	9191	14664	31393	12887
Mean follow-up (months)	49.9	56.0	52.2	48.1	47.2
Cardiovascular					
CHD[1]	910 (0.32%)	53 (0.12%)	94 (0.15%)	428 (0.34%)	335 (0.66%)
CHD death[2]	262 (0.09%)	13 (0.03%)	22 (0.03%)	121 (0.10%)	106 (0.21%)
Total MI[3]	712 (0.25%)	42 (0.10%)	77 (0.12%)	333 (0.26%)	260 (0.51%)
Clinical MI	686 (0.24%)	38 (0.09%)	77 (0.12%)	316 (0.25%)	255 (0.50%)
Definite Silent MI	45 (0.02%)	6 (0.01%)	2 (<0.01%)	27 (0.02%)	10 (0.02%)
Possible Silent MI	161 (0.06%)	15 (0.03%)	26 (0.04%)	68 (0.05%)	52 (0.10%)
Angina	1200 (0.42%)	60 (0.14%)	154 (0.24%)	588 (0.47%)	398 (0.78%)
CABG/PTCA	1093 (0.39%)	49 (0.11%)	136 (0.21%)	536 (0.43%)	372 (0.73%)
Carotid artery disease	222 (0.08%)	5 (0.01%)	23 (0.04%)	106 (0.08%)	88 (0.17%)
Congestive heart failure	594 (0.21%)	26 (0.06%)	62 (0.10%)	258 (0.21%)	248 (0.49%)
Stroke	600 (0.21%)	20 (0.05%)	60 (0.09%)	273 (0.22%)	247 (0.49%)
PVD	152 (0.05%)	6 (0.01%)	17 (0.03%)	71 (0.06%)	58 (0.11%)
CHD[1]/Possible Silent MI	1051 (0.37%)	68 (0.16%)	114 (0.18%)	488 (0.39%)	381 (0.75%)
Coronary disease[4]	2563 (0.91%)	140 (0.33%)	304 (0.48%)	1223 (0.97%)	896 (1.77%)
Total CVD	3288 (1.16%)	164 (0.38%)	380 (0.60%)	1568 (1.25%)	1176 (2.32%)
Cancer					
Breast cancer[5]	1179 (0.42%)	125 (0.29%)	235 (0.37%)	582 (0.46%)	237 (0.47%)
Invasive breast cancer	924 (0.33%)	88 (0.21%)	190 (0.30%)	454 (0.36%)	192 (0.38%)
Non-invasive breast cancer	267 (0.09%)	37 (0.09%)	49 (0.08%)	134 (0.11%)	47 (0.09%)
Ovary cancer	122 (0.04%)	15 (0.03%)	22 (0.03%)	56 (0.04%)	29 (0.06%)
Endometrial cancer[6]	152 (0.09%)	18 (0.07%)	32 (0.08%)	68 (0.09%)	34 (0.12%)
Colorectal cancer	345 (0.12%)	20 (0.05%)	52 (0.08%)	178 (0.14%)	95 (0.19%)
Other cancer[7]	1241 (0.44%)	103 (0.24%)	194 (0.30%)	605 (0.48%)	339 (0.67%)
Total cancer	2972 (1.05%)	275 (0.64%)	519 (0.81%)	1460 (1.16%)	718 (1.42%)
Fractures					
Hip fracture	256 (0.09%)	9 (0.02%)	17 (0.03%)	96 (0.08%)	134 (0.26%)
Vertebral fracture	277 (0.10%)	13 (0.03%)	28 (0.04%)	110 (0.09%)	126 (0.25%)
Other fracture[7]	3773 (1.33%)	447 (1.04%)	690 (1.08%)	1763 (1.40%)	873 (1.72%)
Total fracture	4194 (1.48%)	464 (1.08%)	728 (1.14%)	1925 (1.53%)	1077 (2.12%)
Deaths					
Cardiovascular deaths	342 (0.12%)	14 (0.03%)	28 (0.04%)	151 (0.12%)	149 (0.29%)
Cancer deaths	518 (0.18%)	33 (0.08%)	62 (0.10%)	253 (0.20%)	170 (0.34%)
Deaths: other known cause	143 (0.05%)	10 (0.02%)	21 (0.03%)	61 (0.05%)	51 (0.10%)
Deaths: unknown cause	57 (0.02%)	6 (0.01%)	6 (0.01%)	23 (0.02%)	22 (0.04%)
Deaths: not yet adjudicated	133 (0.05%)	7 (0.02%)	11 (0.02%)	57 (0.05%)	58 (0.11%)
Total death	1193 (0.42%)	70 (0.16%)	128 (0.20%)	545 (0.43%)	450 (0.89%)

[1] "CHD" includes clinical MI, definite silent MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death and "other" and "unknown" cardiovascular death.
[3] "Total MI" includes clinical MI and definite silent MI.
[4] "Coronary disease" includes clinical MI, definite silent MI, possible silent MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[5] Excludes eight cases with borderline malignancy.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] 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 6.9 (Continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Clinical Trial

Data as of: February 28, 2001

Outcome	Race/Ethnicity: American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	293	1519	6984	2877	55526	936
Mean follow-up (months)	48.8	46.4	48.7	47.5	50.3	45.9
Cardiovascular						
CHD[1]	2 (0.17%)	5 (0.09%)	92 (0.32%)	20 (0.18%)	780 (0.34%)	11 (0.31%)
CHD death[2]	2 (0.17%)	2 (0.03%)	40 (0.14%)	4 (0.04%)	210 (0.09%)	4 (0.11%)
Total MI[3]	0 (0.00%)	4 (0.07%)	64 (0.23%)	16 (0.14%)	619 (0.27%)	9 (0.25%)
Clinical MI	0 (0.00%)	4 (0.07%)	60 (0.21%)	16 (0.14%)	598 (0.26%)	8 (0.22%)
Definite Silent MI	0 (0.00%)	0 (0.00%)	4 (0.01%)	0 (0.00%)	39 (0.02%)	2 (0.06%)
Possible Silent MI	0 (0.00%)	4 (0.07%)	17 (0.06%)	4 (0.04%)	135 (0.06%)	1 (0.03%)
Angina	5 (0.42%)	16 (0.27%)	142 (0.50%)	41 (0.36%)	982 (0.42%)	14 (0.39%)
CABG/PTCA	2 (0.17%)	8 (0.14%)	100 (0.35%)	29 (0.25%)	944 (0.41%)	10 (0.28%)
Carotid artery disease	3 (0.25%)	4 (0.07%)	18 (0.06%)	1 (0.01%)	194 (0.08%)	2 (0.06%)
Congestive heart failure	2 (0.17%)	2 (0.03%)	95 (0.34%)	10 (0.09%)	478 (0.21%)	7 (0.20%)
Stroke	4 (0.34%)	13 (0.22%)	71 (0.25%)	17 (0.15%)	487 (0.21%)	8 (0.22%)
PVD	2 (0.17%)	0 (0.00%)	24 (0.08%)	3 (0.03%)	122 (0.05%)	1 (0.03%)
CHD[1]/Possible Silent MI	2 (0.17%)	9 (0.15%)	106 (0.37%)	24 (0.21%)	898 (0.39%)	12 (0.33%)
Coronary disease[4]	8 (0.67%)	27 (0.46%)	310 (1.09%)	69 (0.61%)	2120 (0.91%)	29 (0.81%)
Total CVD	15 (1.26%)	42 (0.72%)	384 (1.35%)	86 (0.75%)	2723 (1.17%)	38 (1.06%)
Cancer						
Breast cancer[5]	2 (0.17%)	25 (0.43%)	77 (0.27%)	28 (0.25%)	1039 (0.45%)	8 (0.22%)
Invasive breast cancer	2 (0.17%)	22 (0.37%)	59 (0.21%)	20 (0.18%)	817 (0.35%)	4 (0.11%)
Non-invasive breast cancer	0 (0.00%)	3 (0.05%)	20 (0.07%)	8 (0.07%)	232 (0.10%)	4 (0.11%)
Ovary cancer	1 (0.08%)	0 (0.00%)	9 (0.03%)	2 (0.02%)	109 (0.05%)	1 (0.03%)
Endometrial cancer[6]	1 (0.19%)	1 (0.03%)	9 (0.07%)	7 (0.11%)	132 (0.09%)	2 (0.10%)
Colorectal cancer	2 (0.17%)	8 (0.14%)	40 (0.14%)	16 (0.14%)	275 (0.12%)	4 (0.11%)
Other cancer[7]	5 (0.42%)	20 (0.34%)	92 (0.32%)	28 (0.25%)	1084 (0.47%)	12 (0.33%)
Total cancer	11 (0.92%)	54 (0.92%)	222 (0.78%)	78 (0.68%)	2582 (1.11%)	25 (0.70%)
Fractures						
Hip fracture	0 (0.00%)	1 (0.02%)	9 (0.03%)	3 (0.03%)	241 (0.10%)	2 (0.06%)
Vertebral fracture	0 (0.00%)	6 (0.10%)	2 (0.01%)	4 (0.04%)	264 (0.11%)	1 (0.03%)
Other fracture[7]	14 (1.17%)	59 (1.00%)	193 (0.68%)	97 (0.85%)	3373 (1.45%)	37 (1.03%)
Total fracture	14 (1.17%)	65 (1.11%)	203 (0.72%)	102 (0.90%)	3770 (1.62%)	40 (1.12%)
Deaths						
Cardiovascular deaths	2 (0.17%)	4 (0.07%)	52 (0.18%)	4 (0.04%)	275 (0.12%)	5 (0.14%)
Cancer deaths	2 (0.17%)	11 (0.19%)	43 (0.15%)	10 (0.09%)	446 (0.19%)	6 (0.17%)
Deaths: other known cause	3 (0.25%)	1 (0.02%)	15 (0.05%)	2 (0.02%)	121 (0.05%)	1 (0.03%)
Deaths: unknown cause	1 (0.08%)	0 (0.00%)	9 (0.03%)	1 (0.01%)	46 (0.02%)	0 (0.00%)
Deaths: not yet adjudicated	0 (0.00%)	3 (0.05%)	17 (0.06%)	2 (0.02%)	108 (0.05%)	3 (0.08%)
Total death	8 (0.67%)	19 (0.32%)	136 (0.48%)	19 (0.17%)	996 (0.43%)	15 (0.42%)

[1] "CHD" includes clinical MI, definite silent MI, and CHD death.
[2] "CHD death" includes definite and possible CHD death and "other" and "unknown" cardiovascular death.
[3] "Total MI" includes clinical MI and definite silent MI.
[4] "Coronary disease" includes clinical MI, definite silent MI, possible silent MI, CHD death, angina, congestive heart failure, and CABG/PTCA.
[5] Excludes eight cases with borderline malignancy.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] 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 6.10
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, 2001

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68135	9191	14664	31393	12887
Mean follow-up (months)	49.9	56.0	52.2	48.1	47.2
Hospitalizations					
Ever	20645 (7.29%)	2090 (4.87%)	3631 (5.69%)	9774 (7.77%)	5150 (10.15%)
Two or more	8277 (2.92%)	745 (1.74%)	1327 (2.08%)	3847 (3.06%)	2358 (4.65%)
Other					
DVT[1]	406 (0.15%)	30 (0.07%)	61 (0.10%)	183 (0.15%)	132 (0.27%)
PE	218 (0.08%)	14 (0.03%)	33 (0.05%)	104 (0.08%)	67 (0.13%)
Diabetes (treated)	2453 (0.91%)	343 (0.82%)	523 (0.85%)	1111 (0.93%)	476 (0.99%)
Gallbladder disease[2]	2821 (1.19%)	426 (1.12%)	650 (1.19%)	1299 (1.25%)	446 (1.09%)
Hysterectomy	1191 (0.72%)	162 (0.66%)	255 (0.64%)	554 (0.77%)	220 (0.78%)
Glaucoma	3567 (1.31%)	328 (0.78%)	627 (1.01%)	1759 (1.46%)	853 (1.82%)
Osteoporosis	7484 (2.80%)	647 (1.54%)	1212 (1.96%)	3686 (3.12%)	1939 (4.28%)
Osteoarthritis[3]	6924 (4.05%)	899 (2.90%)	1511 (3.55%)	3194 (4.43%)	1320 (5.25%)
Rheumatoid arthritis	2149 (0.79%)	297 (0.71%)	503 (0.82%)	918 (0.76%)	431 (0.90%)
Intestinal polyps	4683 (1.78%)	529 (1.27%)	922 (1.52%)	2349 (2.02%)	883 (1.96%)
Lupus	371 (0.13%)	60 (0.14%)	80 (0.13%)	178 (0.14%)	53 (0.10%)
Kidney Stones[3]	803 (0.39%)	108 (0.37%)	170 (0.38%)	378 (0.40%)	147 (0.39%)
Cataracts[3]	10543 (5.68%)	502 (1.70%)	1480 (3.29%)	5778 (6.84%)	2783 (5.68%)
Pills for hypertension	8993 (4.50%)	1133 (3.26%)	1908 (3.92%)	4084 (4.77%)	1868 (6.06%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native	Asian/Pacific Islander	Black/African Am	Hispanic/ Latino	White	Other/ Unspecified
Number randomized	293	1519	6984	2877	55526	936
Mean follow-up (months)	48.8	46.4	48.7	47.5	50.3	45.9
Hospitalizations						
Ever	87 (7.30%)	269 (4.58%)	2128 (7.51%)	664 (5.83%)	17262 (7.42%)	235 (6.56%)
Two or more	43 (3.61%)	90 (1.53%)	871 (3.07%)	236 (2.07%)	6958 (2.99%)	79 (2.21%)
Other						
DVT[1]	2 (0.17%)	1 (0.02%)	37 (0.13%)	6 (0.05%)	357 (0.16%)	3 (0.09%)
PE	3 (0.25%)	2 (0.03%)	17 (0.06%)	3 (0.03%)	189 (0.08%)	4 (0.11%)
Diabetes (treated)	18 (1.67%)	70 (1.27%)	473 (1.89%)	166 (1.56%)	1691 (0.75%)	35 (1.04%)
Gallbladder disease[2]	14 (1.60%)	48 (0.90%)	231 (0.91%)	119 (1.37%)	2367 (1.22%)	42 (1.38%)
Hysterectomy	5 (0.95%)	20 (0.53%)	77 (0.63%)	41 (0.65%)	1041 (0.75%)	7 (0.34%)
Glaucoma	14 (1.24%)	78 (1.38%)	478 (1.81%)	150 (1.36%)	2802 (1.25%)	45 (1.34%)
Osteoporosis	32 (2.83%)	175 (3.14%)	347 (1.27%)	276 (2.60%)	6545 (2.99%)	109 (3.27%)
Osteoarthritis[3]	37 (5.27%)	145 (3.46%)	699 (4.18%)	350 (4.58%)	5592 (4.01%)	101 (4.57%)
Rheumatoid arthritis	17 (1.58%)	45 (0.80%)	390 (1.48%)	208 (1.91%)	1457 (0.65%)	32 (0.94%)
Intestinal polyps	22 (2.01%)	90 (1.67%)	486 (1.84%)	164 (1.50%)	3858 (1.78%)	63 (1.91%)
Lupus	3 (0.25%)	7 (0.12%)	47 (0.17%)	14 (0.12%)	297 (0.13%)	3 (0.08%)
Kidney Stones[3]	5 (0.60%)	21 (0.48%)	76 (0.37%)	49 (0.58%)	642 (0.38%)	10 (0.38%)
Cataracts[3]	48 (6.20%)	213 (5.40%)	955 (5.14%)	403 (4.99%)	8780 (5.78%)	144 (5.99%)
Pills for hypertension	39 (5.06%)	195 (4.88%)	960 (6.76%)	419 (4.92%)	7273 (4.28%)	107 (4.49%)

[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 6.11
Locally Confirmed Other Cancers[1]: CT and OS Participants

Data as of: February 28, 2001

	CT		OS	
Number of participants	68135		93717	
Mean follow-up time (months)	49.9		43.3	
Ppts with other cancer	1169	(0.41%)	1383	(0.41%)
Adrenal gland	1	(<0.01%)	3	(<0.01%)
Anus	4	(<0.01%)	9	(<0.01%)
Biliary tract, parts of (other/unspecifi	17	(0.01%)	11	(<0.01%)
Bladder	70	(0.02%)	83	(0.02%)
Bones/joints/articular cartilage (limbs)	2	(<0.01%)	3	(<0.01%)
Bones/joints/articular cartilage (other)	2	(<0.01%)	1	(<0.01%)
Brain	40	(0.01%)	43	(0.01%)
Cervix	31	(0.01%)	14	(<0.01%)
Connective/subcutaneous/soft tissues	6	(<0.01%)	7	(<0.01%)
Endocrine glands, related structures	2	(<0.01%)	1	(<0.01%)
Esophagus	9	(<0.01%)	16	(<0.01%)
Eye and adnexa	3	(<0.01%)	3	(<0.01%)
Genital organs	13	(<0.01%)	8	(<0.01%)
Kidney	58	(0.02%)	70	(0.02%)
Larynx	4	(<0.01%)	4	(<0.01%)
Leukemia	53	(0.02%)	56	(0.02%)
Liver	14	(<0.01%)	16	(<0.01%)
Lung (bronchus)	236	(0.08%)	286	(0.08%)
Lymph nodes	7	(<0.01%)	3	(<0.01%)
Lymphoma, Hodgkins Disease	7	(<0.01%)	6	(<0.01%)
Lymphoma, Non-Hodgkins	98	(0.03%)	128	(0.04%)
Melanoma of the skin	149	(0.05%)	189	(0.06%)
Multiple myeloma	46	(0.02%)	38	(0.01%)
Oral (mouth)	7	(<0.01%)	10	(<0.01%)
Palate	2	(<0.01%)	4	(<0.01%)
Pancreas	68	(0.02%)	68	(0.02%)
Parotid gland (Stensen's duct)	2	(<0.01%)	8	(<0.01%)
Peripheral nerves and autonomic nervous system	0	(0.00%)	3	(<0.01%)
Respiratory system, intrathoracic, other	1	(<0.01%)	2	(<0.01%)
Salivary glands, major (other/unspecifie	1	(<0.01%)	3	(<0.01%)
Stomach	12	(<0.01%)	16	(<0.01%)
Thyroid	35	(0.01%)	42	(0.01%)
Tongue, part of (other/unspecified)	11	(<0.01%)	7	(<0.01%)
Urinary organs (other/unspecified)	1	(<0.01%)	11	(<0.01%)
Uterus, not otherwise specified	17	(0.01%)	28	(0.01%)
Other/unknown site of cancer	154	(0.05%)	203	(0.06%)

[1] No reported cases of accessory sinus or pyriform sinus cancers.

Table 6.12
Locally Confirmed Other Fractures: CT and OS Participants

Data as of: February 28, 2001

	CT		OS[1]	
Locally Confirmed				
Number of participants	68135		7203	
Mean follow-up time (months)	49.9		48.7	
Ppts with other fractures	3770	(1.33%)	383	(1.31%)
Ankle	638	(0.23%)	62	(0.21%)
Carpal bone(s) in wrist	90	(0.03%)	5	(0.02%)
Clavicle or collar bone	60	(0.02%)	9	(0.03%)
Humerus, shaft/unspecified	36	(0.01%)	4	(0.01%)
Humerus, upper end	385	(0.14%)	32	(0.11%)
Humerus, lower end	48	(0.02%)	5	(0.02%)
Metacarpal bone(s)	140	(0.05%)	10	(0.03%)
Patella	153	(0.05%)	20	(0.07%)
Pelvis	123	(0.04%)	20	(0.07%)
Radius or ulna	1041	(0.37%)	111	(0.38%)
Sacrum and coccyx	35	(0.01%)	6	(0.02%)
Scapula	16	(0.01%)	4	(0.01%)
Shaft of femur	48	(0.02%)	2	(0.01%)
Tarsal/metatarsal bones	644	(0.23%)	70	(0.24%)
Tibia and fibula	341	(0.12%)	25	(0.09%)
Tibial plateau	73	(0.03%)	4	(0.01%)
Upper radius/ulna	204	(0.07%)	22	(0.08%)
Self-Reports				
Number of participants			93717	
Mean follow-up time (months)			43.3	
Elbow			292	(0.09%)
Foot			1138	(0.34%)
Hand			212	(0.06%)
Knee			367	(0.11%)
Lower Arm			1582	(0.47%)
Lower Leg			1283	(0.38%)
Pelvis			240	(0.07%)
Tailbone			74	(0.02%)
Upper Arm			603	(0.18%)
Upper Leg			145	(0.04%)
Vertebra			633	(0.19%)
Other Fracture			1517	(0.45%)

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

Table 6.13
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, 2001

	No Locally Confirmed MI or Open Self-Report of MI	Open Self-Report of MI[1]	Locally Confirmed MI[2]	Total
All CT Participants				
No significant Q or ST-T evolution[3]	47059	7	243	47309
Borderline Q-wave change[4]	1466	1	36	1503
Ischemic ST-T evolution[5]	885	4	30	919
Possible evolving Q-wave MI[6]	119[7]	2	16	137
Evolving Q-wave MI[8]	25[9]	0	15	40
Total	49554	14	340	49908
HRT Participants				
No significant Q or ST-T evolution[3]	18547	4	115	18666
Borderline Q-wave change[4]	626	1	15	642
Ischemic ST-T evolution[5]	402	2	10	414
Possible evolving Q-wave MI[6]	55[7]	1	7	63
Evolving Q-wave MI[8]	9[9]	0	8	17
Total	19639	8	155	19802
DM Participants				
No significant Q or ST-T evolution[3]	34171	4	164	34339
Borderline Q-wave change[4]	1022	1	24	1047
Ischemic ST-T evolution[5]	608	2	22	632
Possible evolving Q-wave MI[6]	73[7]	1	14	88
Evolving Q-wave MI[8]	18[9]	0	7	25
Total	35892	8	231	36131
CaD Participants				
No significant Q or ST-T evolution[3]	26947	5	84	27036
Borderline Q-wave change[4]	853	0	13	866
Ischemic ST-T evolution[5]	469	1	7	477
Possible evolving Q-wave MI[6]	70[7]	0	6	76
Evolving Q-wave MI[8]	17[9]	0	6	23
Total	28356	6	116	28478

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

Table 6.14
Cause of Death: CT and OS Participants (Annualized Percentages)

Data as of: February 28, 2001

	CT		OS	
Number Randomized	68135		93717	
Mean Follow-up Time (months)	49.9		43.3	
Total death	1193	(0.42%)	1783	(0.53%)
Adjudicated death	1060	(0.37%)	1512	(0.45%)
Final Adjudicated Death	972	(0.34%)	1343	(0.40%)
Temporary Adjudicated Death	88	(0.03%)	169	(0.05%)
Cardiovascular				
Atherosclerotic cardiac	168	(0.06%)	193	(0.06%)
CHD deaths adjudicated before 9/99	86	(0.03%)	82	(0.02%)
Definite CHD deaths adjudicated after 9/99	53	(0.02%)	56	(0.02%)
Possible CHD deaths adjudicated after 9/99	29	(0.01%)	55	(0.02%)
Cerebrovascular	76	(0.03%)	103	(0.03%)
Pulmonary Embolism	4	(<0.01%)	7	(<0.01%)
Other cardiovascular	73	(0.03%)	100	(0.03%)
Unknown cardiovascular	21	(0.01%)	25	(0.01%)
Total cardiovascular deaths	342	(0.12%)	428	(0.13%)
Cancer				
Breast cancer	16	(0.01%)	79	(0.02%)
Ovarian cancer	36	(0.01%)	46	(0.01%)
Endometrial cancer	4	(<0.01%)	11	(0.01%)
Colorectal cancer	52	(0.02%)	62	(0.02%)
Other cancer	382	(0.13%)	478	(0.14%)
Unknown cancer site	28	(0.01%)	50	(0.01%)
Total cancer deaths	518	(0.18%)	726	(0.21%)
Accident/injury				
Homicide	4	(<0.01%)	4	(<0.01%)
Accident	31	(0.01%)	37	(0.01%)
Suicide	5	(<0.01%)	14	(<0.01%)
Other injury	3	(<0.01%)	3	(<0.01%)
Total accidental deaths	43	(0.02%)	58	(0.02%)
Other				
Other known cause	100	(0.04%)	196	(0.06%)
Unknown cause	57	(0.02%)	104	(0.03%)
Total deaths – other causes	157	(0.06%)	300	(0.09%)

Table 6.15
Lost-to-Follow-up and Vital Status by Clinic: CT Participants

Data as of: February 28, 2001

	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	33	1.9	1561	90.7	75	4.4	1	0.1	16	0.9	36	2.1	1722
Birmingham	46	2.5	1726	94.5	17	0.9	0	0.0	20	1.1	18	1.0	1827
Bowman	25	1.6	1403	92.5	56	3.7	0	0.0	15	1.0	17	1.1	1516
Brigham	36	1.6	2216	96.1	35	1.5	0	0.0	1	0.0	19	0.8	2307
Buffalo	32	2.0	1553	96.5	12	0.7	0	0.0	9	0.6	3	0.2	1609
Chapel Hill	21	1.4	1486	96.7	2	0.1	0	0.0	22	1.4	5	0.3	1536
Chicago	41	2.5	1479	91.2	35	2.2	0	0.0	39	2.4	28	1.7	1622
Chi-Rush	23	1.7	1204	90.5	43	3.2	1	0.1	28	2.1	31	2.3	1330
Cincinnati	14	1.0	1218	87.2	63	4.5	15	1.1	32	2.3	55	3.9	1397
Columbus	31	2.0	1486	95.5	7	0.4	0	0.0	21	1.3	11	0.7	1556
Detroit	9	0.7	1097	79.6	90	6.5	1	0.1	100	7.3	81	5.9	1378
Gainesville	41	2.0	1952	94.9	11	0.5	0	0.0	40	1.9	12	0.6	2056
GWU-DC	19	1.3	1457	96.2	17	1.1	1	0.1	14	0.9	7	0.5	1515
Honolulu	17	1.2	1321	94.0	18	1.3	0	0.0	36	2.6	14	1.0	1406
Houston	8	0.6	1167	91.8	48	3.8	0	0.0	42	3.3	6	0.5	1271
Iowa City	46	1.9	2340	96.1	21	0.9	0	0.0	13	0.5	15	0.6	2435
Irvine	19	1.2	1480	91.1	39	2.4	3	0.2	39	2.4	45	2.8	1625
L.A.	27	1.6	1579	93.4	42	2.5	0	0.0	26	1.5	16	0.9	1690
La Jolla	41	1.9	1920	89.1	95	4.4	2	0.1	33	1.5	64	3.0	2155
Madison	21	1.4	1500	96.5	10	0.6	0	0.0	18	1.2	6	0.4	1555
Medlantic	34	2.3	1355	90.4	59	3.9	0	0.0	33	2.2	18	1.2	1499
Memphis	47	2.7	1591	91.1	44	2.5	4	0.2	32	1.8	29	1.7	1747
Miami	15	1.0	1201	80.9	131	8.8	0	0.0	34	2.3	103	6.9	1484
Milwaukee	24	1.5	1496	90.6	72	4.4	0	0.0	29	1.8	31	1.9	1652
Minneapolis	37	1.9	1896	95.2	40	2.0	2	0.1	14	0.7	3	0.2	1992
Nevada	36	2.4	1437	96.6	2	0.1	0	0.0	11	0.7	2	0.1	1488
Newark	41	1.7	2231	90.8	91	3.7	1	0.0	72	2.9	22	0.9	2458
NY-City	31	1.6	1739	92.4	43	2.3	6	0.3	20	1.1	44	2.3	1883
Oakland	25	1.6	1506	95.9	16	1.0	0	0.0	12	0.8	12	0.8	1571
Pawtucket	38	1.4	2523	95.2	14	0.5	2	0.1	65	2.5	7	0.3	2649
Pittsburgh	41	2.5	1574	95.3	21	1.3	1	0.1	15	0.9	0	0.0	1652
Portland	29	1.8	1481	91.1	56	3.4	0	0.0	32	2.0	28	1.7	1626
San Antonio	12	0.9	1240	89.5	13	0.9	1	0.1	90	6.5	30	2.2	1386
Seattle	38	2.1	1671	93.3	48	2.7	2	0.1	20	1.1	12	0.7	1791
Stanford	27	1.5	1698	95.2	28	1.6	1	0.1	18	1.0	12	0.7	1784
Stonybrook	22	1.6	1296	95.5	17	1.3	0	0.0	16	1.2	6	0.4	1357
Torrance	19	1.9	888	87.5	51	5.0	1	0.1	32	3.2	24	2.4	1015
Tucson	54	2.6	1842	89.3	57	2.8	2	0.1	36	1.7	72	3.5	2063
U.C. Davis	48	2.5	1731	91.2	70	3.7	5	0.3	22	1.2	23	1.2	1899
Worcester	25	1.5	1555	95.3	26	1.6	1	0.1	7	0.4	17	1.0	1631
Total	1193	1.8	63096	92.6	1635	2.4	53	0.1	1174	1.7	984	1.4	68135

[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] Participiants 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 6.16
Lost-to-Follow-up and Vital Status by Clinic: OS Participants

Data as of: February 28, 2001

	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	42	1.7	2310	93.7	45	1.8	0	0.0	7	0.3	62	2.5	2466
Birmingham	64	2.5	2283	90.3	112	4.4	2	0.1	43	1.7	25	1.0	2529
Bowman	36	1.6	1908	85.8	203	9.1	1	0.0	20	0.9	57	2.6	2225
Brigham	21	0.7	2845	96.6	52	1.8	4	0.1	1	0.0	23	0.8	2946
Buffalo	73	3.2	2136	95.0	18	0.8	1	0.0	7	0.3	13	0.6	2248
Chapel Hill	32	1.5	2027	97.2	13	0.6	0	0.0	12	0.6	1	0.0	2085
Chicago	35	1.9	1714	90.6	77	4.1	7	0.4	13	0.7	45	2.4	1891
Chi-Rush	36	1.8	1768	86.1	156	7.6	3	0.1	45	2.2	45	2.2	2053
Cincinnati	41	1.8	1939	86.2	124	5.5	12	0.5	24	1.1	110	4.9	2250
Columbus	31	1.4	2073	93.3	99	4.5	4	0.2	7	0.3	8	0.4	2222
Detroit	24	1.1	1836	87.0	94	4.5	0	0.0	48	2.3	109	5.2	2111
Gainesville	55	2.0	2627	94.1	39	1.4	3	0.1	51	1.8	17	0.6	2792
GWU-DC	46	2.0	2146	95.4	49	2.2	5	0.2	1	0.0	2	0.1	2249
Honolulu	30	1.4	2003	94.8	18	0.9	1	0.0	55	2.6	6	0.3	2113
Houston	47	2.2	2004	94.2	21	1.0	1	0.0	47	2.2	8	0.4	2128
Iowa City	40	1.3	2976	95.4	57	1.8	0	0.0	13	0.4	33	1.1	3119
Irvine	44	2.0	2064	92.6	39	1.7	3	0.1	35	1.6	44	2.0	2229
L.A.	29	1.3	2125	96.8	13	0.6	0	0.0	15	0.7	14	0.6	2196
La Jolla	60	1.7	3008	86.8	187	5.4	32	0.9	24	0.7	153	4.4	3464
Madison	45	2.3	1902	96.0	23	1.2	0	0.0	7	0.4	4	0.2	1981
Medlantic	35	1.6	1941	88.5	103	4.7	11	0.5	3	0.1	99	4.5	2192
Memphis	51	2.0	2334	92.7	52	2.1	3	0.1	63	2.5	14	0.6	2517
Miami	25	1.8	1063	75.7	144	10.3	2	0.1	19	1.4	151	10.8	1404
Milwaukee	33	1.5	2098	93.3	62	2.8	1	0.0	12	0.5	43	1.9	2249
Minneapolis	46	1.7	2600	95.4	40	1.5	0	0.0	20	0.7	19	0.7	2725
Nevada	86	4.0	2055	94.4	25	1.1	1	0.0	7	0.3	2	0.1	2176
Newark	52	1.5	3078	91.2	145	4.3	4	0.1	31	0.9	64	1.9	3374
NY-City	59	2.0	2603	89.7	90	3.1	5	0.2	23	0.8	123	4.2	2903
Oakland	46	2.2	1919	93.5	62	3.0	0	0.0	13	0.6	12	0.6	2052
Pawtucket	69	1.9	3329	92.8	93	2.6	61	1.7	21	0.6	15	0.4	3588
Pittsburgh	49	2.6	1754	91.5	51	2.7	8	0.4	14	0.7	41	2.1	1917
Portland	34	1.5	2089	93.6	45	2.0	1	0.0	41	1.8	21	0.9	2231
San Antonio	33	1.7	1776	91.5	18	0.9	2	0.1	83	4.3	28	1.4	1940
Seattle	49	2.9	1546	93.0	36	2.2	7	0.4	6	0.4	18	1.1	1662
Stanford	60	2.2	2509	93.7	53	2.0	3	0.1	35	1.3	18	0.7	2678
Stonybrook	30	1.5	1880	92.7	78	3.8	1	0.0	9	0.4	29	1.4	2027
Torrance	29	1.9	1307	86.9	60	4.0	29	1.9	37	2.5	42	2.8	1504
Tucson	73	2.6	2471	89.0	93	3.4	2	0.1	34	1.2	103	3.7	2776
U.C. Davis	57	2.5	2138	94.4	40	1.8	10	0.4	10	0.4	11	0.5	2266
Worcester	36	1.6	2078	92.8	80	3.6	1	0.0	3	0.1	41	1.8	2239
Total	1783	1.9	86262	92.0	2809	3.0	231	0.2	959	1.0	1673	1.8	93717

[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] Participiants 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.

7. Clinical Center Performance Monitoring

7.1 Performance Monitoring

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

7.2 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; Linda Pottern and Shari Ludlum, Project Office; Judy Hsia, George Washington Clinical Center PI; Shirley Beresford, Seattle Clinical Center PI (through December 2000); and Gerardo Heiss, Chapel Hill Clinical Center PI (since January 2001); Michelle Naughton, Sara Wilcox, Mary Ann Sevick, Beth Dugan, CFC; and Andrea LaCroix, Barb Cochrane, Lesley Tinker, Julie Hunt and Bernedine Lund, CCC; Membership of the Outcomes 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, Lori Proulx-Burns, and Bernedine Lund, CCC.

Since September 1, 2000, the A&R PMC held one conference call every 4-6 weeks, 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 levels, and 3) DM C-I. Each measure is compared to study goals as well as study-wide averages. An updated schedule for review of CCs based on CC performance was made, with CCs performing well being reviewed once a year, average CCs being reviewed every 8 months, and lower performing CCs being reviewed every 6 months. The PMC also forwarded the issue of CCs with very low blood collection at OS year 3 visits to the PO for review.

The A&R PMC held a targeted conference call with one CC and began scheduling conference calls with two other CCs. The A&R PMC also finalized the guidelines for conducting PMC visits, incorporating guidelines for conducting PMC targeted phone calls and distributed certificates of appreciation to all CC staff who had assisted in previous PMC visits. Several issues are forwarded to the Executive Committee for recommendations, including encouraging PIs and staff to share problem solving across CCs, encouraging communications between the PMC and PIs, and reviewing CC-specific newsletters.

The PMC continued its discussions on how to best follow-up with Clinical Centers. It is anticipated that PMC visits will only be conducted on rare occasions in the future. Possibilities for more targeted efforts include more focused conference calls, specific training visits, and regional or group training sessions.

In the same period, the Outcomes PMC held one conference call per month, reviewing 5-6 Clinical Centers on each call. A summary of each Clinical Center 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) responsiveness to CCC queries for more information on cancer cases, and 4) a summary of number of staff and local adjudicators. In the letters to CCs, specific goals were listed for CCs.

Since March 1, the Outcomes PMC conducted targeted or specific conference calls with two Clinical Centers to discuss lagging outcomes processing. A CCC outcomes liaison participated in QA Visits to two CCs.

The shortened PMC report was updated for data as of November 30, 2000, and distributed to all CCs. The same report showing data as of February 28, 2001 is in *Tables 7.1-7.6.*

Table 7.1
Performance Monitoring Committee Report
Data as of 2/28/01
DM

	Adjusted C-I[1]				Task Completeness Form 60 - FFQ[4]		% Stopped[5]	
	Average[2]		Mar 00 - Feb 01[3]		Jun -Nov 00		Cum Feb 01	
	%	Rank	%	Rank	%	Rank	%	Rank
Nevada	13.3	1	11.1	2	95.1	3	2.5	5
Oakland	11.8	2	11.5	1	93.9	5	1.9	3
Iowa City	11.6	3	10.0	7	93.7	6	1.2	2
Madison	11.4	4	9.4	13	95.3	2	2.7	7
Stanford	11.3	5	10.5	4	92.4	11	2.9	9
Seattle	11.2	6	10.4	5	92.5	9	3.4	11
Columbus	11.1	7	9.5	10	96.1	1	6.0	28
Minneapolis	11.1	8	10.0	8	91.7	15	2.7	6
Pittsburgh	10.9	9	10.1	6	94.8	4	1.2	1
GWU-DC	10.9	10	9.9	9	89.2	21	3.1	10
Milwaukee	10.8	11	9.5	11	88.7	24	4.4	16
Irvine	10.5	12	9.4	14	88.6	25	5.7	27
Portland	10.1	13	8.2	20	89.2	22	6.6	29
Chicago	10.0	14	10.5	3	89.0	23	10.1	36
Worcester	9.9	15	8.8	16	91.8	14	4.7	18
Gainesville	9.8	16	8.6	18	91.5	16	5.3	23
Chapel Hill	9.5	17	9.1	15	92.9	7	2.0	4
Torrance	9.5	18	6.7	35	81.1	37	9.0	35
UC Davis	9.4	19	9.4	12	90.1	18	5.2	20
LA	9.4	20	7.8	24	83.8	31	5.3	22
Brigham	9.3	21	7.7	27	92.4	12	3.7	12
Memphis	9.2	22	7.9	23	84.8	29	6.7	30
Pawtucket	9.1	23	7.8	25	92.4	10	5.5	25
Buffalo	9.0	24	8.4	19	92.8	8	2.7	8
Stony Brook	8.9	25	8.2	22	89.5	20	4.4	15
Newark	8.9	26	6.8	32	84.3	30	7.4	32
Tucson	8.8	27	8.2	21	81.4	36	5.6	26
Houston	8.8	28	7.7	26	85.9	27	4.5	17
Bowman	8.7	29	7.4	28	90.7	17	4.3	14
Cincinnati	8.5	30	7.0	31	90.1	19	10.4	37
Honolulu	8.4	31	7.3	29	87.8	26	5.2	21
Chi-Rush	8.3	32	8.7	17	82.8	32	6.9	31
Atlanta	8.3	33	6.8	33	81.4	35	3.7	13
LaJolla	8.1	34	7.2	30	85.4	28	4.7	19
NYC	7.7	35	6.8	34	92.3	13	7.7	34
Detroit	7.5	36	6.5	36	72.9	39	16.1	40
Birmingham	7.1	37	6.2	37	82.1	33	5.3	24
San Antonio	6.4	38	4.7	39	81.7	34	15.4	39
Mediantic	6.0	39	5.2	38	74.2	38	7.5	33
Miami	4.9	40	4.3	40	63.5	40	14.9	38
CC Average	**9.4**		**8.3**		**88.1**		**5.6**	

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

[2] Based on FFQs collected after randomization through AV6.

[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 *WHIP CCC0751- DM Intervention & F/U Status*, includes stopped intervention, stopped F/U, and lost-to-F/U; excludes deaths

Table 7.2
Performance Monitoring Committee Report
Data as of 2/28/01

HRT

	Adherence Summary > 80%				Task Completeness Jun-Nov 00				% Stopped[5]	
	Average[1]		Mar 00-Feb 01[2]		Form 10[3]		Form 85[4]		Cum Feb 01	
	%	Rank	%	Rank	%	Rank	%	Rank	%	Rank
Oakland	81.8	1	80.2	1	97.7	8	96.1	3	17.4	1
Iowa City	76.7	2	71.0	2	97.5	9	96.7	1	22.2	2
Stanford	72.6	3	67.3	5	98.2	6	82.3	32	24.8	6
Minneapolis	71.5	4	67.8	4	96.5	12	93.2	8	25.1	7
Chapel Hill	70.2	5	62.7	12	98.3	5	95.0	6	27.8	10
Cincinnati	70.2	6	65.5	7	92.8	27	85.7	25	28.7	12
Madison	70.1	7	62.9	11	97.4	10	95.6	4	29.7	15
Brigham	70.0	8	67.8	3	98.6	3	93.7	7	27.8	11
Gainesville	69.7	9	65.9	6	97.7	7	90.2	14	33.8	22
LA	69.4	10	60.7	16	91.0	35	85.4	26	22.8	3
Milwaukee	69.2	11	63.1	10	91.5	32	85.8	24	24.4	5
Portland	68.6	12	60.5	17	89.7	38	92.2	10	25.5	8
Nevada	67.7	13	63.3	9	99.0	1	92.7	9	29.9	16
Pawtucket	66.7	14	63.5	8	98.9	2	90.9	12	34.0	23
Worcester	66.2	15	62.5	13	94.6	16	95.0	5	32.5	20
Pittsburgh	66.2	16	60.4	18	94.2	19	92.2	11	28.8	13
Chicago	65.2	17	62.4	14	96.0	13	83.5	31	31.4	19
Honolulu	63.8	18	56.9	24	91.6	31	89.3	16	23.8	4
Birmingham	63.4	19	57.6	22	95.5	14	90.1	15	30.8	18
Torrance	62.3	20	59.2	19	92.3	29	85.2	28	34.3	26
UC Davis	62.0	21	57.9	21	94.6	17	90.5	13	34.1	25
Newark	61.4	22	51.5	34	93.7	22	88.7	17	27.1	9
Stony Brook	61.3	23	53.1	28	93.9	20	86.8	21	37.1	33
Columbus	61.1	24	58.5	20	98.5	4	96.4	2	32.6	21
Seattle	60.5	25	57.3	23	93.7	23	87.0	20	35.0	30
Memphis	60.1	26	56.8	25	93.7	21	86.3	22	34.6	28
Chi-Rush	59.7	27	61.8	15	92.8	26	83.8	30	34.6	27
Irvine	58.6	28	53.9	27	91.4	33	76.8	38	29.9	17
Buffalo	56.8	29	56.2	26	96.7	11	85.3	27	34.6	28
GWU-DC	56.8	30	51.8	31	94.9	15	81.5	34	34.0	23
LaJolla	56.2	31	51.7	32	91.6	30	76.3	39	29.2	14
NYC	55.6	32	52.6	29	92.7	28	87.1	19	38.3	35
Tucson	55.2	33	51.4	35	90.5	37	77.3	36	38.6	36
Bowman	54.3	34	50.7	36	94.5	18	87.6	18	36.1	31
Houston	54.2	35	48.1	38	90.8	36	78.0	35	45.2	39
Atlanta	54.0	36	51.8	30	93.0	25	86.0	23	37.7	34
Detroit	53.2	37	50.6	37	79.0	40	77.2	37	38.7	37
San Antonio	52.1	38	51.6	33	91.4	34	84.5	29	38.8	38
Medlantic	49.7	39	47.5	39	93.6	24	81.7	33	36.4	32
Miami	35.7	40	36.0	40	89.5	39	61.5	40	55.0	40
CC Average	**63.3**		**59.0**		**94.4**		**87.4**		**31.5**	

[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 stopped intervention, stopped F/U, and lost-to-F/U; excludes deaths

Table 7.3
Performance Monitoring Committee Report
Data as of 2/28/01

CaD

	Adherence Summary > 80%				Task Completeness Form 17[3]		% Stopped[4]	
	Average[1]		Mar 00 - Feb 01[2]		Jun-Nov 00		Cum Feb 01	
	%	Rank	%	Rank	%	Rank	%	Rank
Oakland	80.3	1	83.1	1	98.4	6	6.7	1
Iowa City	73.2	2	74.2	2	97.4	11	10.0	2
Stanford	72.6	3	74.1	3	97.9	9	15.4	9
Minneapolis	68.7	4	71.4	4	96.3	14	12.5	4
Columbus	68.6	5	68.9	7	99.3	2	17.4	14
Gainesville	68.0	6	70.4	6	98.5	5	21.3	28
Nevada	66.9	7	71.1	5	99.3	3	13.3	5
Chi-Rush	64.7	8	64.6	10	93.7	26	22.3	32
Brigham	64.2	9	65.1	8	97.1	12	21.7	30
Honolulu	63.5	10	61.7	16	94.0	24	19.8	23
Chapel Hill	63.2	11	61.5	17	98.8	4	11.8	3
Pittsburgh	63.1	12	63.4	13	96.2	16	18.6	20
Milwaukee	62.9	13	60.1	22	89.6	37	15.3	8
Pawtucket	62.7	14	64.9	9	99.5	1	21.4	29
Portland	59.7	15	57.3	27	92.2	33	17.9	16
Madison	59.5	16	59.8	23	97.7	10	17.3	13
Worcester	59.0	17	61.4	18	95.8	17	15.1	7
Torrance	58.6	18	64.1	11	92.3	32	18.1	18
LA	58.5	19	60.5	20	93.1	31	17.7	15
Cincinnati	58.4	20	62.4	14	91.9	35	20.1	24
Seattle	57.7	21	61.2	19	93.3	28	20.8	25
Bowman	57.2	22	62.0	15	95.7	19	18.3	19
Stony Brook	57.0	23	56.7	28	93.9	25	21.3	27
Buffalo	56.5	24	63.8	12	97.9	8	16.2	10
UC Davis	55.8	25	60.2	21	95.3	22	19.2	21
LaJolla	55.1	26	55.0	31	93.2	29	16.9	12
GWU-DC	54.7	27	54.2	33	96.2	15	17.9	17
Birmingham	53.7	28	58.8	25	98.1	7	13.7	6
Chicago	52.4	29	56.2	29	95.7	20	24.3	35
Tucson	52.2	30	59.3	24	93.5	27	27.6	39
Atlanta	52.2	31	58.0	26	94.9	23	21.7	31
Houston	52.0	32	52.1	36	92.1	34	24.7	36
Irvine	51.5	33	53.1	34	93.1	30	19.7	22
NYC	51.2	34	55.2	30	95.8	18	23.3	34
Memphis	50.5	35	54.5	32	91.2	36	27.5	38
Detroit	49.6	36	50.4	37	83.1	40	26.8	37
San Antonio	48.9	37	52.2	35	95.6	21	23.0	33
Medlantic	47.1	38	49.0	38	96.6	13	16.8	11
Newark	45.8	39	46.8	39	89.5	38	20.9	26
Miami	31.8	40	38.5	40	88.7	39	39.1	40
CC Average	**58.7**		**60.8**		**95.0**		**18.4**	

[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 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, and lost-to-F/U; excludes deaths

Table 7.4
Performance Monitoring Committee Report
Data as of 2/28/01

OS

	Task Completeness - Year 3[1] Nov 99-Apr 00[2]				% Stopped[3]	
	Form 100		Form 143		Cum Feb 01	
	%	Rank	%	Rank	%	Rank
Oakland	95.1	1	98.5	1	1.3	11
Nevada	95.0	2	96.7	4	0.4	2
GWU-DC	91.5	3	93.8	9	0.2	1
Buffalo	89.9	4	96.8	3	1.0	8
UC Davis	89.5	5	90.7	21	0.9	7
Iowa City	89.4	6	96.8	2	1.5	13
Atlanta	88.6	7	96.2	5	2.8	22
Columbus	88.5	8	93.4	10	0.7	4
Stanford	88.0	9	92.7	13	2.0	17
Chapel Hill	86.8	10	95.8	6	0.7	5
Brigham	86.0	11	94.3	7	0.8	6
Bowman	85.9	12	93.1	11	3.7	30
Pittsburgh	85.7	13	92.9	12	3.0	25
Worcester	84.5	14	90.7	22	2.0	16
Honolulu	84.5	15	92.0	14	2.9	23
Torrance	84.3	16	91.2	17	6.5	38
LaJolla	83.1	17	86.1	30	5.2	35
Milwaukee	81.9	18	85.0	33	3.1	26
Minneapolis	81.2	19	94.3	8	1.4	12
Portland	80.7	20	88.9	23	2.8	20
Chicago	80.7	21	91.1	18	3.1	28
Pawtucket	80.6	22	91.3	16	1.0	9
Gainesville	80.5	23	91.0	19	2.4	18
Madison	80.3	24	90.9	20	0.5	3
Medlantic	80.1	25	85.9	31	4.9	32
Stony Brook	79.1	26	88.5	25	1.9	15
Seattle	78.8	27	91.8	15	1.5	14
Tucson	78.4	28	81.1	35	5.1	34
Birmingham	78.1	29	79.0	36	2.8	20
Cincinnati	77.4	30	81.4	34	6.3	37
Irvine	77.2	31	85.3	32	3.5	29
LA	76.6	32	86.3	28	1.3	10
Newark	75.8	33	86.3	27	2.9	24
NYC	75.0	34	86.2	29	5.1	33
San Antonio	74.2	35	88.1	26	5.8	36
Houston	71.1	36	88.9	24	2.6	19
Chi-Rush	70.5	37	72.4	38	4.4	31
Memphis	66.9	38	72.1	39	3.1	26
Detroit	64.5	39	73.2	37	7.5	39
Miami	37.1	40	49.7	40	12.3	40
CC Average	**80.7**		**87.9**		**2.9**	

[1] From *WHIP1445-Task Completeness;* complete if encounter date is -3/+15 months from AV3 target date

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

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

Table 7.5
Performance Monitoring Committee Report
Data as of 2/28/01

Outcomes

	Task Completeness						Close Cases < 14 weeks[4]	
	CT Form 33[1] Jun-Nov 00		OS Form 33[2] Nov 99-Apr 00		Form 33D[3] Cum Feb 01		Cum Feb 01	
	%	Rank	%	Rank	%	Rank	%	Rank
Nevada	98.6	1	99.0	2	99.7	6	63.7	17
Buffalo	97.7	2	98.7	3	99.9	3	85.8	2
Chapel Hill	97.6	3	99.2	1	99.9	2	70.0	12
Columbus	96.7	4	98.0	6	97.7	31	67.0	15
Brigham	96.3	5	97.6	8	99.9	3	46.8	29
Pawtucket	96.3	6	94.4	26	99.5	16	68.4	14
Stanford	96.3	7	97.1	11	99.0	26	80.9	5
Iowa City	96.2	8	98.0	5	99.3	22	74.5	7
Madison	96.2	9	98.5	4	99.6	10	90.3	1
Oakland	96.1	10	95.5	18	99.5	14	38.1	37
Minneapolis	96.0	11	96.9	13	97.7	31	63.4	18
GWU-DC	96.0	12	97.1	10	99.6	11	70.8	10
Pittsburgh	95.9	13	95.0	22	100.0	1	64.8	16
Birmingham	95.5	14	96.7	15	99.7	6	37.8	38
Gainesville	95.2	15	97.0	12	99.4	19	77.4	6
Worcester	94.4	16	95.1	21	99.6	12	70.3	11
Seattle	93.6	17	95.3	20	99.8	5	74.4	8
Honolulu	93.3	18	96.3	16	98.1	30	72.1	9
Bowman	93.3	19	94.4	27	97.0	36	32.5	39
Stony Brook	93.0	20	94.6	25	99.7	9	81.8	4
NYC	92.7	21	88.7	36	99.4	19	45.3	31
LA	92.3	22	97.9	7	98.5	27	41.4	34
Mediantic	91.4	23	90.5	35	99.4	17	43.6	32
UC Davis	91.4	24	96.9	14	99.5	13	82.3	3
Houston	91.0	25	97.6	9	98.4	28	54.7	26
Chicago	90.9	26	95.4	19	96.6	38	45.7	30
San Antonio	90.1	27	92.6	31	99.5	15	60.5	23
Irvine	90.0	28	94.9	23	98.1	29	42.7	33
Chi-Rush	89.9	29	91.6	32	99.3	21	62.0	22
Memphis	89.9	30	94.4	28	99.2	24	54.3	27
Newark	89.4	31	93.6	30	99.2	25	62.7	19
Atlanta	89.2	32	95.9	17	97.4	35	60.1	24
Tucson	89.1	33	91.1	34	99.4	17	62.1	21
Milwaukee	88.8	34	94.7	24	97.6	33	69.6	13
Portland	87.9	35	94.3	29	99.7	8	59.1	25
LaJolla	87.9	36	88.7	37	99.2	23	62.2	20
Torrance	83.5	37	91.2	33	97.5	34	26.1	40
Cincinnati	82.3	38	87.4	39	89.9	40	39.3	35
Detroit	76.8	39	88.5	38	95.7	39	38.8	36
Miami	75.6	40	80.3	40	96.7	37	48.2	28
CC Average	**92.2**		**94.7**		**98.7**		**62.5**	

[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 1257-Timeliness of Medical History Update Collection*; includes both CT and OS

[4] From *WHIP 1262-Timeliness of Outcomes Processing*; time from receipt of *Form 33, 33D, or 120* to close date

Table 7.6
Performance Monitoring Committee Report
Data as of 2/28/01

Data Quality

	Timeliness of Data Entry[1]		Encounters without Data[2]		Form 100 Aliquot Discrepancies[3]		Undeliverable Addresses[4]		Chart Audit Errors/Chart[5]		Summary Rank[6]
	%	Rank	%	Rank	%	Rank	%	Rank	#	Rank	
Nevada	96.4	3	0.004	11	1.3	3	0.11	19	8.6	14	1
Madison	97.3	1	0.091	29	2.6	15	0.00	1	5.4	7	2
Stanford	85.1	22	0.000	1	1.9	8	0.00	1	12.6	24	3
GWU-DC	96.7	2	0.001	6	2.9	22	0.11	18	-	-	4
Gainesville	96.4	4	0.006	13	2.6	18	0.36	25	2.7	1	5
Stony Brook	96.2	5	0.058	25	1.9	9	0.03	13	6.4	10	6
Brigham	79.4	33	0.006	14	1.8	7	0.02	7	3.3	2	7
Honolulu	91.1	10	0.006	15	1.7	5	0.29	23	9.1	16	8
Columbus	84.7	23	0.010	17	2.6	16	0.00	1	-	-	9
Atlanta	89.4	13	0.004	10	2.3	12	0.44	27	-	-	10
Minneapolis	81.8	31	0.084	27	0.1	1	0.02	8	7.2	12	11
Seattle	82.2	29	0.000	1	2.7	19	0.24	22	5.6	8	11
Chapel Hill	84.3	24	0.005	12	3.0	24	0.00	1	10.0	19	13
Oakland	83.2	26	0.003	7	3.8	28	0.08	16	4.3	3	13
Milwaukee	88.1	15	0.141	33	4.2	30	0.00	1	4.4	4	15
Buffalo	93.8	7	0.001	4	5.3	38	0.03	12	12.0	22	15
Pittsburgh	85.2	21	0.072	26	1.0	2	0.00	1	25.1	33	15
Iowa City	94.8	6	0.004	9	3.0	23	0.22	21	13.8	25	18
Bowman	90.4	11	0.011	18	2.8	21	0.08	15	11.9	21	19
Pawtucket	83.3	25	0.032	20	2.0	10	0.07	14	-	-	20
San Antonio	92.4	8	0.037	21	2.3	13	3.38	40	4.7	5	21
Chicago	82.9	27	0.000	1	3.8	29	0.32	24	6.3	9	22
Miami	87.9	16	0.007	16	1.8	6	1.30	37	-	-	23
Worcester	86.1	19	0.046	24	4.9	37	0.03	11	4.9	6	24
Portland	69.1	39	0.003	8	2.5	14	0.11	17	-	-	25
Newark	85.5	20	0.042	23	2.6	17	0.47	30	7.7	13	26
NYC	79.3	34	0.001	5	2.7	20	0.40	26	9.4	18	26
Tucson	90.3	12	0.040	22	3.1	26	0.47	29	11.2	20	28
LA	82.8	28	0.153	34	4.3	31	0.03	10	8.8	15	29
Irvine	70.6	38	0.015	19	2.1	11	0.90	35	9.1	16	30
Chi-Rush	87.1	17	0.133	31	1.7	4	1.84	39	17.9	29	31
UC Davis	77.3	35	0.091	28	3.4	27	0.02	9	21.7	32	32
LaJolla	92.0	9	0.345	39	3.1	25	1.72	38	12.4	23	33
Houston	86.4	18	0.340	38	4.9	36	0.45	28	14.6	26	34
Birmingham	74.4	36	0.118	30	4.4	34	0.12	20	15.8	27	35
Mediantic	88.4	14	0.215	35	6.0	39	1.21	36	25.7	34	36
Memphis	69.0	40	0.224	37	7.1	40	0.48	31	6.5	11	37
Detroit	81.8	30	0.140	32	4.3	33	0.67	33	19.3	31	37
Torrance	79.4	32	0.682	40	4.6	35	0.61	32	16.3	28	39
Cincinnati	73.9	37	0.215	36	4.3	32	0.70	34	19.2	30	40
CC Average	**85.4**		**0.075**		**3.0**		**0.41**		**9.4**		

[1] From *WHIP1113 - Timelinesss of Data Entry*; percentage of encounters data entered within 14 days of encounter date

[2] From *WHIP794-Encounters w/o Data;* excludes screening encounters, *Form 53,* and encounters within 6 months of the data as of date

[3] From *WHIP1946-Samples (matching by ID) with Aliquot Discrepancies* for *Form 100-Blood Collection and Processing*

[4] From *WHIP1211 - Members with Undeliverable Addresses*; flagged by CC as undeliverable; excludes deaths

[5] From chart audits conducted in 1998 - present; audits not yet completed on several CCs

[6] Summary rank based on average of ranks in this table. The summary rank for CCs w/o a chart audit are averaged over 4 rather than 5 measures in the table.

8. 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 8.1 – Publications presents current and proposed publications that have been approved by the Publications and Presentations Committee.

Table 8.2 – 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 either 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 8.1
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**, 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
21	Hypertension and It's Treatment in Postmenopausal Women: Baseline Data from the Women's Health Initiative	**Wassertheil-Smoller**, Manson, Wong, Lasser, Kotchen, Langer, Grimm, Black, Psaty, Anderson, Francis	OS	11	Hypertension 2000;36:780-89
24	Estimation of the Correlation between Nutrient Intake Measures Under Restricted Sampling	**Wang**, Anderson, Prentice	Gen.	11	Biometrics, in press
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

MS ID	Title	Authors	Data Focus	Stage	Reference
37	Depression as Mediated by Social Support, Life Events, and Sexual Activity in Postmenopausal Non-Hispanic White and Latina Women	**Larisch**, Talavera, Langer, Velasquez, Elder	Gen.	11	
40	The Health Impact of Domestic Violence in Older Women	**Mouton**, Furniss, Lasser, Rovi	OS	11	Journal of Women's Health & Gender-Based Medicine 1999:8(9):1173-1179
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, Bowen, Zapka, Mason, Lillington, Limacher, Kiefe, Sofaer, Pettinger	OS	11	Preventive Medicine 2000;31:261-270
69	Correlates of Serum Lypocene in Older Women	**Casso**, White, Patterson, Agurs-Collins, Kooperberg, Haines	CT	11	Nutrition and Cancer 2000:36:163-69.
70	Correlates of Serum Alpha- and Gamma-Tocopherol in the WHI	**White**, Masaki, Chen, Shikany, Caan, Mares-Perlman, Wilson, Kristal	CT	11	Annals of Epidemiology 2001;11:136-144
71	The Women's Health Initiative: Goals, Rationale, and Current Status	**Liu**	Gen.	11	Menopausal Medicine, Vol.6(2), p.1-4, 1998
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
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
108	Cross-Sectional Geometry and Bone Mass in the Proximal Femur in African-American and White Postmenopausal Women	**Nelson**, Barondess, Hendrix, Beck	CT	11	
10	A Comprehensive Data Management System for Multicenter Studies	**Anderson**, Davis, Koch	Gen.	10	
17	Sexual Orientation and Health: Comparisons in the Women's Health Initiative Sample	**Valanis**, Charney, Whitlock, Wassertheil-Smoller, Bassford, Bowen, Carter	CT	10	
30	Completeness of Purchase Mailing Lists for Identifying Older Women	**Falkner**, Wactawski-Wende, Trevisan	CT	10	
59	Risk Factors for Kidney Stones in Postmenopausal Women in the Southern United States	**Hall**, Pettinger, Oberman, Watts, Johnson, Paskett, Limacher, Hays	Gen.	10	

MS ID	Title	Authors	Data Focus	Stage	Reference
61	WHI Halfway Paper (100K Paper)	**Langer**, Kotchen, Daugherty, Lewis, Elmer, Trevisan, Noonan, Hendrix, Adams-Campbell	Gen.	10	
72	Post-Menopausal Bone Loss and its Relationship to Oral Bone Loss	**Jeffcoat**, Lewis, Reddy, Wang, Redford	Gen.	10	Periodontics 2000
76	Labeling as a Predictor of Dietary Maintenance	**Hopkins**, Burrows, Bowen, Tinker	CT	10	
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	10	
93	Fat Intake in Husbands of Women in the Dietary Component of the Women's Health Initiative	**Shikany**	Gen.	10	
19	Ethnic, Socioeconomic, and Lifestyle Correlates of Obesity in U.S. Women: The Women's Health Initiative	**Manson**, Lewis, Kotchen, Allen, Johnson, Stefanick, Foreyt, Klesges, Tinker, Noonan, Perri, Hall	Gen.	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	
43	Sleep Complaints of Postmenopausal Women	**Kripke**, Freeman, Masaki, Brunner, Jackson, Hendrix, Carter	CT	9	
67	Association of Yogurt Consumption to Breast and Colorectal Cancers Among WHI Participants in the OS	**Mossavar-Rahmani**, Garland, Caan, Hebert, Wodarski, Vitolins, Himes, Parker	OS	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	
85	Women's Health Initiative: Rationale, Design and Progress Report	**Johnson**, Anderson, Barad, Stefanick, McNagny	CT	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	
112	Results of an Adjunct Dietary Intervention Program in the Women's Health Initiative	**Bowen**, Ehret, Pedersen, Snetselaar, Johnson, Tinker, Hollinger, Lichty, Sivertsen, Ocken, Staats, Beedoe	OS	9	

MS ID	Title	Authors	Data Focus	Stage	Reference
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	9	
126	Influences on Older Women's Adherence to a Low-Fat Diet in the Women's Health Initiative	**Kearney**, Rosal, Ockene, Churchill	CT	9	
135	Radiographic Measurements, Bone Mineral Density and the Singh Index in the Proximal Femur of White and African-American Postmenopausal Women	**Barondess**, Singh, Hendrix, Nelson		9	
34	The Relationship between Smoking Status, Body Weight, and Waist-to-Hip Ratio: the WHI	**Johnson**, Klesges, Hays, Noonan, Black, Curb, Liu, Manson	Gen.	8	
62	Self-reported Urogential Symptoms in Postmenopausal Women: The Women's Health Initiative	**Pastore**, Carter, Hulka, Wells	Gen.	8	
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	8	
142	Coronary Artery Calcification in African-American and White Women	**Khurana**, Rosenbaum, Howard, Adams-Campell, Detrano, Hsia	OS	8	
149	Health Status of Postmenopausal White Women with Back and Leg Pain Living in the Community: A Pilot Study	**Vogt**, Lauerman, Chirumbole, Kuller	OS	8	
16	An Examination of the Differences in Total Energy and Several Nutrient Scores Derived from the FFQ vs. Estimates Based on Basal Metabolic Requirements and Food Record - Derived Scores in the WHI	**Hebert**, Beresford, Patterson, Chlebowski, St. Jeor, Coates, Elmer, Hartman, Prentice, Ebbeling	Gen.	7	
22	Prevalence of Pelvic Organ Prolapse and Urinary Incontinence in Women	**Clark**, Harris, Varner, Chang, Hendrix, Barnabei, Mattox, McTiernan, Francis, Nygaard	CT	7	
29	Effects of Diet Intervention on Motivation to make other Health Related Changes	**Langer**, Lo	CT	7	
39	Interactions among HRT and Dietary Fat Intake on Heart Disease Risk Factors in Postmenopausal Women	**Chlebowski**, Stefanick, Wagenknecht, Frid, Mossavar-Rahmani, Cain, McTiernan	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	

MS ID	Title	Authors	Data Focus	Stage	Reference
79	Databased Tracking and Statistical Models of the Clinical Trial Recruitment Process	**Creech**	CT	7	
98	Patterns of Antioxidant Supplement Use in Participants in the Women's Health Initiative	**Shikany**, Patterson, Dunn, Anderson, Agurs-Collins	Gen.	7	
115	Prevalence and 3-year Incidence of Domestic Violence in Older Women	**Mouton**, Hunt, Brzyski, Rodabough		7	
14	Psychosocial and Behavioral Correlates of Moderate Alcohol Consumption in Women	**Powell**, Hymowitz, Criqui, Ockene, Finnegan, Castro, Trevisan, Curb, Hunt, Noonan	CT	6	
31	Comparisons between Never Smokers, Former Smokers, and Current Smokers in the WHI	**Hymowitz**, Ockene, Bowen, Robbins, Brunner, Shikany	OS	6	
53	Dietary, Physical Activity, and Exercise Patterns Among Diabetics	**Agurs-Collins**, Adams-Campbell, Pasaro, Howard	Gen.	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	
81	The Prevalence of Urinary Incontinence in WHI Women	**Hendrix**, Clark, Ling, Dugan, Salmieri, Hurtado, McNeeley, Laube, McTiernan, Francis	Gen.	6	
113	Prior Use of Oral Contraceptives and Fracture Risk in Menopausal Women	**Barad**, Kooperberg, Wactawski-Wende, Hendrix, Watts, Liu	Gen.	6	
13	Cardiovascular and other Physiological Correlates of Depression	**Wassertheil-Smoller**, Campbell, Shumaker, Ockene, Robbins, Dunbar, Greenland, Cochrane, Noonan	Gen.	5	
25	Hormone Replacement Therapy Effects on the Resting ECG	**Greenland**, Daugherty, Frishman, Kadish, Limacher, Schwartz	CT	5	
36	Prevalence of Silent MI	**Sagar**, Kotchen, Wong, Graettinger, Burke, Van Vorhees, McIntosh	CT	5	
38	The Relationship of Selected Dietary Components and Risk of Adenoma and Colorectal Cancer among Postmenopausal Women: WHI	**Frank**, Agurs-Collins, Gams, Garland, Khandekar, Paskett, Wylie-Rosett, Pettinger	Gen.	5	
41	Determinants of Fasting Hyperinsulinemia	**Manson**, LaCroix, Haan, Rodrigues, Wagenknecht, Johnson, Allen, Hendrix	Gen.	5	
44	Effect of Hysterectomy with Ovarian Reservation on Cardiovascular Morbidity and Mortality	**Brzyski**, Barnabei, Barad, Giudice, Satterfield, Margolis, McNeeley	CT	5	
49	Patterns of Use and Characteristics Associated with HRT among Postmenopausal Women	**Dunn**, Greenland, Woods, Stovall, Bartholow, Francis	Gen.	5	

MS ID	Title	Authors	Data Focus	Stage	Reference
51	The Relationship of Quality of Social Support to Frequency of Cancer Screening Behaviors among Postmenopausal Women	**Lane**, Taylor, Glanz, Elam, Klaskala, Powell, Messina, Smith	Gen.	5	
52	Nutrient Intake of Women with Diabetes in the WHI Observational Study Cohort	**Tinker**, Gams, Lee, Smith, West, Snetselaar, Caggiula	Gen.	5	
66	Physical Activity and CVD in Women: the Role of Moderate vs. Vigorous Exercise	**Manson**, Mouton, LaCroix, Greenland, Oberman, Perri, Siscovick, Sheps	OS	5	
74	Baseline Characteristics of the WHI-OS Breast Cancer Survivor Cohort	**Paskett**, Sherman, Anderson, Hays, McDonald, Naughton	OS	5	
83	Physical Activity and Risk of Breast Cancer in Postmenopausal Women: the Women's Health Initiative	**McTiernan**, Wilcox, Coates, Woods, Ockene, Adams-Campbell, White, Kooperberg	Gen.	5	
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	5	
87	Incidence and Correlates of Hip and Knee Replacement in the WHI	**Wallace**, White, 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	
95	The Effects of Becoming a Widow on Health Behaviors and Health Status in Postmenopausal Women: The Women's Health Initiative	**Wilcox**, Evenson, Wassertheil-Smoller, Mouton, Loevinger, Cochrane	OS	5	
100	Outcomes of Six Month Recall Mammography for Abnormal Findings on Screening Mammograms	**Yasmeen**, Romano, Khandekar, Robbins, Chlebowski, Lane, Hendrix	Gen.	5	
102	Cardiovascular and Mortality Outcomes Related to Anti-Hypertensive Drug Therapy in the WHI	**Wassertheil-Smoller**, Margolis, Mouton, Trevisan, Oberman, Greenland, Kotchen, Psaty, Anderson, Black, Hilkert	OS	5	
106	Utility of Body Mass Index (BMI) as a Proxy for Obesity Among White, Black, Asian, Native American and Hispanic Post-menopausal Women	**Going**, Chen, Tinker, Stefanick, St. Jeor, Lewis	Gen.	5	
107	Physical Activity Throughout the Life Course: The Women's Health Initiative	**Evenson**, Wilcox, Heiss, King, Daugherty, McTiernan	OS	5	
120	Anthropometrics and Risk of Breast Cancer in Postmenopausal Women: The WHI	**Morimoto**, White, McTiernan, Chlebowski, Hays, Stefanick, Margolis, Manson, Kuller, Chen, Muti, Lopez	OS	5	

MS ID	Title	Authors	Data Focus	Stage	Reference
20	Correlates of Endogenous Sex Hormone Concentrations in WHI	**McTiernan**, Wactawski-Wende, Chen, Meilahn, La Valluer, Cummings, Hiaat, Baum, Hulka, Wang, McNagny	CT	4	
23	A Comparative Analysis of Predictors of Recruitment for Hispanic and Caucasian Women in the WHI	**Talavera**, Fouad, Howard, Satterfield, Schenken, Simon, Porter, Bonk, Hunt, Wang, Corbie-Smith	Gen.	4	
68	Reliability and Physiologic Correlates of the Physical Activity Questionnaire in the WHI	**White**, Casso, Wang, Stefanick, Siscovick, Cauley, Strickland, Rebar, Rodrigues, Going, Frid	CT	4	
80	Insulin Resistance and Weight Change in Postmenopausal Black and White Women	**Howard**, Adams-Campbell, Passaro, Black, Stevens, Wagenknecht, Rodgrigues, Safford, Allen, Snetselaar	Gen.	4	
84	Research Staff Turnover and Participant Adherence in the WHI	**Jackson**, Chlebowski, Huber, Boe, Granek, Meyer, Milas	CT	4	
127	Plasma Homocysteine Levels and Coronary Heart Disease in Women	**Siscovick**, Manson, Trevisan, Wallace, Howard, Burke, Ridker	OS	4	
128	Inflammatory Markers for Coronary Heart Disease in Women	**Pradhan**, Manson, Siscovick, Rossouw, Wallace, Mouton, Jackson, Ridker	OS	4	
129	Thrombotic Markers for Coronary Heart Disease in Women	**LaCroix**, Trevisan, Langer, Lewis, Hsia, Oberman, Kotchen, Ridker	OS	4	
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	4	
134	Creative Self-Monitoring Tools in the Dietary Modification Component of the Women's Heath Initiative	**Mossavar-Rahmani**, Henry, Brewer, Freed, Kinzel, Pederson, Soule, Vosburg	CT	4	
18	The Relationship of Dietary Phytoestrogens Menopausal to Symptoms and Major Morbidity in Postmenopausal Women	**San Roman**, Woods, Caggiula, Judd, Brzyski, Liu, Burke, Assaf, Patterson	CT	3	
45	Socio-demographic Determinants of Folic Acid Intake	**Beresford**, Patterson, Kritchevsky, Wodarski, Vitolins	Gen.	3	
47	Is a "Too Low" Fat Diet a Marker of Health or Disease	**Gilligan**, Snetselaar, St. Jeor, Van Horn, Stefanick, Kotchen, Patterson	CT	3	
54	Current Treatment Patterns in Women with Hypercholesterolemia	**Manson**, Freed, Chae	Gen.	3	
55	Factor Structure and Factor Invariance of the Women's Health Initiative Insomnia Rating Scale	**Levine**, Shumaker, Naughton, Kaplan, Kripke, Bowen	Gen.	3	

MS ID	Title	Authors	Data Focus	Stage	Reference
56	Psychometric Evaluation of the Urinary Incontinence Scale	**Levine**, Shumaker, Naughton, Kaplan, Bowen	Gen.	3	
58	Influence of Race and Sunlight Exposure on Distribution of Bone Density Among Postmenopausal Women in the Southeast	**Oberman**, Burke, Hays, Hulka, Johnson, Lewis, Limacher, Schenken	Gen.	3	
75	Do Ethnic Differences in Lean and Fat Mass Contribute to Ethnic Differences in Bone Mineral Density (BMD)?	**Cauley**, Jackson, McGowan, LaCroix, Nevitt, Lewis, Ko, Margolis, Snetselaar	CT	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	
118	Association Between Depressive Symptomatology and Physical Activity in Post-menopausal Women	**Rosal**, Ockene, Haan, Brunner, Mouton, Lopez, Perri, Cochrane, Matthews, Jackson	Gen.	3	
121	Quality of Life in Healthy Women and in Breast Cancer Survivors	**Haan**		3	
132	The Association of Non-Melanoma Skin Cancer and a Second Malignancy	**Rosenberg**, Greenland, Khandekar, Ascensao, Lopez	Gen.	3	
145	Inverse Association of Breast Cancer with the Use of Non-Steroidal Anti-Inflammatory Drugs (NSAIDS): Prospective Results from the Women's Health Initiative	**Harris**, Jackson, Frid, McTiernan, Anderson, White, Ascensao, Chlebowski	OS	3	

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

Table 8.2
Ancillary Studies

AS #	Title	Study's PI(s)	WHI Investigator	Initial D&A Approval	Initial PO Approval	Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
137	Platelet Polymorphisms as Risk Factors for Myocardial Infarction in Postmenopausal Women and their Interactions with Hormone Replacement Therapy	Paul Bray	Jennifer Hays	yes	yes	none	OS Blood Comp	200-280	yes	01/01/01-6/30/01	pending
135	Natural History of Pelvic Organ Prolapse in WHI Women	Ingrid Nygaard	Robert Wallace	yes	yes	none	HRT	400	no	7/01-6/06	pending
134	Serum Estrogen Hormone Metabolites, Hormone Replacement Therapy and the Risk of Breast Cancer	Francesmary Modugno	Lew Kuller	yes	yes	none	OS Blood Comp	400	yes	1/01-12/01	pending
133	Biochemical and Genetic Predictors of Incident Hypertension in White and Black Women	Howard Sesso, JoAnn Manson	JoAnn Manson	no		none	OS Blood Comp	1600	yes	1/1/02-12/31/04	
132	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Simin Liu, JoAnn Manson	JoAnn Manson	yes		none	OS Blood Comp	3840	yes	12/01-12/04	pending
131	Sex Steroid Hormones, Inflammatory Cytokines and the Risk of Rheumatoid Arthritis: A Nested Case Control Study	Nancy Shadick, JoAnn Manson	JoAnn Manson	no		none	OS Blood Comp	1200	yes	1/02-1/05	pending
130	A Randomized Controlled Trial of Fat Reduction, Calcium/Vitamin D Supplementation, Hormone Replacement Therapy, and risk of Proliferative Forms of Benign Breast Disease	Thomas Rohan	S. Wassertheil-Smoller	yes	yes	as many as can be recruited	DM, HRT		no	7/01-06/06	pending

AS #	Title	Study's PI(s)	WHI Investigator	Initial D&A Approval	Initial PO Approval	Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
129	The Association of Diabetes and Insulin-Like Growth Factor-I (IGF-I) with Risks of Colorectal, Breast, and Endometrial Cancer	Howard Strickler	S. Wassertheil-Smoller	yes	yes	none	OS Blood Comp	5775	yes	2/02-2/06	pending
128	DNA Mismatch Repair Gene Associated Colorectal, Endometrial and Ovarian Cancer in Postmenopausal Women: a Novel Prospective Population-Based Study	Tom Weber	S. Wassertheil-Smoller	yes	yes	none	OS Blood Comp	3000	yes	12/01-11/06	pending
127	Impact of Risk Perception on Preventive Health Behaviors, Process of Care and Outcomes Among a Diverse Cohort of Women at High Risk of Ischemic Heart Disease	Janice Barnhart	S. Wassertheil-Smoller	yes		none	OS	350	no	7/01-6/02	pending
126	Molecular and Genetic Determinants of Stroke in the Women's Health Initiative Observational Study	Sylvia Smoller	S. Wassertheil-Smoller	yes	yes	none	OS Umbrella Study	2100	yes	7/01-7/04	pending
125	Osteoporosis in Caribbean Hispanic Women	Ellen Cohen	S. Wassertheil-Smoller	yes		none	OS	500	no	7/01-7/05	pending
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
123	Genetic and Ethnic Determinants of Nicotine Addiction in Postmenopausal Women	Sean P. David		no		21 needed	OS Blood, DM, HRT	30371	yes	4/01-4/-03	dropped
122	Feasibility Study of Computerized Tailored Dietary Feedback	Karen Glanz, David Curb	David Curb	yes	yes	none	DM	36	no	3/10/00-9/00	funded

AS #	Title	Study's PI(s)	WHI Investigator	Initial D&A Approval	Initial PO Approval	Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
121	Hyperinsulinemia and Ovarian Cancer	Carrie Cottreau, Lewis Kuller	Lew Kuller	yes	yes	none	OS Blood Comp	206	yes	2000-2004	pending
120	Epidemiology of Cervical and Lumbar Stenosis	Molly T. Vogt	Lew Kuller	yes	yes	Pittsburgh, Arizona	OS	4000	no	12/00 - 11/04	pending
118	Accuracy of Food Portion Estimation Among Postmenopausal Women	Christine L. Coy		yes	yes	none	DM	191	no	12/1999-4/2000	funded
117	Risk Factors for Dry Eye Syndrome in Postmenopausal Women	Kelley A. Kinney	Rebecca Jackson	yes	yes	none	OS	400	no	9/99-8/02	funded
115	Diabetes In Postmenopausal Women	Barbara V. Howard	Barbara V. Howard	yes	yes	none	OS Umbrella Study	93726	yes		pending
114	Effects of Hormone Replacement Therapy on Cardiac Function and Ischemia	Mary Haan	John Robbins	yes		1 other to participate, unknown	HRT	300	no	7/1/99-6/30/04	dropped
113	Some Aspects of Mediterranean Diet in Relation to Risk of Chronic Diseases among Postmenopausal Women	Iman Hakim	Tamsen Bassford	yes	yes	none	OS	1000	yes	8/1/99 - 7/31/02	pending
112	Motivators and Barriers to Exercise in Older Women	Mary Haan/Carol Parise	Mary Haan	yes	yes	none	OS	1100	no	9/1/99 - 9/30/00	dropped
111	Role of Inflammation in Acute Myocardial Infarction in Women	David Brown	S. Wassertheil-Smoller	yes	no	none	OS Blood Comp	750	yes	2/1/00 - 1/31/02	dropped
110	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Kathryn Rexrode/JoAnn Manson	JoAnn Manson	yes	yes	none	OS Blood Comp	700	yes	4/1/00 - 3/31/03	funded
109	Serum xenoestrogens and the risk of breast cancer	Vanessa Barnabei	Jane Kotchen	yes	yes	none	OS Blood Comp		yes	12/99 - 12/01	pending

AS #	Title	Study's PI(s)	WHI Investigator	Initial D&A Approval	Initial PO Approval	Other Participating Clinics	Study Popu-lation	Sample Size	Speci-mens?	Funding Dates	Funding Status
108	Gene-environment effects and colorectal cancer	Rowan Chlebowski/Henry Lin	Rowan Chlebowski	yes	yes	none	OS Blood Comp	2000	yes	4/1/00 - 3/31/05	pending
107	Hashimoto's Thyroiditis in Postmenopausal Women	Margita Zakarija		yes	yes	Medlantic	OS Blood Comp	2900	yes	4/1/00 - 3/31/05	pending
106	Gene-Diet Interactions in Human Breast Cancer Risk	Jennifer Hu	Electra Paskett	yes	yes	none	OS Blood Comp	800	yes	6/1/99 - 5/31/03	pending
105	Carotenoids in Age-Related Eye Disease Study	Julie Mares-Perlman	Catherine Allen	yes	yes	Iowa, Portland	OS Blood Comp	2880	yes	4/1/00 - 3/31/04	funded
104	Tamoxifen Prevention: Is it acceptable to women at risk?	Joy Melnikow	John Robbins	yes	yes	none	OS	150	no	7/1/99 - 6/30/01	pending
103	Effects of Hormone Replacement Therapy on Cognitive Aging: Women's Health Initiative Study of Cognitive Aging (WHISCA)	Sally Shumaker		yes	yes		HRT	1800	no	4/1/99 - 3/31/05	pending
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
101	Women's Health Oral History Project	Catherine Allen	Catherine Allen	yes	yes	none	DM+HRT +OS	50	no	1/99 - 12/00	dropped
100	Genetic, Biochemical and Behavioral Determinants of Obesity	Jennifer Hays	Jennifer Hays	yes	yes		OS	775	yes	through 9/01	funded
99	GENNID Study	Rowan Chlebowski		yes	yes	none	ALL	40	yes	12/1/98 - 3/31/00	funded
98	Bone mineral density as a predictor for periodontitis	Jean Wactawski-Wende		yes	N/A	none	OS	1000	yes	5/1/99 - 4/30/02	pending
97	Modeling serum markers for cost-effective ovarian cancer screening	Garnet Anderson		yes	yes	none	OS Blood Comp	720	yes	4/1/00 - 3/31/04	funded

AS #	Title	Study's PI(s)	WHI Investigator	Initial D&A Approval	Initial PO Approval	Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
95	Work organization, psychological distress, and health among minority older women	Beatriz Rodriguez		yes	N/A	none	OS	500	no	till 6/01	funded
93	The Epidemiology of Venous Disease	Michael Criqui		yes	no		OS	725	no	3/11/98 - 6/30/99	funded
92	Fasting glucose in baseline plasma from all CT participants	Barbara Howard					CT		no	N/A	pending
90	Biochemical and genetic determinants of fracture in postmenopausal women	Cummings and Jamal	Charles Kooperberg	yes	yes	none	OS Umbrella Study	910	yes	6 or 7/99 sub	pending
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			none	HRT	50	no	N/A	funded
84	Apolipoprotein E genotype, ERT use, and fat-soluble vitamin intake: Effects on Cognitive Function in Older Women	Julie E. Dunn	Philip Greenland	yes	yes	none	DM+OS	260	yes	11/98 - 12/03	funded
83	Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study	Paul Ridker	JoAnn Manson	yes	yes	none	OS Umbrella Study	1300	yes	7/1/99 - 6/30/03	funded
82	Extension of Bone Mineral Density Assessment in WHI Native American Women	Zhao Chen	Cheryl Ritenbaugh	yes	yes	none	OS	200	no	7/1/97 - 6/30/01	funded
78	Community Strategy to Retain Women Enrolled in Research	Mona Fouad		yes	N/A	none	CT	40	no	7/1/97 - 9/30/97	funded
76	Tailored Messages to Enhance Adherence of Older Women to Dietary Programs for Breast Cancer control	Rowan Chlebowski	Linda Lillington	yes	yes	none	DM	28	no	9/1/97 - 8/13/98	funded

AS #	Title	Study's PI(s)	WHI Investigator	Initial D&A Approval	Initial PO Approval	Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
75	Adherence to Dietary Modification in the WHI	Milagros C. Rosal	Judith Ochene	yes	N/A	6 (does not specify which CC's)	DM	480	no	9/1/97 - 8/30/02	funded
74	The Effectiveness of Individual Versus Group Behavioral Strategies to Increase Participants Adherence	Lois Wodarski	Maurizio Trevisan	yes	yes	none	DM	50	no	7/1/97 - 9/30/97	funded
73	Psychosocial and Cultural Determinants of NIDDM in Latinas	Deborah Parra-Medina	Robert Langer	yes	yes	La Jolla, San Antonio, Tucson	OS	228	yes	5/1/97 - 4/30/98	funded
72	Ethnicity, Body Composition, Bone Density and Breast Cancer	Zhao Chen	Cheryl Ritenbaugh	yes	yes	none	OS	800	no	9/1/97 - 8/30/02	funded
70	The Prevalence & Prognostic Importance of Myocardial Ischemia During Daily Life, & its Relationship to Migraine Status: WHI (MIMS)	David Sheps	David Sheps	yes	yes	Birmingham, Columbus, Detroit, GWU, Honolulu, Iowa, Irvine, Nevada, New York	OS	3200	no	9/1/97 - 8/31/00	funded
68	Coronary artery calcification detected with Ultrafast CT as an indication of CAD in OS participants	Judith Hsia	Judith Hsia	yes	yes	Medlantic	OS	782	no	1/1/97 - 12/31/05	funded
67	Prevalence and Natural History of Autoimmune Thyroid Disease is Postmenopausal Women	Marjita Zakarija	Marianna Baum	yes	N/A	51	OS Blood Comp	1040	yes	7/97 - 3/31/05	funded

AS #	Title	Study's PI(s)	WHI Investigator	Initial D&A Approval	Initial PO Approval	Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
65	Incidence of Benign breast disease in the DM CT - Pilot	Tom Rohan	A. McTiernan	yes	yes	Buffalo, Cincinnati, Davis, Des Moines, Houston, Iowa, Pauline, Pittsburgh, Seattle, Winston-Salem	DM	200	no	4/1/98 - 6/30/99	funded
63	Development and Evaluation of Eating Style Index	Pam Haines		yes	yes		OS	800	no	10/1/96 - 6/30/99	funded
62	Prevention of age-related maculopathy in the WHI HRT CT: WHI-SE	Mary Haan	Mary Haan	yes	no		HRT	3300	no	1/99 - 1/07	funded
61	Longitudinal Assessment of Memory Functioning in the WHI Clinical Trial	Beth Ober	Mary Haan	yes	yes		HRT	110	no	6 year study	funded
60	Fat Intake in Husbands of WHI Dietary Arm Participants	James Shikany	Al Oberman	yes	yes	none	DM Partners		no	12/1/96	funded
58	Enrollment of Hispanic Women in Prevention Trials	Edward Trapido	Marianna Baum	yes	yes	none	All	120	no	9/1/96 - 8/31/99	dropped
57	Hispanic Women's Advocacy and Retention Strategies	Cheryl Ritenbaugh	Cheryl Ritenbaugh	yes	yes	none	OS	120	no	9/1/96 - 8/31/98	funded
56	Behavioral and psychosocial predictors of dietary change in postmenopausal women	Joan Pleuss	Alice Thomson	yes	yes	none	DM	260	no	9/1/96 - 8/31/98	funded
52	Endogenous Sex Hormones and Breast Cancer in Older Women	Anne McTiernan	A. McTiernan	yes	yes	none	OS Umbrella Study	782	yes	7/1/99 - 6/30/04	pending
50	Nutrition Practice Guidelines for Maintaining Low-Fat Dietary Change in Post Menopausal Women	Beth Burrows	Ross Prentice	yes	yes	none	DM	200	no	10/1/96 - 9/30/97	funded
48	Prostate Ca Survey of Spouses of WHI Screened Women	Sylvia Smoller	Sylvia Smoller	yes	yes	none	All	1607	no	2/1/96 - 6/30/96	funded

AS #	Title	Study's PI(s)	WHI Investigator	Initial D&A Approval	Initial PO Approval	Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
47	Effect of diet intervention on motivation to make other health-related changes	Langer/Lo	Robert Langer	yes	yes	none	DM	150	no	5/1/96 - 4/30/97	funded
44	Estrogen and Vaginal pH	Anthony Schaeffer	Philip Greenland	yes	N/A	none	HRT	100	yes	4/1/96 - 3/31/01	dropped
40	Ethnic and age differences in use of Mammography	S. Wassertheil-Smoller	S. Wassertheil-Smoller	yes	yes	none	All	All	no	N/A	funded
39	The Effects of HRT on the Development and Progression of Dementia	Sally Shumaker	Curt Furberg	yes	yes	all except Seattle	HRT	4800	no	5/1/96 - 4/30/02	funded
36	Hormone Replacement Therapy and Changes in Mammographic Density	Barbara Hulka	A. McTiernan	yes	yes	Birmingham, Boston, Cincinnati, Davenport, Davis, Des Moines, GWU, Iowa, Madison, Memphis, Milwaukee, Nevada, Phoenix, Pittsburgh, Tucson, Winston-Salem	HRT	NA	no	1/98 - 12/07	funded
34	Ethnic Differences in Hip Bone Geometry by DXA and QCT	Dorothy Nelson	Susan Hendrix	yes	yes	none	HRT	330	no	12/1/96 - 12/31/02	funded
33	The Association of HRT with Abdominal and Total Body Fat in Postmenopausal Women	Charlotte Mayo	Al Oberman	yes	yes	none	OS	690	no	7/31/95 - 3/31/96	funded
31	Eye Care Use	Robert Kleinstein	Al Oberman	yes	yes	none	OS	300	no	N/A	funded

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28	Perspectives on Aging	S. Wassertheil-Smoller	S. Wassertheil-Smoller	yes	yes	none	OS	NA	no	5 year follow-up	dropped
25	Ankle-Arm Blood Pressure Index Measurement	Kamal Masaki	David Curb	yes	yes	none	OS	2700	no	2/96 - 1/98	funded
24	Cross-ethnic Comparisons of Skeletal Health of Postmenopausal Women in San Diego County	Diane Schneider	Robert Langer	yes	yes	none	OS	168	no	1/3/95 - 1/2/97	funded
17	Domestic Violence in Older Women	Charles Mouton	Norm Lasser	yes	yes	none	OS	1000	no	10/25/94 - 10/24/96	funded
15	The Relationship between Osteopenia and Periodontitis	Jean Wactawski-Wende	Maurizio Trevisan	yes	yes	none	OS	1300	no	9/16/96 - 9/15/00	funded
14	High Density Lipoprotein Metabolism	Scott Going, Tamsen Bassford	Tom Moon	yes	N/A	none	OS	200	no	7/1/94 - 6/30/96	funded
13	Prevalence and Correlates of Lumbar Spinal Stenosis	Molly Vogt	Lew Kuller	yes	N/A	none	CT	150	no	on-going	funded
11	Validation and Exploration of Sleep and Mood Predictors	Daniel Kripke	Robert Langer	yes	N/A	none	OS	600	yes	8/1/95 - 7/31/99	funded
9	An investigation of oral hard tissue status in relation to skeletal bone mineral density measures and osteoporosis	Marjorie Jeffcoat	Al Oberman	yes	N/A	none	OS	650	no	6/1/95 - 5/31/02	funded