Women's Health Initiative

Clinical Trial and Observational Study

Semi-Annual Progress Report

March 1, 2000 to August 27, 2000

Prepared by
WHI Clinical Coordinating Center
Fred Hutchinson Cancer Research Center

Ross Prentice, Principal Investigator

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

November 30, 2000

WHI Semi-Annual Progress Report

Contents

Executive Summary

This report, summarizing data accumulated through August 27, 2000, presents the current status of the three clinical trial components and the observational study (OS) of the Women's Health Initiative (WHI). With recruitment completed, the primary areas for this report are related to adherence to the interventions, participation in follow-up data collection, and outcomes.

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 3.5 years. The proportion of women who have stopped intervention has been larger than projected in the first two years (approximately 10% per year). Subsequent drop-out rates, now with estimates available through the fifth year, have been close to design assumptions (5-7% per year). Symptom reporting is relatively stable after the second year, with 5-6% of women with a uterus assigned to combined hormones reporting bleeding and 2-3% of women in both hysterectomy strata reporting breast changes. Analyses of a small sample of blood specimens are reported by strata. We note a small increase in bone mineral density at years 1 and 3, particularly in the spine. Vital status is known within the last 18 months for all but 793 women (2.9%). 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 are provided by age and whites vs. minorities. A summary of the recently added stroke information is included. These results for recruitment, adherence, and control group incidence rates are consistent with our previous report where we showed revised power estimates for the estrogen and estrogen/progestin comparisons of 63% and 76%, respectively.

Recruitment into the Dietary Modification (DM) component finished with 48,837 women randomized (102% of goal). With the intervention complete, the current focus is on the quarterly maintenance sessions and options for boosting adherence. The difference between the Intervention and Control arms in FFQ percent energy from fat (C-I) is 10.9%, 9.9%, 9.9%, 9.2%, 8.9%, and 9.2 at years 1 through 6, respectively. The corresponding design assumptions for the C-I comparisons were 13% at year 1, diminishing by 0.25% per year. Analyses of a small sample of blood specimens are reported. Vital status is known within the last 18 months for all but 1,465 women (3%). An additional 0.1% have not provided outcome information recently. The average follow-up time for DM women is approximately 3.75 years. Observed breast cancer and colorectal cancer incidence rates are currently approaching the design values (100% and 70%, respectively). Event rates are provided by age and whites vs. minorities. Using the observed values of the key parameters, the projected power for detecting a 14% reduction in breast cancer incidence is 67%, assuming a lower bound for C-I of 9% and an average of 8.5 years of follow-up.

Randomizations into the Calcium and Vitamin D (CaD) component, designed to occur at a CT participant's first annual follow-up visit, have reached 36,282. This number is nearly final. Adherence to CaD supplements, though still lower than desirable (55%-63% consuming at least 80% of assigned dose), has continued to show some improvement in the last six months. Follow-up rates for CaD participants are better than for the other CT components; only 1.2% have unknown vital status and 0.1% have not provided recent outcomes data. Hip fracture incidence rates are currently much lower than projected (40% of design) suggesting a strong healthy volunteer effect. Event rates by age and white versus minority ethnicity are presented for all monitored outcomes. With these parameter values and a projected average follow-up of 7.5 years, the power to detect a

27% reduction in hip fracture rates is 75%. The power for combined fractures remains high (above 99%).

The Observational Study (OS) enrolled 93,721 women who have now contributed over 3 years of follow-up, on average. Follow-up rates for these early years are close to goal though some additional effort is needed to reach the desired completeness of data collection. Event rates by age and race/ethnicity are provided. Incidence rates for cancers are generally close to expected rates. Observed rates for coronary heart disease and fractures are noticeably lower than projected, suggesting a strong healthy volunteer effect in this cohort.

The timeliness and completeness of local outcomes processing is a continuing area of focus. The improvements made previously have been maintained. The backlog in central adjudication of cancer outcomes has been eliminated. Attention has turned to increasing efficiency to handle the demanding load of ever increasing event rates and to resolving the small number of cases that have been on hold at clinical centers. Additional efforts are being used to complete the documentation of deaths and to assure up-to-date information on vital status. A summary of locally and centrally adjudicated outcomes and the corresponding agreement rate are also provided.

In response to requests from investigators, a new section on laboratory methods and quality assurance has been added. A revised Performance Monitoring Report is also included. This report provides clinic comparisons on priority elements of the program. In addition, a listing of the current status of publications and ancillary studies is provided.

1. Preliminary Remarks

This report documents study activities of the Women's Health Initiative (WHI) Clinical Trial (CT) through August 27, 2000. Topics include continuing recruitment into the Calcium and Vitamin D (CaD) trial, and for all CT components, follow-up, intervention monitoring, 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:

- Implementation of the prior DSMB recommendation to inform HRT women of an early increased risk of cardiovascular disease.
- Continuation of a motivational interviewing protocol to improve adherence to the DM intervention.
- Development and review of a "Tailored Message Campaign" to be implemented in the DM Intervention after the completion of the motivational interviewing protocol.
- A clinic staff workshop held in May 2000 to discuss safety monitoring and adherence in the HRT and CaD trial components, including aspects of motivational interviewing.
- The last few randomizations into the CaD trial as the year 2 window is closing.
- Continuing efforts to assure timely and complete outcomes ascertainment including catch-up on centralized coding of cancer events.
- Approval of guidelines and procedures for access to and analysis of biologic specimens as initiated by the Genetics and Biomarkers Taskforce.
- Final approval of plan to study potential biomarkers for early CVD events in the HRT trial.
- Continued effort to prepare and analyze the full baseline dataset for publishing in a special edition of the Annals of Epidemiology.

All reports summarize Clinical Center (CC) data provided to the CCC by August 27, 2000. 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*. We note 3 changes in PIs in the last 6 months. Dr. Saundra Daugherty, the PI of the Reno, Nevada CC died in May. Dr. Daugherty had been an active and effective member of several WHI committees and a strong advocate for issues of concern to her and the Nevada CC. The WHI community will honor the contribution she has made to WHI at the fall Steering Committee meeting. Dr. Robert Brunner, Project Director for the Nevada CC is acting PI until a permanent PI is named.

Two other Clinical Center PIs have stepped down from their roles as PIs and have named co-investigators as their replacement. Dr. Cora (Beth) Lewis replaces Dr. Albert Oberman at the Birmingham CC. Dr. Linda Van Horn replaces Dr. Phil Greenland at the Chicago-Northwestern CC. We wish to thank Drs. Oberman and Greenland for their service to the WHI community since 1993.

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

Table 1.1 (continued)
Database Abbreviations for WHI CCs

Abbreviation	CC Institution and Location	Principal Investigator
HOUSTON	Baylor College of Medicine Houston, Texas	Jennifer Hays, PhD
IOWACITY	University of Iowa Iowa City and Bettendorf, Iowa	Robert Wallace, MD
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

Table 1.1 (continued)
Database Abbreviations for WHI CCs

Abbreviation	CC Institution and Location	Principal Investigator
PITTSBUR	University of Pittsburgh Pittsburgh, Pennsylvania	Lewis Kuller, MD DrPH
PORTLAND	Kaiser Foundation Research Institute Portland, Oregon	Cheryl Ritenbaugh, PhD
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 their six-month visits. 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, our primary measure for monitoring adherence. It is 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 52% at AV-6. Differences between strata are relatively small but suggest that hysterectomized women have somewhat lower adherence (lower by 3% at AV-2 and AV-3, 5% at AV-4, and 7% at AV-5).

Importantly, there have been no noteworthy changes in adherence measures since the last report, which was based on data collected before the HRT update in April of 2000. *Figure 2.1* shows the adherence summary over calendar time for each visit type. There has been no noteworthy change in this measure of adherence in the last 6 months for AV-3 and AV-4. There is a suggestion of a small decrease in AV-2 adherence during the last 6 months, but these results should be viewed cautiously. These results are based on small numbers and represent the last few participants randomized to HRT. The results for each hysterectomy stratum are consistent with the overall findings.

Table 2.3 presents drop-in and drop-out rates and associated design assumptions. The results in AV-3 through AV-6 generally show a small 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% for hysterectomized and 35.5% for women with a

uterus) are close to the anticipated rate (32.7%). 34.5% of HRT women have stopped their study pills at some point but 69.1% were active at their last contact.

A small proportion (1.5% per year) of the HRT participants were expected to stop study hormone pills and begin taking hormones outside of the trial. Among hysterectomized women the observed (assumed) cumulative rates are 2.9% (1.5%) at AV-1, 7.2% (4.4%) at AV-3, and 7.2% (7.2%) at AV-6. Similarly, in women with a uterus, the "drop-in" rates were 2.1%, 5.9%, and 9.5%.

Table 2.4 shows reasons for stopping by hysterectomy strata. We note that the possible reasons for stopping were expanded with the new version of *Form 7 – Participation Status*, and interpretation of these data is complicated by this change. These tabulations would benefit from further discussion by investigators interested in this topic to create more useful groupings and summaries and 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 and treatment arms 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 about 5-6% after AV-3. Reports of breast changes have also reached a plateau after AV-1 at approximately 2%-3% 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 3,830 total biopsies, 89 (2.3%) yielded an abnormal result: 52 cystic, 12 adenomatous, 19 atypia, and 6 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. This subsample incorporated over-sampling of minorities. The results for micronutrients, clotting factors, glucose, insulin and lipoproteins shown here by hysterectomy strata are weighted to reflect the overall WHI-CT distribution of race/ethnicity.

The DSMB requested further study of potential cardiovascular disease biomarkers in HRT to shed additional light on the results of HERS and the disease rates observed in WHI so far. In response, the Clinical Coordinating Center has developed case-control sampling procedures for CHD, stroke, and venous thromboembolic disease. The Executive Committee formed a task force of experts in CVD biomarkers to recommend the laboratory analyses that would best address these questions. This report was provided to the Steering Committee in October 1999. The Steering Committee has recently authorized the implementation of this study and efforts are underway to begin these analyses. We anticipate that these results will be available in the fall of 2001.

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 2.9*, 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.

2.7 Vital Status

Table 2.10 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 2.9% of the HRT participants are lost-to-follow-up or have stopped follow-up, and 1.6% of the participants are known to be deceased. Virtually all of the remaining participants have completed a *Form 33 – Medical History Update* in the last 18 months. The design assumed that 3% per year would be lost-to-follow-up or death. Currently, the average follow-up for HRT participants is about 3.6 years, suggesting that approximately 10.4% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions. Follow-up in women with a uterus is slightly better than hysterectomized women.

2.8 Outcomes

Table 2.11 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 10% of the self-reported outcomes have not yet been verified, so the numbers in this table can be seen as a lower bound of the actual number of outcomes that have occurred. Compared to the design assumptions, we have observed about 65-75% 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 2.12 compares the rates of the same locally verified outcomes between women who have and who have not been hysterectomized. 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. Many of these differences are small and based on few events. The differences in cardiovascular disease rates are consistent with the risk profile differences we have previously observed, however.

Table 2.13 compares the stroke diagnosis for HRT participants with and without a uterus. Women with a uterus appear to get slightly fewer strokes of every type. *Table 2.14* compares the Glasgow scale for strokes among HRT participants. From this table it appears that the larger number of strokes for women without a uterus fall predominantly in Glasgow classes 1 and 2, the lighter strokes.

Table 2.15 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 2.16*. 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 Issues

The primary issues of concern in the HRT trial have been around adherence and the notification to participants of the early adverse effects. Regarding the notification, though the release of this information caused considerable debate among investigators, the participants have received the news with little fanfare. Anecdotal information suggests that adherence was in some instances possibly improved by this action as some participants' providers were now more supportive of the trial. A somewhat more common story relayed to the coordinating center was that women were not very interested in these results, claiming it was either old news or that the questions raised were the very reasons that motivated their participation originally. Importantly, we note that there has been

no evidence of an increase in drop-out rates in the last 6 months, indicating that this release of information did not create a crisis for participants.

Regarding adherence, though the rates in WHI are far better than observed in the general population, study investigators and staff are still being asked to identify ways 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. Other activities are under consideration as time and resources permit.

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

Data as of: August 27, 2000

HRT Participants	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age				
Overall	**27,348**			
50-54	3,426	125%	13%	10
55-59	5,409	99%	20%	20
60-69	12,363	100%	45%	45
70-79	6,150	90%	22%	25
Without Uterus	**10,739**			
50-54	1,396	113%	13%	10
55-59	1,916	78%	18%	20
60-69	4,852	88%	45%	45
70-79	2,575	84%	24%	25
With uterus	**16,609**			
50-54	2,030	135%	12%	10
55-59	3,493	116%	21%	20
60-69	7,511	111%	45%	45
70-79	3,575	95%	22%	25
Race/Ethnicity				
Overall	**27,348**			
American Indian	131		<1%	
Asian	527		2%	
Black	2,739		10%	
Hispanic	1,538		6%	
White	22,030		81%	
Other/unspecified	383		1%	
Without Uterus	**10,739**			
American Indian	75		1%	
Asian	164		2%	
Black	1,617		15%	
Hispanic	651		6%	
White	8,084		75%	
Other/unspecified	148		1%	
With uterus	**16,609**			
American Indian	56		<1%	
Asian	363		2%	
Black	1,122		7%	
Hispanic	887		5%	
White	13,946		84%	
Other/unspecified	235		1%	

Table 2.2
HRT Adherence Summary

Data as of: August 27, 2000

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	26691	98	22783	83	1382	5	1452	5	25525	95	1035	4	1904	8	22586	89	84
Annual Visit-1	27348	26495	97	21881	80	1299	5	1420	6	23769	94	1021	4	2066	9	20682	87	77
Annual Visit-2	27260	25753	94	20442	75	2507	9	2444	10	21051	90	740	4	2012	10	18299	87	68
Without Uterus	10701	10001	93	7918	74	1071	10	1066	12	8220	89	268	3	878	11	7074	86	67
With Uterus	16559	15752	95	12524	76	1436	9	1378	10	12831	90	472	4	1134	9	11225	88	70
Annual Visit –3	20787	19393	93	15035	72	1495	7	1373	9	14680	91	539	4	1400	10	12741	87	63
Without Uterus	8188	7562	92	5877	72	631	8	578	9	5751	91	192	3	611	11	4948	86	61
With Uterus	12599	11831	94	9158	73	864	7	795	8	8929	92	347	4	789	9	7793	87	64
Annual Visit –4	11166	10291	92	7799	70	673	6	605	8	7293	92	272	4	635	9	6386	88	60
Without Uterus	4469	4064	91	3097	69	291	7	254	8	2903	92	107	4	282	10	2514	87	57
With Uterus	6697	6227	93	4702	70	382	6	351	7	4390	93	165	4	353	8	3872	88	62
Annual Visit –5	4772	4376	92	3436	72	235	5	247	8	2783	92	102	4	251	9	2430	87	56
Without Uterus	1952	1774	91	1389	71	107	6	105	8	1156	92	48	4	125	11	983	85	52
With Uterus	2820	2602	92	2047	73	128	5	142	8	1627	92	54	3	126	8	1447	89	59
Annual Visit –6	1286	1154	90	874	68	50	5	65	9	657	91	30	5	57	9	570	87	52
Without Uterus	537	480	89	378	70	20	4	27	8	310	92	11	4	25	8	274	88	52
With Uterus	749	674	90	496	66	30	5	38	10	347	90	19	6	32	9	296	85	52

[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 August 27, 2000

All Participants

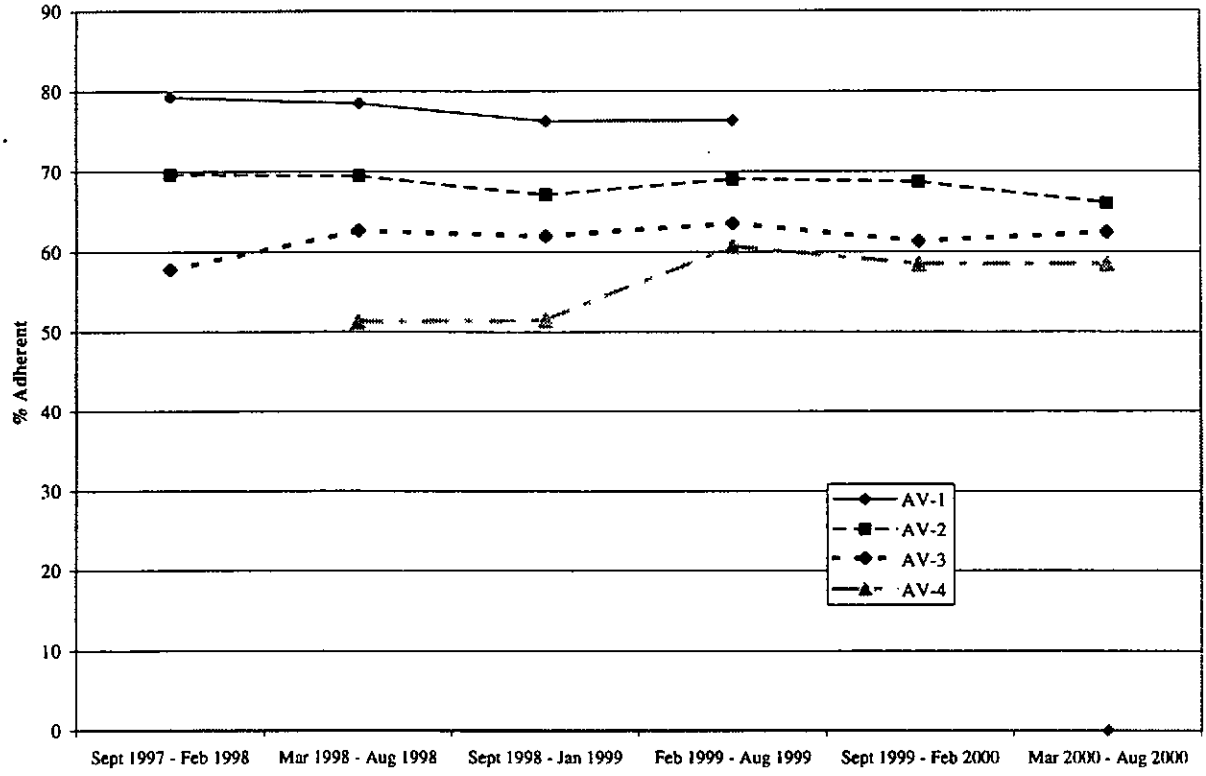
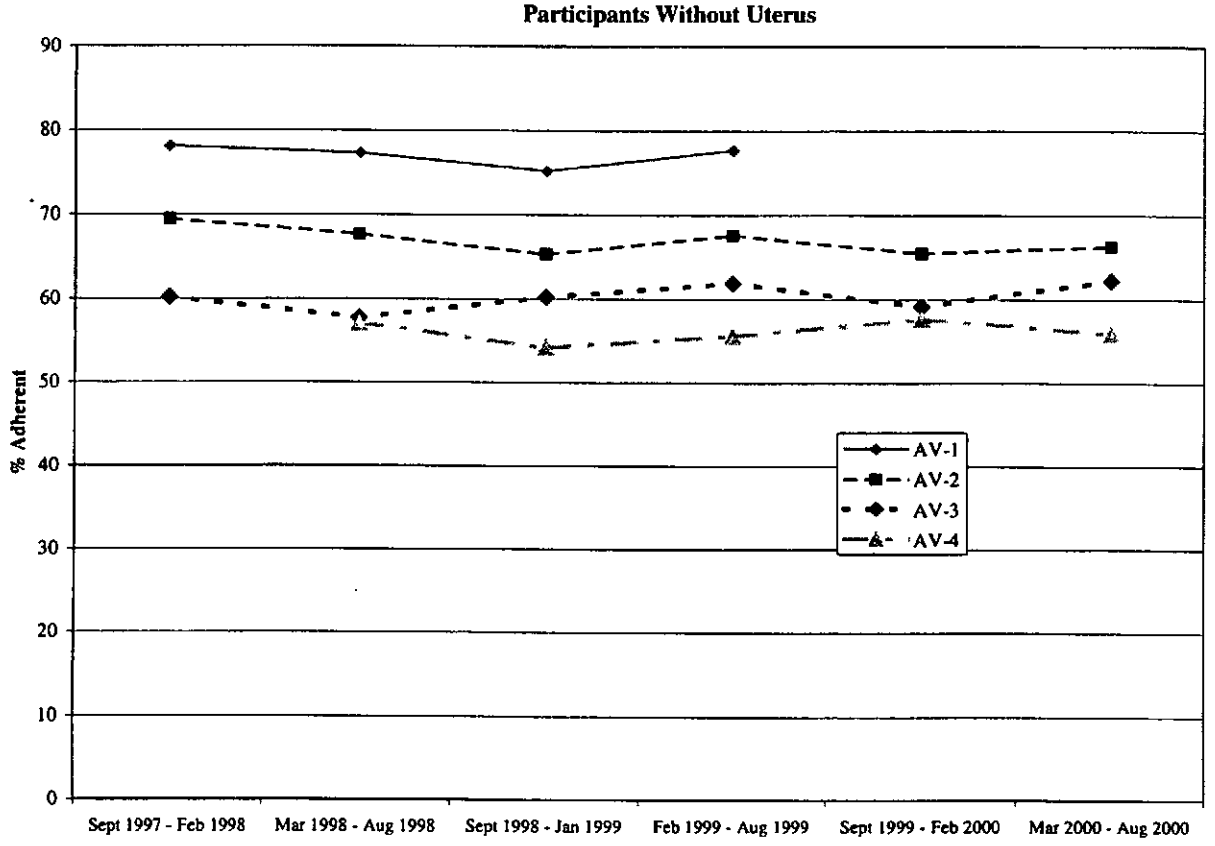


Figure 2.1 (continued)
HRT Adherence Summary
% Participants Due for a Visit Who Took at Least 80% of Study Pills

Data as of August 27, 2000



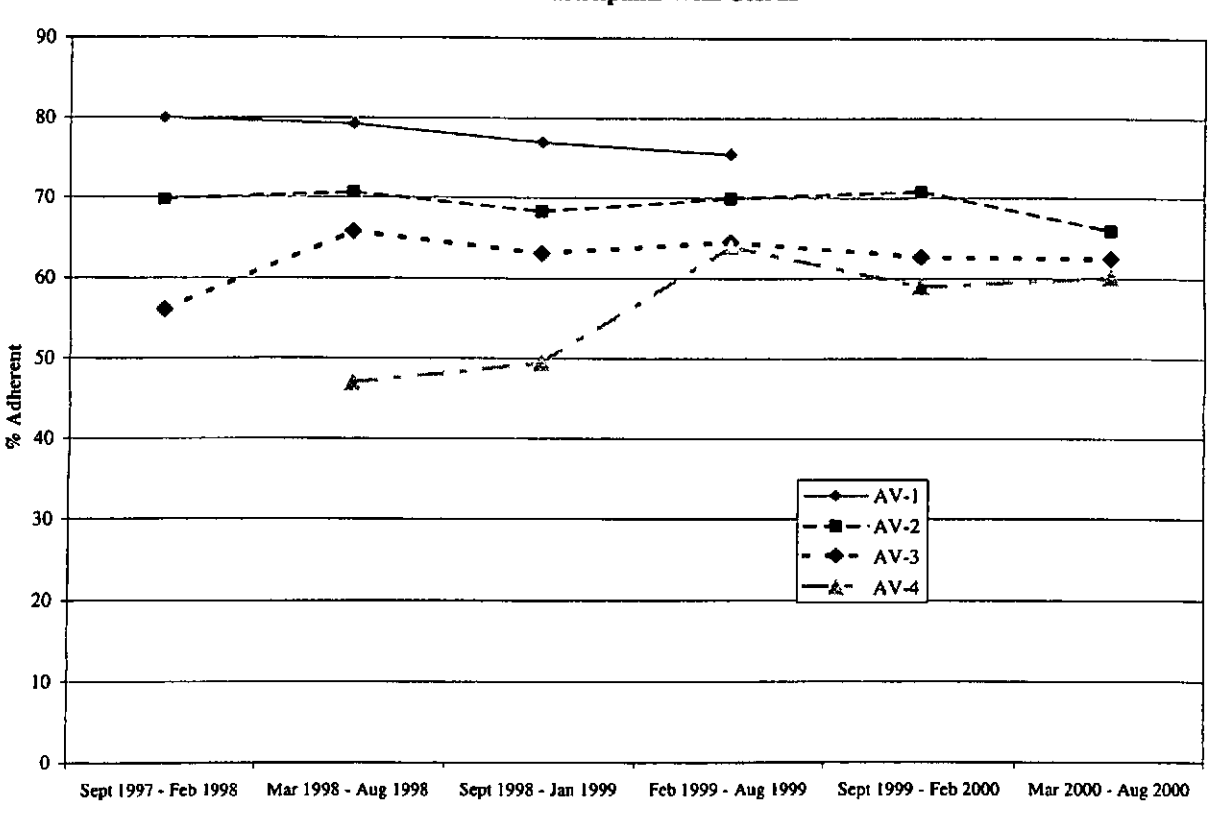


Table 2.3
HRT Drop-Out and Drop-In Rates by Follow-Up Time
(Design-specified values in parentheses)

Data as of: August 27, 2000

	Without Uterus				With Uterus				Overall Total			
	Interval[1]		Cumulative[2]		Interval		Cumulative		Interval		Cumulative	
Drop-Outs[3]												
AV-1	9.8%	(8.8)	9.8%	(8.8)	9.7%	(8.8)	9.7%	(8.8)	9.7%	(8.8)	9.7%	(8.8)
AV-2	10.1%	(5.9)	19.0%	(14.2)	8.9%	(5.9)	17.7%	(14.2)	9.4%	(5.9)	18.1%	(14.2)
AV-3	7.8%	(5.9)	25.3%	(19.2)	7.1%	(5.9)	23.5%	(19.2)	7.4%	(5.9)	24.2%	(19.2)
AV-4	6.6%	(5.9)	30.2%	(24.0)	6.1%	(5.9)	28.2%	(24.0)	6.3%	(5.9)	29.0%	(24.0)
AV-5	5.6%	(5.9)	34.1%	(28.5)	5.2%	(5.9)	31.9%	(28.5)	5.4%	(5.9)	32.8%	(28.5)
AV-6	3.8%	(5.9)	36.6%	(32.7)	5.3%	(5.9)	35.5%	(32.7)	4.6%	(5.9)	35.9%	(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	4.4%	(2.9)	7.2%	(4.4)	3.9%	(2.9)	5.9%	(4.4)	4.1%	(2.9)	6.4%	(4.4)
AV-6	3.1%	(2.9)	10.1%	(7.2)	3.8%	(2.9)	9.5%	(7.2)	3.6%	(2.9)	9.8%	(7.2)

[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 August 27, 2000

Reasons[1]	Without Uterus (N = 3513)		With Uterus (N = 4930)	
Personal				
Demands of work	75	(2.1%)	93	(1.9%)
Death in family[2]	3	(0.1%)	5	(0.1%)
Family illness, emergency or other family demands	148	(4.2%)	164	(3.3%)
Caregiving responsibilities[2]	15	(0.4%)	12	(0.2%)
Conflicting priorites	55	(1.6%)	51	(1.0%)
Financial problems	7	(0.2%)	4	(0.1%)
Lack of cooperation/support from family /friends	27	(0.8%)	35	(0.7%)
Family/friends request withdraw[2]	1	(<0.1%)	7	(0.1%)
Living in nursing home	4	(0.1%)	11	(0.2%)
Feels discouraged regarding participation overall[2]	0	(0.0%)	7	(0.1%)
Loss of interest, boredom[2]	5	(0.1%)	7	(0.1%)
Feels it is not an important study[2]	1	(<0.1%)	2	(<0.1%)
In another study in conflict with WHI[2]	1	(<0.1%)	0	(0.0%)
Travel				
Too far to CC	131	(3.7%)	127	(2.6%)
Transportation problems	63	(1.8%)	47	(1.0%)
Traffic	13	(0.4%)	7	(0.1%)
Parking at CC	3	(0.1%)	3	(0.1%)
CC neighborhood/safety	0	(0.0%)	1	(<0.1%)
Moved out of area[2]	12	(0.3%)	15	(0.3%)
Visits and Procedures				
Doesn't like visits, calls	40	(1.1%)	31	(0.6%)
Doesn't like having blood drawn	2	(0.1%)	1	(<0.1%)
Doesn't like ECG	0	(0.0%)	0	(0.0%)
Doesn't like mammograms[2]	7	(0.2%)	7	(0.1%)
Cost of mammograms[2]	0	(0.0%)	2	(<0.1%)
Doesn't like gynecologic procedures	9	(0.3%)	35	(0.7%)
Doesn't like required safety forms and/or procedures	58	(1.7%)	74	(1.5%)
Doesn't like filling out forms	4	(0.1%)	11	(0.2%)
Doesn't like other procedures (non-safety)	8	(0.2%)	18	(0.4%)
Worried about health effects of medical tests/procedures	16	(0.5%)	20	(0.4%)
Wants results of blood analyses[2]	0	(0.0%)	0	(0.0%)
Wants results of bone mineral density[2]	0	(0.0%)	0	(0.0%)
Problem with CC	18	(0.5%)	30	(0.6%)
Problem with CC staff person (other than DM Nutritionist)	5	(0.1%)	16	(0.3%)
Staff change/turnover[2]	0	(0.0%)	0	(0.0%)

(continues)

[1] Multiple reasons may be reported for a woman

[2] Version 3 only.

Table 2.4 (continued)
Reasons for Stopping HRT

Data as of August 27, 2000

Reasons[1]	Without Uterus (N = 3513)		With Uterus (N = 4930)	
Symptoms				
Vaginal bleeding	4	(0.1%)	422	(8.6%)
Breast tenderness	128	(3.6%)	204	(4.1%)
Other breast changes[2]	6	(0.2%)	24	(0.5%)
Bloating/gas[2]	4	(0.1%)	5	(0.1%)
Constipation[2]	6	(0.2%)	1	(<0.1%)
Other gastrointestinal problems[2]	4	(0.1%)	9	(0.2%)
Headaches[2]	2	(0.1%)	4	(0.1%)
Vaginal changes[2]	6	(0.2%)	6	(0.1%)
Hair/skin changes[2]	3	(0.1%)	3	(0.1%)
Hot flashes/night sweats[2]	13	(0.4%)	3	(0.1%)
Weight loss/gain[2]	3	(0.1%)	10	(0.2%)
Low energy/too tired[2]	1	(<0.1%)	5	(0.1%)
Possible allergic reaction[2]	1	(<0.1%)	0	(0.0%)
Other symptoms[2]	21	(0.6%)	31	(0.6%)
Health problems or symptoms not due to intervention[3]	520	(14.8%)	603	(12.2%)
Health Conditions				
Breast cancer[2]	20	(0.6%)	40	(0.8%)
Complex or atypical hyperplasia[2]	0	(0.0%)	2	(<0.1%)
Endometrial cancer[2]	1	(<0.1%)	5	(0.1%)
Deep vein thrombosis[2]	8	(0.2%)	16	(0.3%)
Pulmonary embolism[2]	4	(0.1%)	6	(0.1%)
Gallbladder disease[2]	3	(0.1%)	1	(<0.1%)
Hypercalcemia[2]	0	(0.0%)	1	(<0.1%)
Kidney failure/dialysis[2]	2	(0.1%)	2	(<0.1%)
Renal calculi[2]	1	(<0.1%)	0	(0.0%)
High triglycerides[2]	0	(0.0%)	2	(<0.1%)
Malignant melanoma[2]	1	(<0.1%)	5	(0.1%)
Meningioma[2]	4	(0.1%)	1	(<0.1%)
Heart attack[2]	12	(0.3%)	11	(0.2%)
Stroke[2]	16	(0.5%)	26	(0.5%)
Arthritis[2]	2	(0.1%)	0	(0.0%)
Diabetes[2]	6	(0.2%)	0	(0.0%)
Depresssion[2]	4	(0.1%)	5	(0.1%)
Cholesterol[2]	4	(0.1%)	1	(<0.1%)
Osteoporosis[2]	20	(0.6%)	19	(0.4%)
Loss of vision and/or hearing[2]	1	(<0.1%)	0	(0.0%)
Communication problem	6	(0.2%)	11	(0.2%)
Cognitive/memory changes[2]	4	(0.1%)	8	(0.2%)
Other health conditions[2]	79	(2.3%)	105	(2.1%)
Other health problems or symptoms from the WHI intervention[3]	323	(9.2%)	547	(11.1%)
Intervention-General				
Doesn't like randomized nature of intervention	76	(2.2%)	113	(2.3%)
Expected some benefit from intervention	37	(1.1%)	39	(0.8%)
Feels guilty, unhappy or like a failure for not meeting study goals[2]	0	(0.0%)	2	(<0.1%)
Removed from intervention due to WHI symptom management[3]	17	(0.5%)	54	(1.1%)
Removed from intervention due to adverse health event[3]	157	(4.5%)	263	(5.3%)

(continues)

[1] Multiple reasons may be reported for a woman

[2] Version 3 only.

[3] Version 1 & 2 only.

Table 2.4 (continued)
Reasons for Stopping HRT

Data as of August 27, 2000

Reasons[1]	Without Uterus (N = 3513)		With Uterus (N = 4930)	
HRT/CaD Intervention				
Doesn't like taking pills	93	(2.7%)	106	(2.2%)
Doesn't like taste of pills[2]	0	(0.0%)	0	(0.0%)
Unable to swallow pills[2]	2	(0.1%)	1	(<0.1%)
Takes too many pills[2]	10	(0.3%)	11	(0.2%)
Has made a personal decision to go on active HRT[2]	18	(0.5%)	17	(0.3%)
Has made a personal decision that she doesn not want to be on HRT[2]	54	(1.5%)	71	(1.4%)
Advised to go on active HRT by health care provider[2]	68	(1.9%)	57	(1.2%)
Advised to not be on active HRT by health care provider[2]	37	(1.1%)	41	(0.8%)
Has made a personal decision to go on SERM[2]	4	(0.1%)	6	(0.1%)
Advised to go on SERM by health care provider[2]	14	(0.4%)	19	(0.4%)
Wants to take her own calcium[2]	9	(0.3%)	10	(0.2%)
Feels diet is already sufficient in calcium/Vit D[2]	1	(<0.1%)	0	(0.0%)
Taking more than the max allowable IU of Vit D[2]	0	(0.0%)	1	(<0.1%)
Taking Calcitriol[2]	0	(0.0%)	0	(0.0%)
Taking testosterone medications[2]	0	(0.0%)	1	(<0.1%)
DM Intervention				
Problem with DM Group Nutritionist or group members	1	(<0.1%)	2	(<0.1%)
Doesn't like attending DM intervention classes[2]	0	(0.0%)	0	(0.0%)
Doesn't like self-monitoring[2]	0	(0.0%)	1	(<0.1%)
Doesn't like budgeting fat grams[2]	0	(0.0%)	0	(0.0%)
Has concerns regarding long-term risks/benefits of low-fat diet[2]	0	(0.0%)	0	(0.0%)
Unhappy that not losing weight[2]	0	(0.0%)	0	(0.0%)
Not in control of meal preparation[2]	0	(0.0%)	0	(0.0%)
Too difficult to meet or maintain dietary goals[2]	0	(0.0%)	0	(0.0%)
Doesn't like eating low fat diet[2]	0	(0.0%)	0	(0.0%)
Doesn't like eating 5 veg/fruits per day[2]	0	(0.0%)	0	(0.0%)
Doesn't like eating 6 grains per day[2]	0	(0.0%)	0	(0.0%)
Feels fat gram goal is unrealistic[2]	0	(0.0%)	0	(0.0%)
Eating pattern conflicts with personal health[2]	0	(0.0%)	0	(0.0%)
Doesn't like DM requirements[3]	1	(<0.1%)	6	(0.1%)
Doesn't like DM eating pattern[3]	1	(<0.1%)	3	(0.1%)
Other Health Issues				
Worried about costs if adverse effects occur	11	(0.3%)	6	(0.1%)
Expected more health care	11	(0.3%)	14	(0.3%)
Advised not to participate by health care provider for other reason[2]	23	(0.7%)	22	(0.5%)
Study conflicts with other health issues[2]	29	(0.8%)	34	(0.7%)
Advised not to participate by health care provider[3]	580	(16.5%)	784	(15.9%)
Study conflicts with health care needs[3]	526	(15.0%)	660	(13.4%)
Other				
Other reason not listed above	817	(23.3%)	1097	(22.3%)
Refuses to give a reason	63	(1.8%)	75	(1.5%)

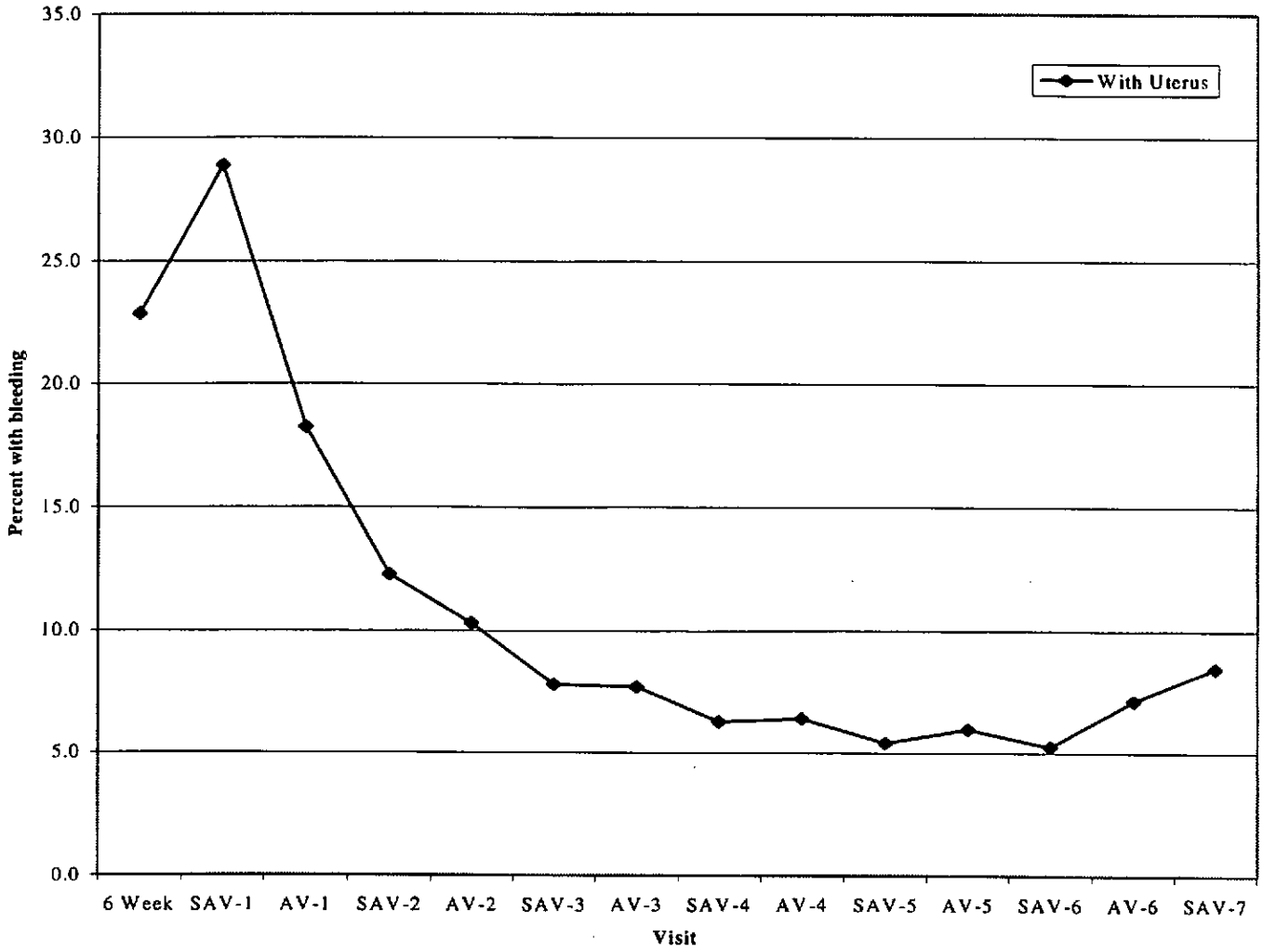
[1] Multiple reasons may be reported for a woman

[2] Version 3 only.

[3] Version 1 & 2 only.

Table 2.5
Reports of Bleeding

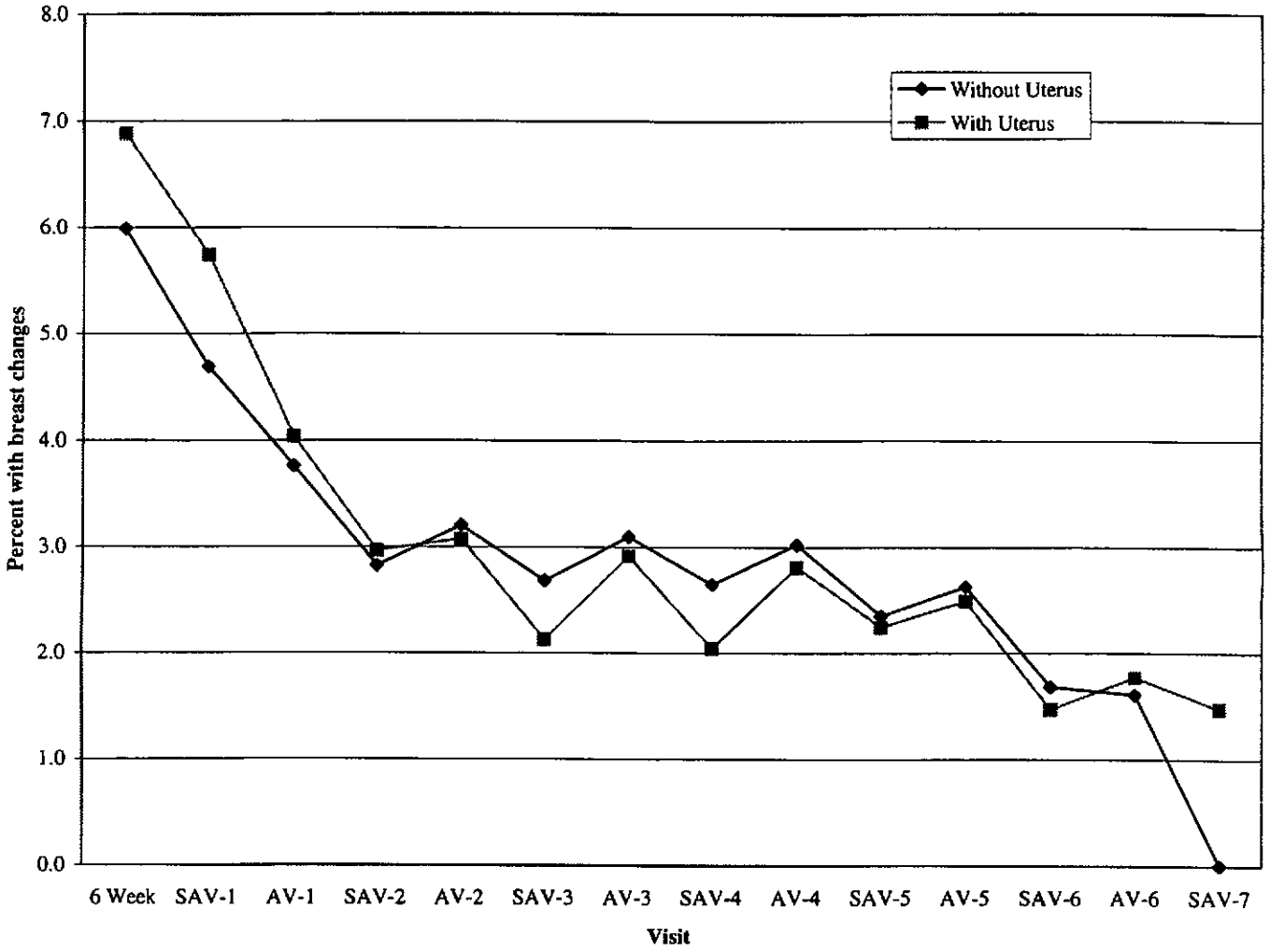
Data as of: August 27, 2000



Contact	With Uterus	
6 Week HRT Phone Call – Number with Bleeding	3578	(22.8%)
Semi-Annual Visit 1 – Number with Bleeding	4693	(28.9%)
Annual Visit 1 – Number with Bleeding	2948	(18.3%)
Semi-Annual Visit 2 – Number with Bleeding	1938	(12.3%)
Annual Visit 2 – Number with Bleeding	1622	(10.3%)
Semi-Annual Visit 3 – Number with Bleeding	1089	(7.8%)
Annual Visit 3 – Number with Bleeding	909	(7.7%)
Semi-Annual Visit 4 – Number with Bleeding	554	(6.3%)
Annual Visit 4 – Number with Bleeding	398	(6.4%)
Semi-Annual Visit 5 – Number with Bleeding	228	(5.4%)
Annual Visit 5 – Number with Bleeding	155	(6.0%)
Semi-Annual Visit 6 – Number with Bleeding	80	(5.2%)
Annual Visit 6 – Number with Bleeding	48	(7.1%)
Semi-Annual Visit 7 – Number with Bleeding	6	(8.5%)

Table 2.6
Reports of Breast Changes

Data as of: August 27, 2000



Contact	Without Uterus	With Uterus
6 Week HRT Phone Call – Number with Breast Changes	603 (6.0%)	1078 (6.9%)
Semi-Annual Visit 1 – Number with Breast Changes	469 (4.7%)	900 (5.7%)
Annual Visit 1 – Number with Breast Changes	373 (3.8%)	628 (4.0%)
Semi-Annual Visit 2 – Number with Breast Changes	259 (2.8%)	431 (3.0%)
Annual Visit 2 – Number with Breast Changes	288 (3.2%)	439 (3.1%)
Semi-Annual Visit 3 – Number with Breast Changes	204 (2.7%)	257 (2.1%)
Annual Visit 3 – Number with Breast Changes	198 (3.1%)	294 (2.9%)
Semi-Annual Visit 4 – Number with Breast Changes	121 (2.6%)	148 (2.0%)
Annual Visit 4 – Number with Breast Changes	98 (3.0%)	143 (2.8%)
Semi-Annual Visit 5 – Number with Breast Changes	49 (2.3%)	74 (2.2%)
Annual Visit 5 – Number with Breast Changes	35 (2.6%)	51 (2.5%)
Semi-Annual Visit 6 – Number with Breast Changes	13 (1.7%)	17 (1.5%)
Annual Visit 6 – Number with Breast Changes	6 (1.6%)	9 (1.8%)
Semi-Annual Visit 7 – Number with Breast Changes	0 (0.0%)	1 (1.5%)

Table 2.7
Endometrial Aspiration Results

Data as of: August 27, 2000

Months since randomized	N of aspirations[2,3]	Number with Abnormal Results[1]				
		Cystic	Adenomatous	Atypia	Cancer	Total[4]
0-6	105	5	1	1	-	2
6-12	719	11	2	4	-	6
12-18	706	13	3	3	3	9
18-24	522	14	4	4	-	8
24-36	378	2	-	1	-	1
36-42	555	1	-	4	2	6
42-48	432	2	2	2	1	5
48-54	167	2	-	-	-	-
54-60	112	-	-	-	-	-
60-66	73	2	-	-	-	-
66-72	34	-	-	-	-	-
72-78	17	-	-	-	-	-
78-84	10	-	-	-	-	-
Total	3830	52	12	19	6	37

[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: August 27, 2000

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	992	0.07	0.05	1319	0.09	0.07
AV-1	989	0.07	0.04	1319	0.08	0.06
AV-1 - Baseline	987	-0.01	0.05	1318	-0.01	0.05
Alpha-tocopherol (µg/ml)						
Baseline	992	16.16	5.82	1319	16.36	6.50
AV-1	989	17.78	7.58	1320	16.85	6.05
AV-1 - Baseline	987	1.63	5.28	1319	0.49	4.78
Beta-Carotene (µg/ml)						
Baseline	991	0.29	0.17	1319	0.35	0.28
AV-1	988	0.26	0.18	1320	0.31	0.25
AV-1 - Baseline	986	-0.03	0.17	1319	-0.04	0.17
Beta-Cryptoxanthine (µg/ml)						
Baseline	992	0.08	0.04	1319	0.10	0.06
AV-1	989	0.08	0.05	1319	0.09	0.06
AV-1 - Baseline	987	0.00	0.03	1318	-0.01	0.05
Gamma-tocopherol (µg/ml)						
Baseline	992	2.50	1.43	1319	2.21	1.14
AV-1	989	2.20	1.57	1320	1.84	1.01
AV-1 - Baseline	987	-0.30	0.95	1319	-0.37	0.76
Lycopene (µg/ml)						
Baseline	992	0.40	0.16	1319	0.41	0.16
AV-1	989	0.39	0.16	1320	0.40	0.15
AV-1 - Baseline	987	-0.01	0.14	1319	-0.01	0.14
Lutein and Zeaxanthin (µg/ml)						
Baseline	992	0.20	0.07	1319	0.21	0.08
AV-1	989	0.21	0.08	1320	0.21	0.08
AV-1 - Baseline	987	0.00	0.05	1319	0.00	0.05
Retinol (µg/ml)						
Baseline	992	0.60	0.12	1319	0.60	0.12
AV-1	989	0.63	0.13	1320	0.61	0.12
AV-1 - Baseline	987	0.03	0.09	1319	0.01	0.08

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

Table 2.8 (Continued)
Blood Specimen Analysis: HRT Participants

Data as of: August 27, 2000

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	962	129.38	24.14	1272	123.87	23.54
AV-1	942	139.38	29.09	1274	129.96	25.73
AV-1 – Baseline	916	10.42	21.18	1235	5.88	18.96
Factor VII C (%)						
Baseline	943	129.76	22.21	1253	125.01	22.09
AV-1	930	136.11	26.53	1264	125.04	23.00
AV-1 – Baseline	888	6.12	20.12	1208	-0.52	18.31
Fibrinogen (mg/dl)						
Baseline	960	312.00	51.83	1270	307.08	47.70
AV-1	940	301.60	49.54	1271	298.52	47.68
AV-1 – Baseline	912	-11.41	42.78	1230	-8.27	44.15
Hormones / Other						
Glucose (mg/dl)						
Baseline	989	105.47	28.38	1316	100.82	20.50
AV-1	987	102.89	24.86	1317	99.03	17.41
AV-1 – Baseline	982	-2.78	15.31	1313	-1.80	13.24
Insulin (μIU/ml)						
Baseline	971	12.70	6.01	1281	11.49	5.46
AV-1	974	12.06	5.89	1277	11.38	5.88
AV-1 – Baseline	953	-0.71	4.69	1253	-0.09	4.55

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

Table 2.8 (Continued)
Blood Specimen Analysis: HRT Participants

Data as of: August 27, 2000

	Without Uterus			With Uterus		
	N	Mean[1]	S.D.[1]	N	Mean[1]	S.D.[1]
Lipoproteins						
HDL-2 (mg/dl)						
Baseline	963	17.40	6.35	1277	17.95	6.35
AV-1	962	19.53	7.32	1287	19.24	6.74
AV-1 – Baseline	939	2.07	4.10	1251	1.20	3.84
HDL-3 (mg/dl)						
Baseline	964	38.72	7.00	1277	39.04	6.78
AV-1	964	40.98	7.92	1288	40.14	6.81
AV-1 – Baseline	941	2.14	4.77	1252	1.04	4.35
HDL-C (mg/dl)						
Baseline	987	56.00	12.15	1314	57.06	12.01
AV-1	985	60.20	14.06	1319	59.33	12.37
AV-1 – Baseline	980	4.17	7.73	1313	2.27	6.77
LDL-C (mg/dl)						
Baseline	970	142.26	30.42	1298	138.74	26.55
AV-1	966	128.89	29.13	1297	127.27	26.14
AV-1 – Baseline	953	-13.25	22.59	1284	-11.40	21.42
Lp(a) (mg/dl)						
Baseline	974	26.47	21.27	1300	27.04	23.03
AV-1	972	25.39	21.82	1306	25.05	22.77
AV-1 – Baseline	959	-1.04	8.87	1289	-1.92	8.78
Total Cholesterol (mg/dl)						
Baseline	991	230.02	33.81	1319	225.06	29.96
AV-1	987	223.93	33.45	1319	216.14	28.76
AV-1 – Baseline	984	-5.97	25.01	1318	-8.93	23.75
Triglyceride (mg/dl)						
Baseline	991	162.33	87.70	1319	145.88	60.96
AV-1	987	175.74	116.40	1318	148.46	57.70
AV-1 – Baseline	984	13.64	63.46	1317	2.57	44.17

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

Table 2.9
Bone Mineral Density Analysis: HRT Participants

Data as of: August 27, 2000

	Without Uterus			With Uterus		
	N	Mean	S.D.	N	Mean	S.D.
Whole Body Scan						
Baseline[1]	937	1.01	0.11	1025	0.99	0.10
AV-1	839	1.01	0.11	929	1.00	0.10
AV-3	705	1.03	0.12	766	1.02	0.10
AV6	88	1.05	0.12	109	1.02	0.11
AV-1 % Change from baseline BMD[2]	837	0.43	2.79	927	0.27	2.35
AV-3 % Change from baseline BMD[3]	703	1.92	4.15	764	1.88	3.76
AV6% Change from baseline BMD[4]	88	2.91	4.95	109	3.09	5.72
Spine Scan						
Baseline	911	0.97	0.16	999	0.95	0.16
AV1	821	0.99	0.16	903	0.97	0.16
AV3	700	1.00	0.17	754	0.99	0.17
AV6	93	1.00	0.18	112	0.99	0.18
AV1 % Change from baseline BMD	817	1.90	4.57	900	2.09	4.36
AV3 % Change from baseline BMD	696	3.50	6.20	752	4.07	6.01
AV6% Change from baseline BMD	93	3.92	6.73	112	4.82	6.95
Hip Scan						
Baseline	933	0.86	0.14	1024	0.84	0.13
AV1	837	0.86	0.14	928	0.84	0.13
AV3	708	0.88	0.15	773	0.86	0.14
AV6	93	0.89	0.15	119	0.85	0.12
AV1 % Change from baseline BMD	834	0.71	3.27	927	0.62	3.16
AV3 % Change from baseline BMD	705	2.03	4.73	772	2.17	4.71
AV6% Change from baseline BMD	93	2.14	5.81	119	1.92	6.01

[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 2.10
Lost-to-Follow-up and Vital Status by Hysterectomy Status

Data as of: August 27, 2000

	With Uterus (N=16,609)		Without Uterus (N=10,739)		HRT Participants (N=27,348)	
	N	%	N	%	N	%
Vital Status/Participation						
Deceased	241	1.5	209	1.9	450	1.6
Alive: Current Participation[1]	15657	94.3	9947	92.6	25604	93.6
Alive: Recent Participation[2]	275	1.7	210	2.0	485	1.8
Alive: Past/Unknown Participation[3]	9	0.1	7	0.1	16	0.1
Stopped Follow-Up[4]	223	1.3	180	1.7	403	1.5
Lost to Follow-Up[5]	204	1.2	186	1.7	390	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 2.11
Locally Verified Outcomes (Annualized Percentages) by Age for Hormone Replacement Therapy
Data as of: August 27, 2000

Outcomes	Total	Age 50-54	Age 55-59	Age 60-69	Age 70-79
Number randomized	27348	3426	5409	12363	6150
Mean follow-up (months)	42.8	48.2	44.8	41.7	40.2
Cardiovascular					
CHD[1]	358 (0.37%)	22 (0.16%)	31 (0.15%)	172 (0.40%)	133 (0.65%)
Coronary death	104 (0.11%)	5 (0.04%)	10 (0.05%)	47 (0.11%)	42 (0.20%)
Total MI[2]	281 (0.29%)	18 (0.13%)	21 (0.10%)	136 (0.32%)	106 (0.52%)
Clinical MI	274 (0.28%)	17 (0.12%)	21 (0.10%)	131 (0.30%)	105 (0.51%)
Definite Silent MI	15 (0.02%)	2 (0.01%)	1 (<0.01%)	9 (0.02%)	3 (0.01%)
Possible Silent MI	56 (0.06%)	5 (0.04%)	8 (0.04%)	20 (0.05%)	23 (0.11%)
Angina	492 (0.50%)	17 (0.12%)	60 (0.30%)	238 (0.55%)	177 (0.86%)
CABG/PTCA	415 (0.43%)	16 (0.12%)	46 (0.23%)	202 (0.47%)	151 (0.73%)
Carotid artery disease	105 (0.11%)	1 (0.01%)	11 (0.05%)	49 (0.11%)	44 (0.21%)
Congestive heart failure	238 (0.24%)	10 (0.07%)	26 (0.13%)	93 (0.22%)	109 (0.53%)
Stroke	242 (0.25%)	8 (0.06%)	24 (0.12%)	112 (0.26%)	98 (0.48%)
Non-disabling stroke	152 (0.16%)	8 (0.06%)	17 (0.08%)	73 (0.17%)	54 (0.26%)
Fatal/disabling stroke	54 (0.06%)	0 (0.00%)	1 (<0.01%)	24 (0.06%)	29 (0.14%)
Unknown status from stroke	36 (0.04%)	0 (0.00%)	6 (0.03%)	15 (0.03%)	15 (0.07%)
PVD	70 (0.07%)	4 (0.03%)	7 (0.03%)	33 (0.08%)	26 (0.13%)
DVT	156 (0.16%)	10 (0.07%)	18 (0.09%)	78 (0.18%)	50 (0.24%)
PE	83 (0.09%)	4 (0.03%)	12 (0.06%)	36 (0.08%)	31 (0.15%)
CHD[1]/Possible Silent MI	408 (0.42%)	27 (0.20%)	37 (0.18%)	190 (0.44%)	154 (0.75%)
Coronary disease[3]	1013 (1.04%)	47 (0.34%)	109 (0.54%)	469 (1.09%)	388 (1.89%)
DVT/PE	201 (0.21%)	11 (0.08%)	24 (0.12%)	99 (0.23%)	67 (0.33%)
Total CVD	1492 (1.53%)	70 (0.51%)	159 (0.79%)	706 (1.64%)	557 (2.71%)
Cancer					
Breast cancer[4]	315 (0.32%)	37 (0.27%)	44 (0.22%)	159 (0.37%)	75 (0.36%)
Invasive breast cancer	246 (0.25%)	28 (0.20%)	38 (0.19%)	121 (0.28%)	59 (0.29%)
Non-invasive breast cancer	72 (0.07%)	9 (0.07%)	6 (0.03%)	41 (0.10%)	16 (0.08%)
Ovary cancer	29 (0.03%)	1 (0.01%)	4 (0.02%)	17 (0.04%)	7 (0.03%)
Endometrial Cancer[5]	26 (0.04%)	0 (0.00%)	4 (0.03%)	13 (0.05%)	9 (0.08%)
Colorectal cancer	129 (0.13%)	7 (0.05%)	16 (0.08%)	64 (0.15%)	42 (0.20%)
Other cancer[6,7]	426 (0.44%)	31 (0.23%)	52 (0.26%)	198 (0.46%)	145 (0.70%)
Total cancer	913 (0.94%)	76 (0.55%)	118 (0.58%)	444 (1.03%)	275 (1.34%)
Fractures					
Hip fracture	94 (0.10%)	3 (0.02%)	4 (0.02%)	25 (0.06%)	62 (0.30%)
Vertebral fracture	95 (0.10%)	5 (0.04%)	11 (0.05%)	39 (0.09%)	40 (0.19%)
Other fracture[6,8]	1415 (1.45%)	164 (1.19%)	225 (1.12%)	677 (1.58%)	349 (1.70%)
Total fracture	1563 (1.60%)	170 (1.23%)	236 (1.17%)	730 (1.70%)	427 (2.07%)
Deaths					
Cardiovascular deaths	137 (0.14%)	6 (0.04%)	12 (0.06%)	56 (0.13%)	63 (0.31%)
Cancer deaths	179 (0.18%)	8 (0.06%)	16 (0.08%)	86 (0.20%)	69 (0.34%)
Deaths: other known cause	49 (0.05%)	5 (0.04%)	8 (0.04%)	22 (0.05%)	14 (0.07%)
Deaths: unknown cause	22 (0.02%)	2 (0.01%)	2 (0.01%)	9 (0.02%)	9 (0.04%)
Deaths: not yet adjudicated	63 (0.06%)	3 (0.02%)	7 (0.03%)	24 (0.06%)	29 (0.14%)
Total death	450 (0.46%)	24 (0.17%)	45 (0.22%)	197 (0.46%)	184 (0.89%)

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

[2] "Total MI' includes clinical MI and definite silent MI.

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

[4] Excludes four 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.

[7] Excludes non-melanoma skin cancer

[8] "Other fracture" excludes fractures indicated as pathological.

Table 2.11 (Continued)
Locally Verified Outcomes (Annualized Percentages) by RaceEthnicity for Hormone Replacement Therapy

Data as of: August 27, 2000

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)	42.0	39.9	42.3	41.8	43.0	39.1
Cardiovascular						
CHD[1]	0 (0.00%)	3 (0.17%)	34 (0.35%)	11 (0.21%)	304 (0.38%)	6 (0.48%)
Coronary death	0 (0.00%)	2 (0.11%)	17 (0.18%)	2 (0.04%)	81 (0.10%)	2 (0.16%)
Total MI[2]	0 (0.00%)	2 (0.11%)	20 (0.21%)	9 (0.17%)	245 (0.31%)	5 (0.40%)
Clinical MI	0 (0.00%)	2 (0.11%)	19 (0.20%)	9 (0.17%)	239 (0.30%)	5 (0.40%)
Definite Silent MI	0 (0.00%)	0 (0.00%)	1 (0.01%)	0 (0.00%)	13 (0.02%)	1 (0.08%)
Possible Silent MI	0 (0.00%)	1 (0.06%)	7 (0.07%)	3 (0.06%)	45 (0.06%)	0 (0.00%)
Angina	4 (0.87%)	7 (0.40%)	48 (0.50%)	21 (0.39%)	408 (0.52%)	4 (0.32%)
CABG/PTCA	1 (0.22%)	4 (0.23%)	33 (0.34%)	16 (0.30%)	356 (0.45%)	5 (0.40%)
Carotid artery disease	1 (0.22%)	0 (0.00%)	5 (0.05%)	0 (0.00%)	99 (0.13%)	0 (0.00%)
Congestive heart failure	0 (0.00%)	1 (0.06%)	35 (0.36%)	6 (0.11%)	193 (0.24%)	3 (0.24%)
Stroke	2 (0.44%)	5 (0.29%)	30 (0.31%)	9 (0.17%)	195 (0.25%)	1 (0.08%)
Non-disabling stroke	1 (0.22%)	4 (0.23%)	22 (0.23%)	7 (0.13%)	117 (0.15%)	1 (0.08%)
Fatal/disabling stroke	1 (0.22%)	0 (0.00%)	7 (0.07%)	1 (0.02%)	45 (0.06%)	0 (0.00%)
Unknown status from stroke	0 (0.00%)	1 (0.06%)	1 (0.01%)	1 (0.02%)	33 (0.04%)	0 (0.00%)
PVD	1 (0.22%)	0 (0.00%)	6 (0.06%)	2 (0.04%)	61 (0.08%)	0 (0.00%)
DVT	1 (0.22%)	1 (0.06%)	15 (0.16%)	2 (0.04%)	137 (0.17%)	0 (0.00%)
PE	1 (0.22%)	1 (0.06%)	8 (0.08%)	0 (0.00%)	73 (0.09%)	0 (0.00%)
CHD[1]/Possible Silent MI	0 (0.00%)	4 (0.23%)	40 (0.41%)	14 (0.26%)	344 (0.44%)	6 (0.48%)
Coronary disease[3]	4 (0.87%)	12 (0.69%)	109 (1.13%)	36 (0.67%)	840 (1.06%)	12 (0.96%)
DVT/PE	2 (0.44%)	1 (0.06%)	19 (0.20%)	2 (0.04%)	177 (0.22%)	0 (0.00%)
Total CVD	9 (1.96%)	18 (1.03%)	154 (1.60%)	47 (0.88%)	1251 (1.58%)	13 (1.04%)
Cancer						
Breast cancer[4]	0 (0.00%)	6 (0.34%)	21 (0.22%)	10 (0.19%)	278 (0.35%)	0 (0.00%)
Invasive breast cancer	0 (0.00%)	5 (0.29%)	18 (0.19%)	6 (0.11%)	217 (0.27%)	0 (0.00%)
Non-invasive breast cancer	0 (0.00%)	1 (0.06%)	3 (0.03%)	4 (0.07%)	64 (0.08%)	0 (0.00%)
Ovary cancer	0 (0.00%)	0 (0.00%)	2 (0.02%)	0 (0.00%)	27 (0.03%)	0 (0.00%)
Endometrial Cancer[5]	1 (0.53%)	0 (0.00%)	0 (0.00%)	1 (0.03%)	24 (0.05%)	0 (0.00%)
Colorectal cancer	0 (0.00%)	3 (0.17%)	14 (0.15%)	8 (0.15%)	102 (0.13%)	2 (0.16%)
Other cancer[6,7]	3 (0.65%)	9 (0.51%)	32 (0.33%)	9 (0.17%)	368 (0.47%)	5 (0.40%)
Total cancer	4 (0.87%)	18 (1.03%)	68 (0.70%)	27 (0.50%)	789 (1.00%)	7 (0.56%)
Fractures						
Hip fracture	0 (0.00%)	1 (0.06%)	2 (0.02%)	1 (0.02%)	90 (0.11%)	0 (0.00%)
Vertebral fracture	0 (0.00%)	1 (0.06%)	1 (0.01%)	0 (0.00%)	93 (0.12%)	0 (0.00%)
Other fracture[6,8]	6 (1.31%)	20 (1.14%)	75 (0.78%)	54 (1.01%)	1245 (1.58%)	15 (1.20%)
Total fracture	6 (1.31%)	21 (1.20%)	78 (0.81%)	54 (1.01%)	1389 (1.76%)	15 (1.20%)
Deaths						
Cardiovascular deaths	0 (0.00%)	2 (0.11%)	22 (0.23%)	2 (0.04%)	109 (0.14%)	2 (0.16%)
Cancer deaths	1 (0.22%)	6 (0.34%)	14 (0.15%)	3 (0.06%)	154 (0.19%)	1 (0.08%)
Deaths: other known cause	2 (0.44%)	1 (0.06%)	4 (0.04%)	0 (0.00%)	42 (0.05%)	0 (0.00%)
Deaths: unknown cause	1 (0.22%)	0 (0.00%)	4 (0.04%)	1 (0.02%)	16 (0.02%)	0 (0.00%)
Deaths: not yet adjudicated	1 (0.22%)	5 (0.29%)	8 (0.08%)	1 (0.02%)	47 (0.06%)	1 (0.08%)
Total death	5 (1.09%)	14 (0.80%)	52 (0.54%)	7 (0.13%)	368 (0.47%)	4 (0.32%)

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

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

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

[4] Excludes four 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.

[7] Excludes non-melanoma skin cancer

[8] "Other fracture" excludes fractures indicated as pathological.

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

Data as of: August 27, 2000

Outcomes	Without Uterus		With Uterus	
Number randomized	10739		16609	
Mean follow-up (months)	42.9		42.7	
Cardiovascular				
CHD[1]	158	(0.41%)	200	(0.34%)
Coronary death	52	(0.14%)	52	(0.09%)
Total MI[2]	118	(0.31%)	163	(0.28%)
Clinical MI	114	(0.30%)	160	(0.27%)
Definite Silent MI	7	(0.02%)	8	(0.01%)
Possible Silent MI	20	(0.05%)	36	(0.06%)
Angina	264	(0.69%)	228	(0.39%)
CABG/PTCA	205	(0.53%)	210	(0.36%)
Carotid artery disease	52	(0.14%)	53	(0.09%)
Congestive heart failure	139	(0.36%)	99	(0.17%)
Stroke	122	(0.32%)	120	(0.20%)
Non-disabling stroke	80	(0.21%)	72	(0.12%)
Fatal/disabling stroke	24	(0.06%)	30	(0.05%)
Unknown status from stroke	18	(0.05%)	18	(0.03%)
PVD	32	(0.08%)	38	(0.06%)
DVT	47	(0.12%)	109	(0.18%)
PE	22	(0.06%)	61	(0.10%)
CHD[1]/Possible Silent MI	174	(0.45%)	234	(0.40%)
Coronary disease[3]	509	(1.33%)	504	(0.85%)
DVT/PE	58	(0.15%)	143	(0.24%)
Total CVD	711	(1.85%)	781	(1.32%)
Cancer				
Breast cancer[4]	110	(0.29%)	205	(0.35%)
Invasive breast cancer	80	(0.21%)	166	(0.28%)
Non-invasive breast cancer	31	(0.08%)	41	(0.07%)
Ovary cancer	7	(0.02%)	22	(0.04%)
Endometrial Cancer	0	(0.00%)	26	(0.04%)
Colorectal cancer	65	(0.17%)	64	(0.11%)
Other cancer[5,6]	157	(0.41%)	269	(0.46%)
Total cancer	337	(0.88%)	576	(0.97%)
Fractures				
Hip fracture	31	(0.08%)	63	(0.11%)
Vertebral fracture	33	(0.09%)	62	(0.10%)
Other fracture[5,7]	564	(1.47%)	851	(1.44%)
Total fracture	612	(1.60%)	951	(1.61%)
Deaths				
Cardiovascular deaths	67	(0.17%)	70	(0.12%)
Cancer deaths	78	(0.20%)	101	(0.17%)
Deaths: other known cause	18	(0.05%)	31	(0.05%)
Deaths: unknown cause	15	(0.04%)	7	(0.01%)
Deaths: not yet adjudicated	31	(0.08%)	32	(0.05%)
Total death	209	(0.54%)	241	(0.41%)

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

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

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

[4] Excludes four cases with borderline malignancy.

[5] 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.

[6] Excludes non-melanoma skin cancer

[7] "Other fracture" excludes fractures indicated as pathological.

Table 2.13
Stroke Diagnosis (Annualized Percentages): HRT Participants

Data as of: August 27, 2000

	With Uterus		Without Uterus	
Number randomized	16609		10739	
Mean follow-up (months)	42.7		42.9	
Stroke Diagnosis				
Subarachoid hemorrhage	5	(0.01%)	7	(0.02%)
Intracerebral hemorrhage	13	(0.02%)	15	(0.04%)
Other intracranial hemorrhage	0	(0.00%)	2	(0.01%)
Occlusion of cerebral arteries with infarction	73	(0.12%)	66	(0.17%)
Acute cerebrovascular disease	23	(0.04%)	26	(0.07%)
Central nervous system complications	6	(0.01%)	6	(0.02%)
Total	120	(0.20%)	122	(0.32%)

Table 2.14
Stroke – Glasgow Scale (Annualized Percentages): HRT Participants

Data as of: August 27, 2000

	With Uterus		Without Uterus	
Number randomized	16609		10739	
Mean follow-up (months)	42.7		42.9	
Glasgow scale				
Good recovery	38	(0.06%)	43	(0.11%)
Moderately disabled	34	(0.06%)	37	(0.10%)
Severely disabled	17	(0.03%)	11	(0.03%)
Vegetative survival	2	(<0.01%)	0	(0.00%)
Death or death within 1 month	11	(0.02%)	13	(0.03%)
Unable to categorize stroke	5	(0.01%)	6	(0.02%)
Not yet categorized	13	(0.02%)	12	(0.03%)
Total	120	(0.20%)	122	(0.32%)

Table 2.15
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for Hormone Replacement Therapy

Data as of: August 27, 2000

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	27348		3426		5409		12363		6150	
Mean follow-up (months)	42.8		48.2		44.8		41.7		40.2	
Hospitalizations										
Ever	7452	(7.65%)	684	(4.97%)	1175	(5.83%)	3432	(7.99%)	2161	(10.50%)
Two or more	2873	(2.95%)	233	(1.69%)	416	(2.06%)	1337	(3.11%)	887	(4.31%)
Other										
Diabetes (treated)	2114	(2.17%)	250	(1.82%)	439	(2.18%)	970	(2.26%)	455	(2.21%)
Gallbladder disease[1]	1197	(1.23%)	156	(1.13%)	247	(1.22%)	558	(1.30%)	236	(1.15%)
Hysterectomy[2]	303	(0.51%)	27	(0.33%)	53	(0.41%)	147	(0.56%)	76	(0.64%)
Glaucoma	1513	(1.55%)	120	(0.87%)	219	(1.09%)	711	(1.66%)	463	(2.25%)
Osteoporosis	2819	(2.89%)	158	(1.15%)	384	(1.90%)	1326	(3.09%)	951	(4.62%)
Osteoarthritis[3]	4507	(4.92%)	397	(3.12%)	737	(3.90%)	2048	(5.08%)	1325	(6.74%)
Rheumatoid arthritis	996	(1.02%)	120	(0.87%)	209	(1.04%)	435	(1.01%)	232	(1.13%)
Intestinal polyps	1790	(1.84%)	158	(1.15%)	266	(1.32%)	917	(2.13%)	449	(2.18%)
Lupus	167	(0.17%)	24	(0.17%)	28	(0.14%)	82	(0.19%)	33	(0.16%)
Kidney Stones[3]	361	(0.51%)	42	(0.45%)	64	(0.45%)	173	(0.54%)	82	(0.53%)
Cataracts[3]	4853	(6.82%)	168	(1.81%)	512	(3.57%)	2442	(7.63%)	1731	(11.18%)
Pills for hypertension	8814	(9.04%)	831	(6.04%)	1487	(7.37%)	4039	(9.40%)	2457	(11.94%)

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)	42.0		39.9		42.3		41.8		43.0		39.1	
Hospitalizations												
Ever	37	(8.07%)	92	(5.26%)	761	(7.89%)	322	(6.02%)	6164	(7.80%)	76	(6.09%)
Two or more	17	(3.71%)	29	(1.66%)	311	(3.22%)	104	(1.94%)	2390	(3.03%)	22	(1.76%)
Other												
Diabetes (treated)	22	(4.80%)	64	(3.66%)	450	(4.67%)	199	(3.72%)	1346	(1.70%)	33	(2.64%)
Gallbladder disease[1]	7	(1.53%)	18	(1.03%)	102	(1.06%)	74	(1.38%)	977	(1.24%)	19	(1.52%)
Hysterectomy[2]	1	(0.53%)	0	(0.00%)	12	(0.31%)	13	(0.42%)	273	(0.55%)	4	(0.53%)
Glaucoma	9	(1.96%)	32	(1.83%)	240	(2.49%)	90	(1.68%)	1118	(1.42%)	24	(1.92%)
Osteoporosis	14	(3.05%)	66	(3.77%)	128	(1.33%)	140	(2.62%)	2424	(3.07%)	47	(3.76%)
Osteoarthritis[3]	24	(5.49%)	90	(5.33%)	510	(5.58%)	293	(5.82%)	3514	(4.74%)	76	(6.35%)
Rheumatoid arthritis	10	(2.18%)	23	(1.31%)	189	(1.96%)	142	(2.65%)	616	(0.78%)	16	(1.28%)
Intestinal polyps	4	(0.87%)	28	(1.60%)	173	(1.79%)	96	(1.79%)	1469	(1.86%)	20	(1.60%)
Lupus	0	(0.00%)	4	(0.23%)	19	(0.20%)	11	(0.21%)	131	(0.17%)	2	(0.16%)
Kidney Stones[3]	2	(0.60%)	13	(0.98%)	34	(0.50%)	37	(0.94%)	272	(0.47%)	3	(0.32%)
Cataracts[3]	24	(7.16%)	98	(7.40%)	462	(6.75%)	235	(5.94%)	3969	(6.87%)	65	(6.89%)
Pills for hypertension	49	(10.69%)	185	(10.57%)	1389	(14.40%)	504	(9.42%)	6555	(8.30%)	132	(10.57%)

[1] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

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

[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 2.16
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.

3. DM Component

3.1 Recruitment

Age and race/ethnicity-specific DM recruitment data are presented in *Table 3.1*. The age distributions 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 mean difference between Intervention and Control women is 10.9% energy from fat at AV-1, decreasing to 8.9% at AV-5 and increasing to 9.2% at AV6. This recent, if modest, improvement in the C-I is especially hopeful in view of the early cohort effect. That is, women randomized early in WHI received higher fat gram goals than the majority (81%) of WHI participants who were randomized after implementation of reduced fat gram goals. Nonetheless, these results are based on scarce data and should be interpreted with caution. 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. At AV-2 through AV-5, the C-I difference is larger for women who have reduced fat gram goals than the original goals (*Table 3.3*). The C-I value in minority women is roughly 1-2 percentage points below that for the full sample. For the first time, 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 makes these estimates unstable.

The overall C-I for percent energy from fat is roughly 2 to 3 percentage points lower than the original 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 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 AV1, decreasing to slightly less than one-half serving at AV6.

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 statistically significant participant characteristic associated with a lower C-I difference was being older. 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 not independent from 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 0.5 kg at AV-6. Participants with revised fat gram goals have maintained a C-I difference of 1.2 kg at AV-5. From a

trend perspective, these results are consistent with changes in energy intake estimated with the FFQ. The current body weight data shown by race/ethnicity suggest 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. On the other hand, Hispanic women in the Intervention appear not to be as successful in weight control as the control arm, though the magnitude of this difference is generally quite small. Some of these results are based on still sparse data, so further follow-up and analyses are needed to determine if these trends persist.

3.3 Blood Specimen and Bone Density Analyses

Table 3.7 presents 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. Note that baseline and AV-1 specimens were batched together for concurrent analyses by Medical Research Labs.

Table 3.8 presents 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. 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. This topic warrants further investigation.

3.4 Adherence to Follow-up

Table 3.9 summarizes adherence to follow-up contacts by treatment arm and contact type. Follow-up participation has been roughly equivalent in the two arms. The acceptable adherence rates specified by the Steering Committee for collection of outcome data are 90% at AV-1, with a decline of no more than 1% per year. WHI follow-up contact adherence rates are above or at these rates for years 1 through 6 with no substantial difference by arm.

3.5 Vital Status

Table 3.10 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 3.0% of the DM 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 DM participants is about 3.7 years,

suggesting that approximately 10.7% could be expected to be dead or lost-to-follow-up. Our overall rates compare favorably to design assumptions.

3.6 Outcomes

Table 3.11 and *Table 3.12* contain counts of the number of locally verified major WHI outcomes for DM participants by race/ethnicity and age. Approximately 7% of the self-reported outcomes have not yet been verified, so the numbers in this table can be seen as a lower bound to the actual number of outcomes that have occurred. Compared to the design assumptions, we have observed almost 90% of the expected number of breast cancers, 75% of the expected number of colorectal cancers, about 60% of the expected number of CHD events, and about 30% of the expected number hip fractures.

Table 3.13 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

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 3.14* 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 consists of interviews using motivational enhancement techniques. Nutritionists are prioritizing their efforts by working first with "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). As of August 27, 2000, 69% of medium adherers had received at least one IIP contact. The study goal is to complete a series of three motivational interviewing contacts with all medium adherers by December 2000.

When Clinical Center resources permit, nutritionists are also working with high and low-adherers: 29% and 22% of these women have received at least one contact, respectively.

The Steering Committee and Project Office have approved a targeted message campaign consisting of five components: (1) A 2000 Fall/Winter Kickoff Newsletter to raise awareness and excitement, (2) an Eat & Tell Drive asking participants to report on one-day's intake of fruits and vegetables, (3) a mailing introducing five themes designed to help participants rediscover their intrinsic motivation(s) for participating in WHI, (4) a tailored motivational enhancement phone call that supports participants in the process of identifying their primary motivation, and (5) a second targeted mailing with a menu of options such that women can choose an "action" consistent with her readiness to change. This campaign will include all DM Intervention participants. Additional DM intervention boosters are under consideration by investigators.

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

Data as of: August 27, 2000

	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: August 27, 2000

	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]	18089	25.2	7.5	26757	36.1	6.9	10.9	0.1	0.00
FFQ Year 2[4]	5876	26.3	7.6	8603	36.2	7.0	9.9	0.1	0.00
FFQ Year 3[5]	1918	27.1	7.9	2833	37.0	7.1	9.9	0.2	0.00
FFQ Year 4[6]	1370	28.1	8.2	2121	37.3	7.0	9.2	0.3	0.00
FFQ Year 5[7]	633	28.6	8.0	1022	37.5	7.6	8.9	0.4	0.00
FFQ Year 6[8]	340	28.3	8.8	537	37.5	7.2	9.2	0.5	0.00
4DFR Baseline	892	32.8	6.4	1351	33.0	6.8	0.2	0.3	0.54
4DFR Year 1	804	21.7	7.3	1171	32.9	6.8	11.2	0.3	0.00
24 Hr Recall, Post-baseline	226	23.0	9.2	262	32.1	7.6	9.1	0.8	0.00
24 Hr Recall, Year 1	220	22.4	7.8	268	32.6	7.7	10.2	0.7	0.00
24 Hr Recall, Year 2	182	23.3	9.4	209	32.5	8.2	9.2	0.9	0.00
24 Hr Recall, Year 3	115	25.6	9.6	152	33.6	8.2	8.0	1.1	0.00
24 Hr Recall, Year 3 Cohort	520	24.6	8.5	792	32.8	7.5	8.2	0.4	0.00
24 Hr Recall, Year 4	57	26.1	8.8	76	32.2	8.0	6.1	1.5	0.00
24 Hr Recall, Year 5	16	28.2	9.9	33	31.5	6.6	3.3	2.4	0.16
Total Energy (kcal)									
FFQ Baseline	19542	1789	713	29295	1789	707	0	6.6	0.94
FFQ Year 1	18089	1474	534	26757	1584	641	110	5.8	0.00
FFQ Year 2	5876	1479	533	8603	1575	626	96	10.0	0.00
FFQ Year 3	1918	1475	537	2833	1578	657	103	18.1	0.00
FFQ Year 4	1370	1454	529	2121	1588	663	134	21.3	0.00
FFQ Year 5	633	1484	519	1022	1567	612	83	29.2	0.04
FFQ Year 6	340	1456	555	537	1569	573	113	39.2	0.01
4DFR Baseline	892	1707	454	1351	1713	459	6	19.7	0.79
4DFR Year 1	804	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	220	1485	416	268	1636	477	151	41.0	0.00
24 Hr Recall, Year 2	182	1458	427	209	1617	531	159	49.2	0.01
24 Hr Recall, Year 3	115	1489	421	152	1679	527	190	59.8	0.00
24 Hr Recall, Year 3 Cohort	520	1454	390	792	1611	496	157	25.8	0.00
24 Hr Recall, Year 4	57	1498	398	76	1548	461	50	76.3	0.67
24 Hr Recall, Year 5	16	1494	408	33	1622	470	128	137.4	0.39

(continues)

[1] Absolute difference.

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

[3] 4950 (27%) Intervention women had <=20% energy from fat at year 1.

[4] 1267 (22%) Intervention women had <=20% energy from fat at year 2.

[5] 367 (19%) Intervention women had <=20% energy from fat at year 3

[6] 216 (16%) Intervention women had <=20% energy from fat at year 4.

[7] 98 (15%) Intervention women had <=20% energy from fat at year 5.

[8] 56 (16%) Intervention women had <=20% energy from fat at year 6.

Table 3.2 (continued)
Nutrient Intake Monitoring
Data as of: August 27, 2000

	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	0.1	0.3	0.87
FFQ Year 1	18089	41.5	21.8	26757	64.5	31.7	23.0	0.3	0.00
FFQ Year 2	5876	43.4	22.1	8603	64.5	31.3	21.1	0.5	0.00
FFQ Year 3	1918	44.8	23.4	2833	65.8	33.1	21.0	0.9	0.00
FFQ Year 4	1370	45.8	23.6	2121	66.7	33.4	20.9	1.0	0.00
FFQ Year 5	633	47.6	24.3	1022	66.3	31.9	18.7	1.5	0.00
FFQ Year 6	340	45.3	22.8	537	66.0	29.4	20.7	1.9	0.00
4DFR Baseline	892	63.0	23.6	1351	63.8	24.6	0.8	1.0	0.72
4DFR Year 1	804	34.1	14.5	1171	60.4	23.5	26.3	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	220	37.0	17.1	268	60.6	25.1	23.6	2.0	0.00
24 Hr Recall, Year 2	182	38.4	22.0	209	59.7	27.6	21.3	2.5	0.00
24 Hr Recall, Year 3	115	42.5	20.6	152	64.1	29.0	21.6	3.2	0.00
24 Hr Recall, Year 3 Cohort	520	40.2	19.2	792	60.3	25.8	20.1	1.3	0.00
24 Hr Recall, Year 4	57	42.8	16.9	76	57.2	25.3	14.4	3.9	0.00
24 Hr Recall, Year 5	16	46.4	20.8	33	58.9	24.1	12.5	7.0	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	18089	14.2	8.1	26757	22.5	11.9	8.3	0.1	0.00
FFQ Year 2	5876	14.8	8.1	8603	22.5	11.7	7.7	0.2	0.00
FFQ Year 3	1918	15.2	8.7	2833	22.8	12.3	7.6	0.3	0.00
FFQ Year 4	1370	15.5	8.7	2121	23.2	12.6	7.7	0.4	0.00
FFQ Year 5	633	16.3	9.1	1022	23.3	12.1	7.0	0.6	0.00
FFQ Year 6	340	15.3	8.3	537	23.3	11.4	8.0	0.7	0.00
4DFR Baseline	892	20.6	8.9	1351	20.9	9.3	0.3	0.4	0.72
4DFR Year 1	804	10.6	5.2	1171	19.5	8.3	8.9	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	220	11.7	6.2	268	20.1	10.1	8.4	0.8	0.00
24 Hr Recall, Year 2	182	12.1	7.9	209	19.7	10.1	7.6	0.9	0.00
24 Hr Recall, Year 3	115	14.2	7.8	152	21.6	11.4	7.4	1.2	0.00
24 Hr Recall, Year 3 Cohort	520	12.5	7.1	792	19.8	9.4	7.3	0.5	0.00
24 Hr Recall, Year 4	57	13.8	6.4	76	19.9	11.1	6.1	1.6	0.00
24 Hr Recall, Year 5	16	14.2	7.7	33	19.7	10.1	5.5	2.9	0.05

(continues)

[1] Absolute difference.

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

Table 3.2 (continued)
Nutrient Intake Monitoring

Data as of: August 27, 2000

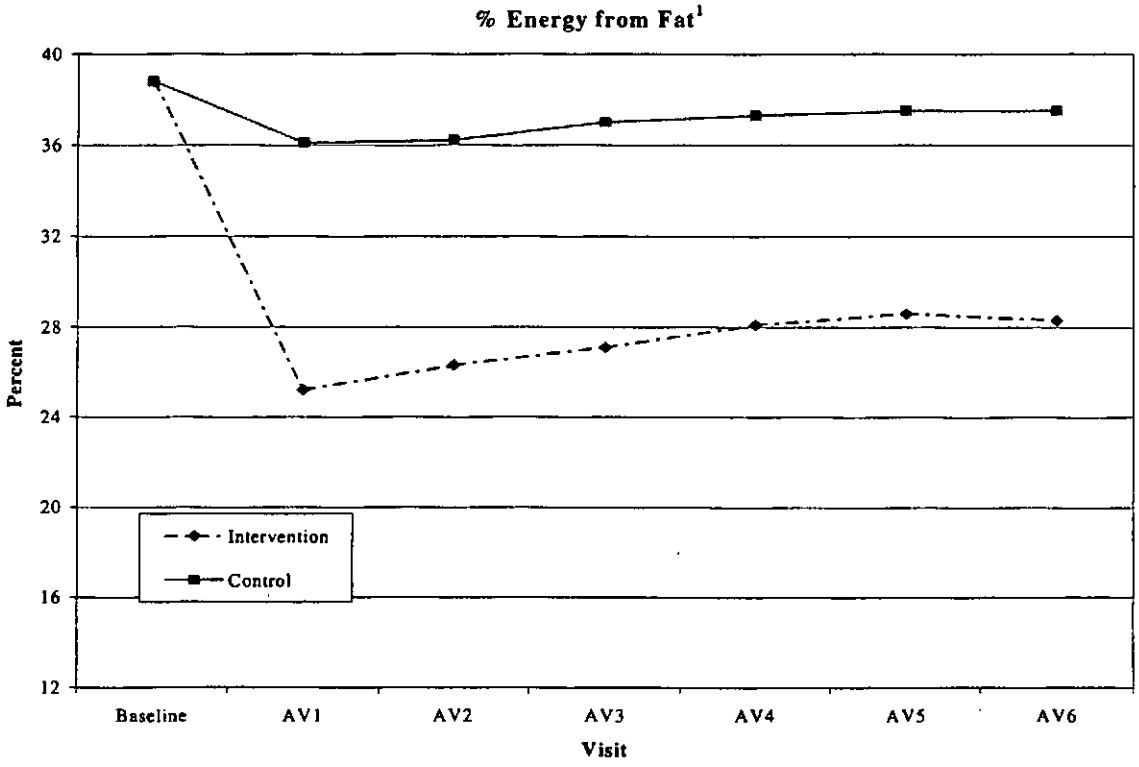
	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Polyunsaturated Fat (g)									
FFQ Baseline	19542	15.3	7.6	29295	15.3	7.6	0.0	0.1	0.78
FFQ Year 1	18089	7.9	4.4	26757	12.5	6.7	4.6	0.1	0.00
FFQ Year 2	5876	8.3	4.5	8603	12.4	6.5	4.1	0.1	0.00
FFQ Year 3	1918	8.6	4.7	2833	12.8	6.9	4.2	0.2	0.00
FFQ Year 4	1370	8.9	4.9	2121	13.0	6.9	4.1	0.2	0.00
FFQ Year 5	633	9.1	4.9	1022	12.8	6.7	3.7	0.3	0.00
FFQ Year 6	340	9.0	5.1	537	12.7	6.2	3.7	0.4	0.00
4DFR Baseline	892	13.1	5.8	1351	13.5	6.1	0.4	0.3	0.40
4DFR Year 1	804	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	220	7.8	4.4	268	12.4	6.3	4.6	0.5	0.00
24 Hr Recall, Year 2	182	8.3	5.6	209	12.4	7.6	4.1	0.7	0.00
24 Hr Recall, Year 3	115	8.6	5.1	152	13.2	6.9	4.6	0.8	0.00
24 Hr Recall, Year 3 Cohort	520	8.8	4.7	792	12.4	6.6	3.6	0.3	0.00
24 Hr Recall, Year 4	57	9.3	4.5	76	10.8	5.3	1.5	0.9	0.10
24 Hr Recall, Year 5	16	10.5	5.3	33	11.7	4.8	1.2	1.5	0.25
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	18008	5.0	2.3	26675	3.8	2.0	1.2	0.0	0.00
FFQ Year 2	5853	5.1	2.4	8574	3.9	2.0	1.2	0.0	0.00
FFQ Year 3	2075	5.2	2.5	3067	3.9	2.0	1.3	0.1	0.00
FFQ Year 4	1544	5.2	2.4	2402	3.9	2.0	1.3	0.1	0.00
FFQ Year 5	715	5.2	2.4	1174	4.0	2.1	1.2	0.1	0.00
FFQ Year 6	412	5.2	2.4	617	3.9	2.0	1.3	0.1	0.00
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	19469	4.7	2.5	29215	4.8	2.5	0.1	0.0	0.43
FFQ Year 1	18004	5.1	2.7	26665	4.2	2.3	0.9	0.0	0.00
FFQ Year 2	5852	4.9	2.5	8568	4.1	2.2	0.8	0.0	0.00
FFQ Year 3	2074	4.7	2.6	3064	4.0	2.3	0.7	0.1	0.00
FFQ Year 4	1543	4.5	2.4	2398	4.0	2.3	0.5	0.1	0.00
FFQ Year 5	715	4.3	2.1	1172	3.9	2.0	0.4	0.1	0.00
FFQ Year 6	412	4.3	2.5	617	3.9	2.2	0.4	0.1	0.03

[1] Absolute difference.

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

Figure 3.1
Nutrient Intake: Intervention vs. Control

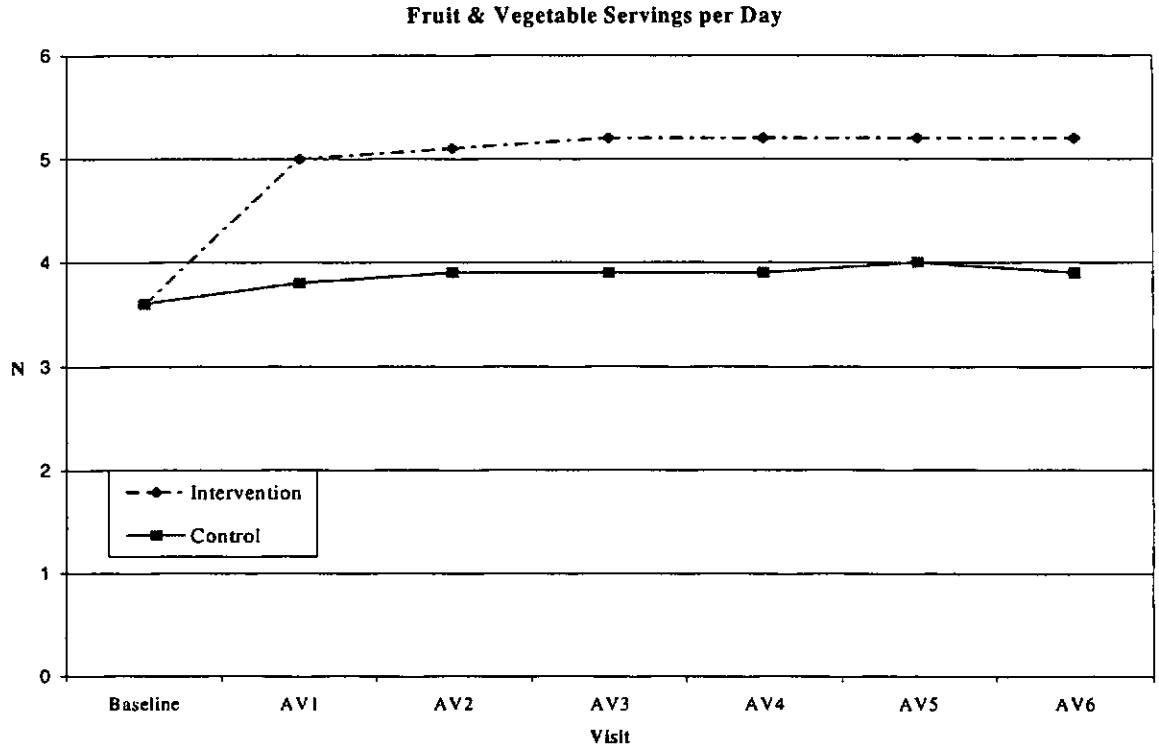
Data as of: August 27, 2000



[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: August 27, 2000



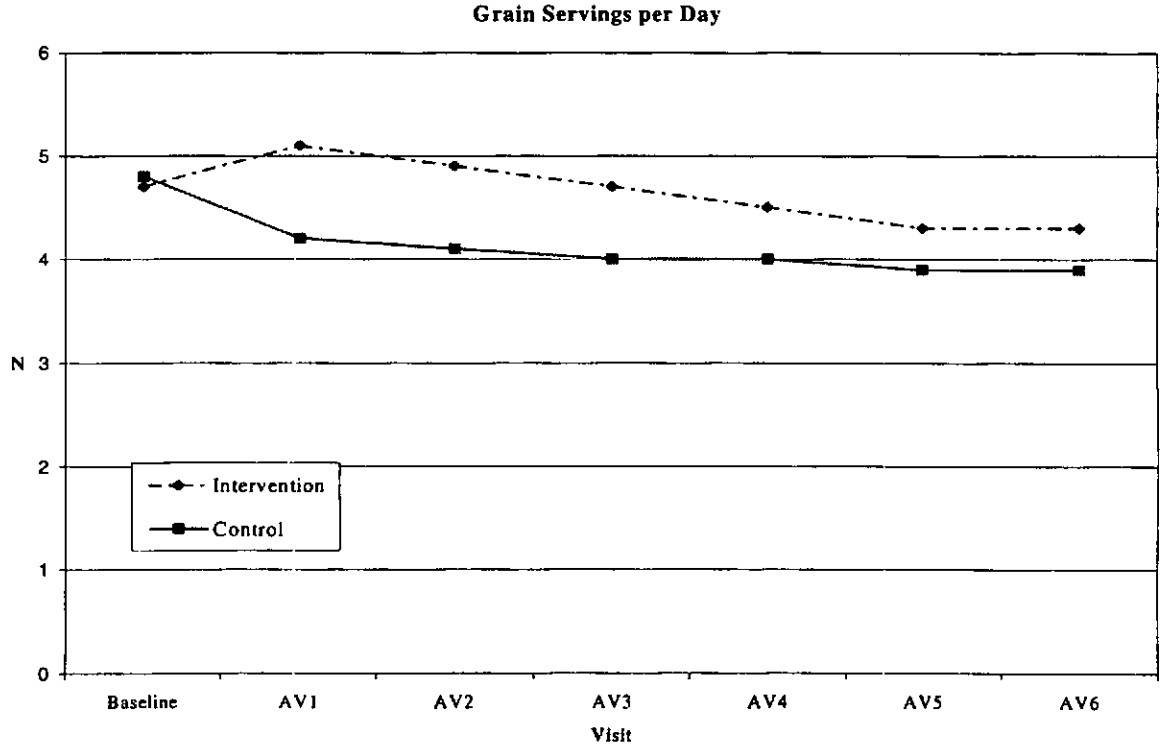


Table 3.3
Nutrient Intake Monitoring For Women With Revised Fat Gram Goals

Data as of: August 27, 2000

	Intervention[1]			Control[2]			Difference		
	N	Mean	SD	N	Mean	SD	Mean[3]	SE	p-value[4]
% Energy from Fat									
FFQ Baseline	15859	38.8	5.0	23754	38.8	4.9	0.0	0.1	0.49
FFQ Year 1	14661	25.3	7.6	21749	36.2	6.9	10.9	0.1	0.00
FFQ Year 2	4821	26.5	7.7	6944	36.6	7.0	10.1	0.1	0.00
FFQ Year 3	1505	27.3	8.0	2296	37.3	7.0	10.0	0.2	0.00
FFQ Year 4	1044	28.1	8.4	1643	37.5	6.9	9.4	0.3	0.00
FFQ Year 5	213	28.6	8.4	369	38.0	7.5	9.4	0.7	0.00
4DFR Baseline	691	32.4	6.5	1038	33.0	6.9	0.6	0.3	0.07
4DFR Year 1	621	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	171	22.2	7.8	200	32.7	7.6	10.5	0.8	0.00
24 Hr Recall, Year 2	145	22.9	8.9	148	32.4	8.2	9.5	1.0	0.00
24 Hr Recall, Year 3	66	25.2	10.2	90	32.5	8.1	7.3	1.5	0.00
24 Hr Recall, Year 3 Cohort	351	24.6	8.5	537	33.1	7.8	8.5	0.6	0.00
24 Hr Recall, Year 4	15	25.1	10.8	16	32.2	10.1	7.1	3.8	0.07
Total Energy (kcal)									
FFQ Baseline	15859	1780	701	23754	1786	706	6	7.2	0.47
FFQ Year 1	14661	1468	533	21749	1588	644	120	6.4	0.00
FFQ Year 2	4821	1470	534	6944	1577	629	107	11.1	0.00
FFQ Year 3	1505	1461	527	2296	1586	664	125	20.3	0.00
FFQ Year 4	1044	1435	530	1643	1601	678	166	24.7	0.00
FFQ Year 5	213	1506	569	369	1560	621	54	51.8	0.41
4DFR Baseline	691	1688	455	1038	1713	469	25	22.8	0.30
4DFR Year 1	621	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	171	1481	423	200	1654	489	173	47.9	0.00
24 Hr Recall, Year 2	145	1451	423	148	1597	504	146	54.4	0.05
24 Hr Recall, Year 3	66	1517	452	90	1645	548	128	82.6	0.14
24 Hr Recall, Year 3 Cohort	351	1446	386	537	1589	500	143	31.5	0.00
24 Hr Recall, Year 4	15	1409	389	16	1531	438	122	149.2	0.42
Total Fat (g)									
FFQ Baseline	15859	77.4	34.6	23754	77.6	34.6	0.2	0.4	0.62
FFQ Year 1	14661	41.6	22.0	21749	64.9	31.9	23.3	0.3	0.00
FFQ Year 2	4821	43.4	22.6	6944	65.0	31.6	21.6	0.5	0.00
FFQ Year 3	1505	44.7	23.0	2296	66.7	33.7	22.0	1.0	0.00
FFQ Year 4	1044	45.0	23.5	1643	67.8	34.4	22.8	1.2	0.00
FFQ Year 5	213	49.0	28.1	369	66.5	32.3	17.5	2.7	0.00
4DFR Baseline	691	61.5	23.3	1038	63.8	25.1	2.3	1.2	0.12
4DFR Year 1	621	33.6	14.9	892	60.5	23.9	26.9	1.1	0.00
24 Hr Recall, Post-baseline	186	39.7	22.1	205	60.2	27.7	20.5	2.6	0.00
24 Hr Recall, Year 1	171	36.2	16.2	200	61.5	25.4	25.3	2.3	0.00
24 Hr Recall, Year 2	145	37.6	21.3	148	58.7	26.5	21.1	2.8	0.00
24 Hr Recall, Year 3	66	42.6	22.4	90	60.7	28.7	18.1	4.3	0.00
24 Hr Recall, Year 3 Cohort	351	39.9	19.2	537	60.2	26.4	20.3	1.6	0.00
24 Hr Recall, Year 4	15	38.4	16.1	16	57.1	26.3	18.7	7.9	0.08

(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: August 27, 2000

	Intervention[1]			Control[2]			Difference		
	N	Mean	SD	N	Mean	SD	Mean[3]	SE	p-value[4]
Saturated Fat (g)									
FFQ Baseline	15859	27.2	13.2	23754	27.2	13.1	0.0	0.1	0.81
FFQ Year 1	14661	14.2	8.1	21749	22.6	11.9	8.4	0.1	0.00
FFQ Year 2	4821	14.7	8.3	6944	22.7	11.8	8.0	0.2	0.00
FFQ Year 3	1505	15.2	8.6	2296	23.1	12.5	7.9	0.4	0.00
FFQ Year 4	1044	15.2	8.7	1643	23.6	13.0	8.4	0.5	0.00
FFQ Year 5	213	16.7	10.4	369	23.5	12.5	6.8	1.0	0.00
4DFR Baseline	691	20.0	8.8	1038	20.8	9.5	0.8	0.5	0.17
4DFR Year 1	621	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	171	11.4	5.8	200	20.4	10.2	9.0	0.9	0.00
24 Hr Recall, Year 2	145	11.7	7.8	148	19.3	9.4	7.6	1.0	0.00
24 Hr Recall, Year 3	66	14.2	8.4	90	20.4	12.1	6.2	1.7	0.00
24 Hr Recall, Year 3 Cohort	351	12.2	7.3	537	19.8	9.5	7.6	0.6	0.00
24 Hr Recall, Year 4	15	11.3	5.7	16	21.0	12.1	9.7	3.4	0.03
Polyunsaturated Fat (g)									
FFQ Baseline	15859	15.1	7.4	23754	15.1	7.4	0.0	0.1	0.54
FFQ Year 1	14661	7.9	4.4	21749	12.5	6.7	4.6	0.1	0.00
FFQ Year 2	4821	8.3	4.6	6944	12.5	6.6	4.2	0.1	0.00
FFQ Year 3	1505	8.6	4.6	2296	13.0	7.0	4.4	0.2	0.00
FFQ Year 4	1044	8.8	4.8	1643	13.2	7.0	4.4	0.2	0.00
FFQ Year 5	213	9.6	5.9	369	12.8	6.7	3.2	0.6	0.00
4DFR Baseline	691	12.8	5.7	1038	13.5	6.3	0.7	0.3	0.06
4DFR Year 1	621	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	171	7.7	4.3	200	12.6	6.2	4.9	0.6	0.00
24 Hr Recall, Year 2	145	8.3	5.2	148	12.1	7.2	3.8	0.7	0.00
24 Hr Recall, Year 3	66	8.6	5.2	90	12.4	6.7	3.8	1.0	0.00
24 Hr Recall, Year 3 Cohort	351	8.9	4.5	537	12.4	6.6	3.5	0.4	0.00
24 Hr Recall, Year 4	15	10.0	5.3	16	10.7	4.4	0.7	1.7	0.58
Fruits and Vegetables (servings)									
FFQ Baseline	15818	3.6	1.8	23708	3.6	1.8	0.0	0.0	0.64
FFQ Year 1	14612	5.0	2.3	21693	3.9	2.0	1.1	0.0	0.00
FFQ Year 2	4806	5.1	2.4	6929	3.9	2.0	1.2	0.0	0.00
FFQ Year 3	1666	5.2	2.5	2537	3.9	2.0	1.3	0.1	0.00
FFQ Year 4	1221	5.2	2.4	1931	3.9	2.0	1.3	0.1	0.00
FFQ Year 5	286	5.2	2.4	526	4.0	2.1	1.2	0.2	0.00
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	15816	4.7	2.5	23706	4.8	2.5	0.1	0.0	0.21
FFQ Year 1	14608	5.0	2.6	21684	4.2	2.3	0.8	0.0	0.00
FFQ Year 2	4805	4.8	2.5	6924	4.1	2.2	0.7	0.0	0.00
FFQ Year 3	1665	4.6	2.5	2534	4.0	2.3	0.6	0.1	0.00
FFQ Year 4	1220	4.4	2.3	1929	3.9	2.3	0.5	0.1	0.00
FFQ Year 5	286	4.3	2.0	526	3.8	2.0	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: August 27, 2000

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFO Baseline	88	39.5	5.7	115	40.0	5.2	0.5	0.8	0.53
FFQ Year 1[3]	73	27.6	8.9	97	37.9	8.0	10.3	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]	9	31.4	10.1	21	36.3	7.2	4.9	3.2	0.14
FFQ Year 4[6]	13	31.8	9.7	14	39.0	7.4	7.2	3.3	0.04
FFQ Year 5[7]	3	31.2	3.1	3	35.1	7.4	3.9	4.6	0.45
FFQ Year 6[8]	0	N/A	N/A	0	N/A	N/A	N/A	N/A	N/A
4DFR Baseline	24	34.0	6.7	45	33.4	7.7	0.6	1.9	0.73
4DFR Year 1	18	20.5	6.2	33	34.3	7.5	13.8	2.1	0.00
24 Hr Recall, Post-baseline	0	N/A	N/A	0	N/A	N/A	N/A	N/A	N/A
24 Hr Recall, Year 1	2	19.4	5.6	3	40.4	2.5	21.0	3.5	0.01
24 Hr Recall, Year 2	1	15.2	N/A	2	34.8	4.7	19.6	N/A	N/A
24 Hr Recall, Year 3	1	22.8	N/A	1	30.1	N/A	7.3	N/A	N/A
24 Hr Recall, Year 3 Cohort	6	30.8	10.4	5	31.5	4.8	0.7	5.1	0.89
24 Hr Recall, Year 4	1	54.2	N/A	0	N/A	N/A	N/A	N/A	N/A
Total Energy (kcal)									
FFO Baseline	88	1717	796	115	1776	716	59	106.5	0.38
FFQ Year 1	73	1646	690	97	1551	751	95	112.4	0.47
FFQ Year 2	28	1508	566	31	1568	714	60	169.0	0.89
FFQ Year 3	9	1505	642	21	1705	724	200	279.5	0.49
FFQ Year 4	13	1527	427	14	1712	478	185	175.0	0.31
FFQ Year 5	3	2217	452	3	1237	731	980	496.2	0.15
FFQ Year 6	0	N/A	N/A	0	N/A	N/A	N/A	N/A	N/A
4DFR Baseline	24	1524	426	45	1690	612	166	140.3	0.43
4DFR Year 1	18	1284	419	33	1637	604	353	160.3	0.05
24 Hr Recall, Post-baseline	0	N/A	N/A	0	N/A	N/A	N/A	N/A	N/A
24 Hr Recall, Year 1	2	1455	320	3	1625	130	170	194.5	0.43
24 Hr Recall, Year 2	1	1313	N/A	2	1262	912	51	N/A	N/A
24 Hr Recall, Year 3	1	1453	N/A	1	1043	N/A	410	N/A	N/A
24 Hr Recall, Year 3 Cohort	6	1475	286	5	1535	497	60	238.6	0.95
24 Hr Recall, Year 4	1	601	N/A	0	N/A	N/A	N/A	N/A	N/A
Total Fat (g)									
FFO Baseline	88	76.5	40.3	115	79.4	35.5	2.9	5.3	0.32
FFQ Year 1	73	50.8	29.5	97	67.1	43.3	16.3	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	9	56.1	34.5	21	71.1	38.9	15.0	15.0	0.25
FFQ Year 4	13	53.4	18.9	14	75.0	26.5	21.6	8.9	0.03
FFQ Year 5	3	77.1	18.3	3	51.8	40.5	25.3	25.7	0.29
FFQ Year 6	0	N/A	N/A	0	N/A	N/A	N/A	N/A	N/A
4DFR Baseline	24	57.4	17.5	45	64.4	30.8	7.0	6.8	0.79
4DFR Year 1	18	29.4	12.9	33	64.4	32.6	35.0	8.0	0.00
24 Hr Recall, Post-baseline	0	N/A	N/A	0	N/A	N/A	N/A	N/A	N/A
24 Hr Recall, Year 1	2	30.3	2.0	3	74.8	12.2	44.5	9.2	0.01
24 Hr Recall, Year 2	1	22.9	N/A	2	51.1	41.8	28.2	N/A	N/A
24 Hr Recall, Year 3	1	36.7	N/A	1	34.9	N/A	1.8	N/A	N/A
24 Hr Recall, Year 3 Cohort	6	49.4	13.2	5	56.0	13.9	6.6	8.2	0.46
24 Hr Recall, Year 4	1	36.2	N/A	0	N/A	N/A	N/A	N/A	N/A

[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 (11%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 3

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

[7] 0 (0%) 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: August 27, 2000

	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	0.38
FFQ Year 1[3]	73	17.6	10.9	97	23.7	17.9	6.1	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]	9	20.4	13.9	21	23.8	13.3	3.4	5.4	0.39
FFQ Year 4[6]	13	18.1	7.1	14	26.5	11.0	8.4	3.6	0.04
FFQ Year 5[7]	3	25.0	7.9	3	18.1	15.8	6.9	10.2	0.37
FFQ Year 6[8]	0	N/A	N/A	0	N/A	N/A	N/A	N/A	N/A
4DFR Baseline	24	19.1	6.9	45	21.7	12.3	2.6	2.7	0.82
4DFR Year 1	18	9.0	4.2	33	20.8	10.8	11.8	2.7	0.00
24 Hr Recall, Post-baseline	0	N/A	N/A	0	N/A	N/A	N/A	N/A	N/A
24 Hr Recall, Year 1	2	8.5	0.2	3	22.3	5.3	13.8	4.0	0.01
24 Hr Recall, Year 2	1	4.4	N/A	2	15.9	12.6	11.5	N/A	N/A
24 Hr Recall, Year 3	1	8.8	N/A	1	10.5	N/A	1.7	N/A	N/A
24 Hr Recall, Year 3 Cohort	6	16.7	7.3	5	17.6	5.4	0.9	4.0	0.74
24 Hr Recall, Year 4	1	6.3	N/A	0	N/A	N/A	N/A	N/A	N/A
Polyunsaturated Fat (g)									
FFQ Baseline	88	15.2	9.5	115	15.3	7.6	0.1	1.2	0.47
FFQ Year 1	73	9.5	6.3	97	12.7	8.4	3.2	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	9	9.2	5.0	21	14.2	7.6	5.0	2.8	0.08
FFQ Year 4	13	10.9	4.5	14	14.4	5.6	3.5	2.0	0.11
FFQ Year 5	3	13.3	2.9	3	8.8	6.5	4.5	4.1	0.30
FFQ Year 6	0	N/A	N/A	0	N/A	N/A	N/A	N/A	N/A
4DFR Baseline	24	11.5	4.6	45	12.2	6.2	0.7	1.4	0.98
4DFR Year 1	18	6.9	3.8	33	13.4	9.5	6.5	2.3	0.00
24 Hr Recall, Post-baseline	0	N/A	N/A	0	N/A	N/A	N/A	N/A	N/A
24 Hr Recall, Year 1	2	6.8	0.7	3	17.6	3.8	10.8	2.9	0.01
24 Hr Recall, Year 2	1	9.3	N/A	2	7.2	5.6	2.1	N/A	N/A
24 Hr Recall, Year 3	1	12.3	N/A	1	10.0	N/A	2.3	N/A	N/A
24 Hr Recall, Year 3 Cohort	6	10.6	3.4	5	11.6	4.4	1.0	2.3	0.72
24 Hr Recall, Year 4	1	16.8	N/A	0	N/A	N/A	N/A	N/A	N/A
Fruits and Vegetables (servings)									
FFQ Baseline	88	3.5	1.9	115	3.1	1.7	0.4	0.3	0.27
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	1.8	0.7	0.06
FFQ Year 3	11	4.8	2.2	21	4.0	2.5	0.8	0.9	0.28
FFQ Year 4	14	5.4	3.0	16	4.4	2.2	1.0	1.0	0.57
FFQ Year 5	3	5.8	2.3	3	2.0	0.4	3.8	1.3	0.03
FFQ Year 6	0	N/A	N/A	1	6.3	N/A	N/A	N/A	N/A
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	0.02
FFQ Year 2	28	5.5	3.0	31	4.2	3.0	1.3	0.8	0.14
FFQ Year 3	11	3.7	2.7	21	5.0	2.8	1.3	1.0	0.12
FFQ Year 4	14	3.9	2.4	16	3.7	1.5	0.2	0.7	0.91
FFQ Year 5	3	5.0	2.9	3	4.1	2.6	0.9	2.2	0.62
FFQ Year 6	0	N/A	N/A	1	7.9	N/A	N/A	N/A	N/A

[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 (11%) American Indian/Alaskan Native Intervention women had <=20% energy from fat at year 3

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

[7] 0 (0%) 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: August 27, 2000

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFO Baseline	431	37.7	4.4	674	38.4	4.7	0.7	0.3	0.02
FFQ Year 1[3]	407	25.8	7.3	628	36.1	6.6	10.3	0.4	0.00
FFQ Year 2[4]	146	27.1	7.4	213	36.0	6.8	8.9	0.8	0.00
FFQ Year 3[5]	49	27.4	6.4	68	35.9	6.7	8.5	1.2	0.00
FFQ Year 4[6]	25	27.8	8.8	47	38.1	7.3	10.3	1.9	0.00
FFQ Year 5[7]	7	27.1	7.5	8	32.3	7.1	5.2	3.8	0.19
FFQ Year 6[8]	1	23.5	N/A	0	N/A	N/A	N/A	N/A	N/A
4DFR Baseline	70	30.2	5.4	104	31.4	6.8	1.2	1.0	0.20
4DFR Year 1	68	21.5	7.6	88	31.6	5.8	10.1	1.1	0.00
24 Hr Recall, Post-baseline	3	19.8	6.3	9	30.2	9.7	10.4	6.1	0.12
24 Hr Recall, Year 1	6	23.4	9.4	4	23.6	7.8	0.2	5.7	0.97
24 Hr Recall, Year 2	5	23.0	12.1	7	26.7	5.5	3.7	5.1	0.48
24 Hr Recall, Year 3	1	41.1	N/A	2	42.4	12.0	1.3	N/A	N/A
24 Hr Recall, Year 3 Cohort	27	22.8	8.0	46	30.6	6.7	7.8	1.7	0.00
24 Hr Recall, Year 4	0	N/A	N/A	1	27.8	N/A	N/A	N/A	N/A
Total Energy (kcal)									
FFO Baseline	431	1700	723	674	1675	711	25	44.1	0.50
FFQ Year 1	407	1502	588	628	1524	636	22	39.3	0.95
FFQ Year 2	146	1512	639	213	1508	779	4	77.9	0.33
FFQ Year 3	49	1430	575	68	1339	529	91	102.8	0.32
FFQ Year 4	25	1312	409	47	1375	582	63	131.0	0.79
FFQ Year 5	7	1257	211	8	1625	465	368	191.5	0.09
FFQ Year 6	1	2411	N/A	0	N/A	N/A	N/A	N/A	N/A
4DFR Baseline	70	1683	400	104	1732	388	49	60.7	0.37
4DFR Year 1	68	1525	374	88	1620	397	95	62.5	0.12
24 Hr Recall, Post-baseline	3	2015	146	9	1536	338	479	206.2	0.04
24 Hr Recall, Year 1	6	1381	261	4	1189	231	192	161.5	0.28
24 Hr Recall, Year 2	5	1554	725	7	1532	349	22	311.7	0.87
24 Hr Recall, Year 3	1	1348	N/A	2	2028	985	680	N/A	N/A
24 Hr Recall, Year 3 Cohort	27	1506	341	46	1604	517	98	111.6	0.67
24 Hr Recall, Year 4	0	N/A	N/A	1	1250	N/A	N/A	N/A	N/A
Total Fat (g)									
FFO Baseline	431	71.9	34.1	674	72.2	34.8	0.3	2.1	0.99
FFQ Year 1	407	43.5	23.5	628	62.4	31.4	18.9	1.8	0.00
FFQ Year 2	146	46.0	24.7	213	61.5	35.7	15.5	3.4	0.00
FFQ Year 3	49	43.7	23.1	68	53.8	25.1	10.1	4.6	0.02
FFQ Year 4	25	40.6	20.2	47	58.3	27.9	17.7	6.3	0.04
FFQ Year 5	7	37.3	11.2	8	57.8	19.6	20.5	8.4	0.02
FFQ Year 6	1	63.1	N/A	0	N/A	N/A	N/A	N/A	N/A
4DFR Baseline	70	57.1	19.1	104	61.8	23.4	4.7	3.4	0.25
4DFR Year 1	68	36.6	17.4	88	57.6	19.9	21.0	3.0	0.00
24 Hr Recall, Post-baseline	3	43.9	11.9	9	53.9	29.5	10.0	17.9	0.68
24 Hr Recall, Year 1	6	34.4	11.7	4	32.1	13.6	2.3	8.0	0.75
24 Hr Recall, Year 2	5	46.7	47.7	7	48.4	19.2	1.7	19.7	0.45
24 Hr Recall, Year 3	1	61.6	N/A	2	102.1	73.5	40.5	N/A	N/A
24 Hr Recall, Year 3 Cohort	27	39.2	19.9	46	56.1	25.5	16.9	5.7	0.00
24 Hr Recall, Year 4	0	N/A	N/A	1	40.1	N/A	N/A	N/A	N/A

[1] Absolute difference.

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

[3] 98 (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] 7 (14%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 3.

[6] 4 (16%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 4.

[7] 1 (14%) 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: August 27, 2000

	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]	407	13.5	8.0	628	19.6	10.8	6.1	0.6	0.00
FFQ Year 2[4]	146	14.2	8.5	213	19.4	12.0	5.2	1.2	0.00
FFQ Year 3[5]	49	13.2	7.3	68	16.5	8.0	3.3	1.4	0.01
FFQ Year 4[6]	25	13.2	7.8	47	17.5	9.0	4.3	2.1	0.14
FFQ Year 5[7]	7	11.9	4.3	8	18.6	7.4	6.7	3.2	0.06
FFQ Year 6[8]	1	18.7	N/A	0	N/A	N/A	N/A	N/A	N/A
4DFR Baseline	70	17.2	7.1	104	18.8	8.4	1.6	1.2	0.27
4DFR Year 1	68	10.5	5.5	88	17.7	7.2	7.2	1.1	0.00
24 Hr Recall, Post-baseline	3	13.3	4.2	9	13.3	7.3	0.0	4.5	0.82
24 Hr Recall, Year 1	6	9.5	2.6	4	10.1	4.2	0.6	2.1	0.87
24 Hr Recall, Year 2	5	13.4	14.4	7	14.7	7.6	1.3	6.3	0.48
24 Hr Recall, Year 3	1	23.7	N/A	2	20.1	15.5	3.6	N/A	N/A
24 Hr Recall, Year 3 Cohort	27	11.1	6.0	46	16.8	8.1	5.7	1.8	0.00
24 Hr Recall, Year 4	0	N/A	N/A	1	10.9	N/A	N/A	N/A	N/A
Polyunsaturated Fat (g)									
FFQ Baseline	431	15.6	7.4	674	15.7	7.8	0.1	0.5	0.55
FFQ Year 1	407	9.1	5.0	628	13.6	7.2	4.5	0.4	0.00
FFQ Year 2	146	9.9	5.5	213	13.2	8.1	3.3	0.8	0.00
FFQ Year 3	49	9.5	5.5	68	11.7	6.0	2.2	1.1	0.06
FFQ Year 4	25	8.9	4.5	47	12.9	6.1	4.0	1.4	0.03
FFQ Year 5	7	7.4	1.8	8	11.9	4.1	4.5	1.7	0.02
FFQ Year 6	1	15.8	N/A	0	N/A	N/A	N/A	N/A	N/A
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
24 Hr Recall, Post-baseline	3	9.7	4.9	9	15.2	8.9	5.5	5.5	0.31
24 Hr Recall, Year 1	6	9.0	3.4	4	8.3	3.6	0.7	2.2	0.79
24 Hr Recall, Year 2	5	11.8	14.4	7	11.0	5.3	0.8	5.8	0.44
24 Hr Recall, Year 3	1	11.0	N/A	2	25.7	9.1	14.7	N/A	N/A
24 Hr Recall, Year 3 Cohort	27	9.2	5.4	46	12.7	6.7	3.5	1.5	0.01
24 Hr Recall, Year 4	0	N/A	N/A	1	7.4	N/A	N/A	N/A	N/A
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	405	4.7	2.4	628	3.5	1.9	1.2	0.1	0.00
FFQ Year 2	145	4.8	2.7	213	3.4	1.9	1.4	0.2	0.00
FFQ Year 3	54	4.7	2.3	70	3.4	2.0	1.3	0.4	0.00
FFQ Year 4	29	5.0	2.6	50	3.4	2.2	1.6	0.5	0.02
FFQ Year 5	8	4.1	2.2	8	4.9	2.6	0.8	1.2	0.50
FFQ Year 6	2	7.0	0.9	0	N/A	N/A	N/A	N/A	N/A
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	429	5.0	2.6	674	4.8	2.3	0.2	0.1	0.42
FFQ Year 1	405	5.8	2.7	628	4.5	2.1	1.3	0.1	0.00
FFQ Year 2	145	5.4	2.7	213	4.3	2.4	1.1	0.3	0.00
FFQ Year 3	54	4.8	2.0	70	4.1	2.4	0.7	0.4	0.04
FFQ Year 4	29	5.0	2.1	50	4.1	2.0	0.9	0.5	0.07
FFQ Year 5	8	3.7	1.6	8	5.4	2.7	1.7	1.1	0.11
FFQ Year 6	2	9.0	1.9	0	N/A	N/A	N/A	N/A	N/A

[1] Absolute difference.

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

[3] 98 (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] 7 (14%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 3.

[6] 4 (16%) Asian/Pacific Islander Intervention women had <=20% energy from fat at year 4.

[7] 1 (14%) 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: August 27, 2000

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFO Baseline	2135	39.7	5.3	3127	39.9	5.2	0.2	0.1	0.41
FFQ Year 1[3]	1859	28.0	8.4	2622	36.9	7.4	8.9	0.2	0.00
FFQ Year 2[4]	601	29.5	8.0	816	36.4	7.4	6.9	0.4	0.00
FFQ Year 3[5]	201	29.3	7.9	297	37.6	7.3	8.3	0.7	0.00
FFQ Year 4[6]	119	30.3	7.9	191	37.6	7.6	7.3	0.9	0.00
FFQ Year 5[7]	58	29.9	7.6	77	35.7	7.1	5.8	1.3	0.00
FFQ Year 6[8]	20	28.2	9.3	24	35.7	5.5	7.5	2.3	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	10.7	0.7	0.00
24 Hr Recall, Post-baseline	27	23.9	9.5	27	31.0	7.8	7.1	2.4	0.00
24 Hr Recall, Year 1	18	22.9	6.7	21	30.3	5.7	7.4	2.0	0.00
24 Hr Recall, Year 2	17	27.3	11.3	24	32.7	9.2	5.4	3.2	0.10
24 Hr Recall, Year 3	17	27.4	8.8	17	34.9	8.2	7.5	2.9	0.01
24 Hr Recall, Year 3 Cohort	141	25.4	8.1	215	33.7	7.8	8.3	0.9	0.00
24 Hr Recall, Year 4	6	25.9	7.8	7	36.4	10.2	10.5	5.1	0.06
Total Energy (kcal)									
FFO Baseline	2135	1745	828	3127	1739	835	6	23.4	0.70
FFQ Year 1	1859	1383	633	2622	1491	770	108	21.7	0.00
FFQ Year 2	601	1392	719	816	1446	727	54	38.9	0.43
FFQ Year 3	201	1402	671	297	1586	855	184	71.8	0.02
FFQ Year 4	119	1294	574	191	1546	952	252	96.7	0.01
FFQ Year 5	58	1328	467	77	1340	690	12	105.1	0.63
FFQ Year 6	20	1306	996	24	1410	629	104	247.0	0.29
4DFR Baseline	243	1704	526	371	1651	478	53	41.1	0.31
4DFR Year 1	219	1346	342	307	1585	482	239	38.0	0.00
24 Hr Recall, Post-baseline	27	1403	528	27	1570	434	167	131.5	0.11
24 Hr Recall, Year 1	18	1402	379	21	1481	400	79	125.4	0.58
24 Hr Recall, Year 2	17	1338	413	24	1462	568	124	161.7	0.95
24 Hr Recall, Year 3	17	1295	366	17	1498	541	203	158.4	0.36
24 Hr Recall, Year 3 Cohort	141	1412	390	215	1469	440	57	45.6	0.29
24 Hr Recall, Year 4	6	998	367	7	1621	608	623	285.2	0.07
Total Fat (g)									
FFO Baseline	2135	77.8	40.8	3127	77.8	41.3	0.0	1.2	0.90
FFQ Year 1	1859	43.6	26.8	2622	62.2	37.1	18.6	1.0	0.00
FFQ Year 2	601	46.5	32.7	816	60.0	36.2	13.5	1.9	0.00
FFQ Year 3	201	46.7	28.9	297	67.2	41.2	20.5	3.4	0.00
FFQ Year 4	119	43.7	24.0	191	65.6	44.1	21.9	4.4	0.00
FFQ Year 5	58	44.3	20.7	77	54.1	32.7	9.8	4.9	0.08
FFQ Year 6	20	41.8	41.9	24	57.1	29.9	15.3	10.8	0.02
4DFR Baseline	243	65.1	25.7	371	63.9	26.3	1.2	2.2	0.54
4DFR Year 1	219	34.9	14.7	307	61.5	25.7	26.6	1.9	0.00
24 Hr Recall, Post-baseline	27	37.7	22.9	27	54.9	20.6	17.2	5.9	0.00
24 Hr Recall, Year 1	18	35.6	15.5	21	51.4	18.9	15.8	5.6	0.01
24 Hr Recall, Year 2	17	43.0	26.9	24	55.2	29.5	12.2	9.0	0.32
24 Hr Recall, Year 3	17	40.3	19.2	17	58.0	21.8	17.7	7.0	0.03
24 Hr Recall, Year 3 Cohort	141	40.2	18.2	215	56.8	24.5	16.6	2.4	0.00
24 Hr Recall, Year 4	6	26.5	6.0	7	66.6	35.0	40.1	14.6	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] 26 (13%) Black/African American Intervention women had <=20% energy from fat at year 3

[6] 12 (10%) Black/African American Intervention women had <=20% energy from fat at year 4.

[7] 5 (9%) Black/African American Intervention women had <=20% energy from fat at year 5.

[8] 4 (20%) 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: August 27, 2000

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFO Baseline	2135	25.8	14.3	3127	25.9	14.7	0.1	0.4	0.89
FFQ Year 1[3]	1859	14.3	9.2	2622	20.4	12.7	6.1	0.3	0.00
FFQ Year 2[4]	601	15.3	11.9	816	19.7	12.4	4.4	0.7	0.00
FFQ Year 3[5]	201	15.3	10.1	297	22.1	14.2	6.8	1.2	0.00
FFQ Year 4[6]	119	14.1	8.1	191	21.5	15.2	7.4	1.5	0.00
FFQ Year 5[7]	58	14.1	7.0	77	18.0	10.6	3.9	1.6	0.03
FFQ Year 6[8]	20	13.3	13.0	24	19.0	10.9	5.7	3.6	0.02
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
24 Hr Recall, Post-baseline	27	11.3	7.2	27	18.5	9.3	7.2	2.3	0.00
24 Hr Recall, Year 1	18	11.0	6.1	21	14.2	5.1	3.2	1.8	0.04
24 Hr Recall, Year 2	17	13.1	9.4	24	17.4	10.4	4.3	3.2	0.31
24 Hr Recall, Year 3	17	12.7	6.7	17	19.7	8.9	7.0	2.7	0.02
24 Hr Recall, Year 3 Cohort	141	12.0	6.0	215	17.9	8.2	5.9	0.8	0.00
24 Hr Recall, Year 4	6	7.3	2.8	7	17.0	4.3	9.7	2.1	0.00
Polyunsaturated Fat (g)									
FFO Baseline	2135	16.0	8.9	3127	16.0	8.9	0.0	0.2	0.96
FFQ Year 1	1859	8.7	5.6	2622	12.7	7.9	4.0	0.2	0.00
FFQ Year 2	601	9.2	6.2	816	12.1	7.5	2.9	0.4	0.00
FFQ Year 3	201	9.5	6.2	297	13.6	8.3	4.1	0.7	0.00
FFQ Year 4	119	8.9	5.2	191	13.6	9.4	4.7	0.9	0.00
FFQ Year 5	58	9.0	4.5	77	11.1	7.9	2.1	1.2	0.17
FFQ Year 6	20	8.9	11.3	24	11.8	6.2	2.9	2.7	0.01
4DFR Baseline	243	14.5	6.7	371	13.8	6.7	0.7	0.6	0.15
4DFR Year 1	219	7.6	3.2	307	13.7	6.9	6.1	0.5	0.00
24 Hr Recall, Post-baseline	27	8.6	5.5	27	10.9	4.9	2.3	1.4	0.03
24 Hr Recall, Year 1	18	7.2	3.2	21	12.4	5.4	5.2	1.5	0.00
24 Hr Recall, Year 2	17	9.3	4.5	24	12.0	9.8	2.7	2.6	0.60
24 Hr Recall, Year 3	17	8.3	4.2	17	10.9	5.6	2.6	1.7	0.20
24 Hr Recall, Year 3 Cohort	141	9.1	5.0	215	12.1	6.6	3.0	0.7	0.00
24 Hr Recall, Year 4	6	6.2	2.3	7	15.3	11.1	9.1	4.6	0.08
Fruits and Vegetables (servings)									
FFO Baseline	2132	3.3	1.9	3123	3.2	1.9	0.1	0.1	0.72
FFQ Year 1	1853	4.5	2.6	2616	3.4	2.1	1.1	0.1	0.00
FFQ Year 2	600	4.5	2.5	813	3.5	2.2	1.0	0.1	0.00
FFQ Year 3	217	4.8	2.7	318	3.8	2.4	1.0	0.2	0.00
FFQ Year 4	143	4.9	2.8	219	3.5	2.3	1.4	0.3	0.00
FFQ Year 5	61	4.9	2.9	91	3.9	2.4	1.0	0.4	0.01
FFQ Year 6	28	5.4	3.2	30	3.5	1.6	1.9	0.7	0.23
Grain Servings (Not including desserts/pastries)									
FFO Baseline	2132	4.5	2.8	3122	4.4	2.8	0.1	0.1	0.30
FFQ Year 1	1852	4.4	2.8	2614	3.8	2.5	0.6	0.1	0.00
FFQ Year 2	600	4.2	2.6	812	3.7	2.4	0.5	0.1	0.00
FFQ Year 3	217	4.3	3.0	318	3.9	2.7	0.4	0.2	0.08
FFQ Year 4	143	3.6	2.1	219	3.8	3.0	0.2	0.3	0.86
FFQ Year 5	61	3.8	1.9	91	3.3	2.1	0.5	0.3	0.08
FFQ Year 6	28	4.0	3.3	30	3.4	1.9	0.6	0.7	0.62

[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] 26 (13%) Black/African American Intervention women had <=20% energy from fat at year 3

[6] 12 (10%) Black/African American Intervention women had <=20% energy from fat at year 4.

[7] 5 (9%) Black/African American Intervention women had <=20% energy from fat at year 5.

[8] 4 (20%) 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: August 27, 2000

	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	0.3	0.2	0.13
FFQ Year 1[3]	617	27.9	8.0	916	36.1	7.4	8.2	0.4	0.00
FFQ Year 2[4]	224	27.6	8.3	304	36.9	7.5	9.3	0.7	0.00
FFQ Year 3[5]	72	29.3	9.1	109	37.0	7.1	7.7	1.2	0.00
FFQ Year 4[6]	43	30.3	8.3	73	35.8	7.2	5.5	1.5	0.00
FFQ Year 5[7]	12	27.4	7.0	19	37.2	5.8	9.8	2.3	0.00
FFQ Year 6[8]	11	26.0	9.4	11	35.3	6.1	9.3	3.4	0.01
4DFR Baseline	96	32.4	5.7	135	32.4	6.5	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
24 Hr Recall, Post-baseline	9	28.9	14.9	6	29.9	4.7	1.0	6.3	0.88
24 Hr Recall, Year 1	8	22.9	5.3	6	33.5	11.1	10.6	4.4	0.03
24 Hr Recall, Year 2	6	25.2	10.4	5	23.5	7.5	1.7	5.6	0.77
24 Hr Recall, Year 3	2	30.7	14.2	2	33.4	4.4	2.7	10.5	0.82
24 Hr Recall, Year 3 Cohort	52	25.7	8.2	55	32.4	8.1	6.7	1.6	0.00
24 Hr Recall, Year 4	0	N/A	N/A	1	34.8	N/A	N/A	N/A	N/A
Total Energy (kcal)									
FFQ Baseline	751	1847	836	1095	1859	870	12	40.6	0.87
FFQ Year 1	617	1419	665	916	1573	866	154	41.2	0.00
FFQ Year 2	224	1416	616	304	1618	768	202	62.3	0.00
FFQ Year 3	72	1576	674	109	1549	763	27	110.7	0.67
FFQ Year 4	43	1403	640	73	1605	841	202	148.6	0.21
FFQ Year 5	12	1669	868	19	1411	519	258	248.2	0.39
FFQ Year 6	11	996	363	11	1503	881	507	287.3	0.29
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
24 Hr Recall, Post-baseline	9	1466	367	6	1799	473	333	216.6	0.15
24 Hr Recall, Year 1	8	1597	512	6	1538	312	59	237.6	0.93
24 Hr Recall, Year 2	6	1437	476	5	1698	937	261	435.0	0.71
24 Hr Recall, Year 3	2	1416	98	2	1099	82	317	90.4	0.07
24 Hr Recall, Year 3 Cohort	52	1395	371	55	1603	456	208	80.6	0.01
24 Hr Recall, Year 4	0	N/A	N/A	1	1109	N/A	N/A	N/A	N/A
Total Fat (g)									
FFQ Baseline	751	81.6	41.0	1095	80.8	40.5	0.8	1.9	0.57
FFQ Year 1	617	44.5	27.2	916	64.5	41.5	20.0	1.9	0.00
FFQ Year 2	224	43.8	24.4	304	67.9	38.5	24.1	2.9	0.00
FFQ Year 3	72	53.0	33.5	109	64.6	36.5	11.6	5.4	0.01
FFQ Year 4	43	46.4	24.2	73	64.7	36.7	18.3	6.3	0.01
FFQ Year 5	12	55.5	44.3	19	58.8	24.5	3.3	12.3	0.32
FFQ Year 6	11	27.7	13.5	11	59.2	37.7	31.5	12.1	0.03
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	24.6	22.8	3.2	0.00
24 Hr Recall, Post-baseline	9	46.2	27.0	6	58.9	17.8	12.7	12.6	0.18
24 Hr Recall, Year 1	8	41.0	15.3	6	58.3	22.3	17.3	10.0	0.21
24 Hr Recall, Year 2	6	40.3	19.4	5	47.2	35.8	6.9	16.9	0.84
24 Hr Recall, Year 3	2	47.5	19.1	2	42.7	12.1	4.8	16.0	0.83
24 Hr Recall, Year 3 Cohort	52	39.9	16.2	55	58.5	22.7	18.6	3.8	0.00
24 Hr Recall, Year 4	0	N/A	N/A	1	45.3	N/A	N/A	N/A	N/A

[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] 46 (21%) Hispanic/Latino Intervention women had <=20% energy from fat at year 2.

[5] 10 (14%) Hispanic/Latino Intervention women had <=20% energy from fat at year 3

[6] 4 (9%) Hispanic/Latino Intervention women had <=20% energy from fat at year 4.

[7] 2 (17%) Hispanic/Latino Intervention women had <=20% energy from fat at year 5.

[8] 3 (27%) 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: August 27, 2000

	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	27.6	15.1	0.2	0.7	0.65
FFQ Year 1[3]	617	15.0	9.8	916	21.7	14.4	6.7	0.7	0.00
FFQ Year 2[4]	224	14.4	8.4	304	23.0	14.2	8.6	1.1	0.00
FFQ Year 3[5]	72	17.4	11.8	109	21.4	12.8	4.0	1.9	0.01
FFQ Year 4[6]	43	14.7	8.7	73	21.1	12.9	6.4	2.2	0.01
FFQ Year 5[7]	12	17.8	13.3	19	19.3	7.6	1.5	3.7	0.27
FFQ Year 6[8]	11	8.4	4.0	11	20.5	15.5	12.1	4.8	0.03
4DFR Baseline	96	19.8	7.6	135	21.1	10.2	1.3	1.2	0.51
4DFR Year 1	82	11.5	6.7	111	19.5	8.9	8.0	1.2	0.00
24 Hr Recall, Post-baseline	9	15.4	9.1	6	22.9	6.2	7.5	4.3	0.07
24 Hr Recall, Year 1	8	13.1	7.1	6	16.4	6.6	3.3	3.7	0.34
24 Hr Recall, Year 2	6	12.8	7.3	5	14.0	7.3	1.2	4.4	0.76
24 Hr Recall, Year 3	2	21.3	7.4	2	16.0	6.5	5.3	7.0	0.52
24 Hr Recall, Year 3 Cohort	52	12.1	5.7	55	19.2	8.5	7.1	1.4	0.00
24 Hr Recall, Year 4	0	N/A	N/A	1	12.4	N/A	N/A	N/A	N/A
Polyunsaturated Fat (g)									
FFQ Baseline	751	15.9	8.4	1095	15.7	8.1	0.2	0.4	0.49
FFQ Year 1	617	8.6	5.5	916	12.8	8.6	4.2	0.4	0.00
FFQ Year 2	224	8.7	5.4	304	13.4	8.2	4.7	0.6	0.00
FFQ Year 3	72	10.7	7.3	109	12.5	7.7	1.8	1.1	0.05
FFQ Year 4	43	9.6	5.7	73	13.4	7.9	3.8	1.4	0.01
FFQ Year 5	12	11.6	10.2	19	12.4	6.4	0.8	3.0	0.33
FFQ Year 6	11	6.3	4.1	11	11.4	6.1	5.1	2.2	0.04
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
24 Hr Recall, Post-baseline	9	9.8	5.6	6	9.4	4.1	0.4	2.7	0.99
24 Hr Recall, Year 1	8	8.7	2.4	6	14.9	7.8	6.2	2.9	0.10
24 Hr Recall, Year 2	6	7.0	2.2	5	6.7	2.7	0.3	1.5	0.82
24 Hr Recall, Year 3	2	6.5	4.4	2	8.5	1.9	2.0	3.4	0.56
24 Hr Recall, Year 3 Cohort	52	8.8	3.8	55	12.1	6.4	3.3	1.0	0.00
24 Hr Recall, Year 4	0	N/A	N/A	1	13.1	N/A	N/A	N/A	N/A
Fruits and Vegetables (servings)									
FFQ Baseline	748	3.0	1.9	1095	2.9	1.8	0.1	0.1	0.28
FFQ Year 1	614	4.2	2.3	916	3.1	1.9	1.1	0.1	0.00
FFQ Year 2	222	4.4	2.4	304	3.2	1.7	1.2	0.2	0.00
FFQ Year 3	87	4.9	3.0	117	3.4	2.1	1.5	0.4	0.00
FFQ Year 4	48	5.0	2.7	84	3.5	2.6	1.5	0.5	0.00
FFQ Year 5	12	5.3	1.9	20	3.0	2.2	2.3	0.8	0.00
FFQ Year 6	14	5.6	2.7	16	2.6	2.1	3.0	0.9	0.01
Grain Servings (Not including desserts/pastries)									
FFQ Baseline	748	5.5	3.3	1095	5.7	3.5	0.2	0.2	0.54
FFQ Year 1	614	5.1	3.3	916	4.8	3.4	0.3	0.2	0.07
FFQ Year 2	222	5.0	3.5	304	4.9	3.1	0.1	0.3	0.65
FFQ Year 3	87	5.2	3.1	117	4.6	2.7	0.6	0.4	0.20
FFQ Year 4	48	4.7	3.3	84	4.9	2.9	0.2	0.6	0.47
FFQ Year 5	12	5.5	3.7	20	4.2	2.2	1.3	1.0	0.52
FFQ Year 6	14	3.5	1.6	16	5.4	4.0	1.9	1.1	0.29

[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] 46 (21%) Hispanic/Latino Intervention women had <=20% energy from fat at year 2.

[5] 10 (14%) Hispanic/Latino Intervention women had <=20% energy from fat at year 3

[6] 4 (9%) Hispanic/Latino Intervention women had <=20% energy from fat at year 4.

[7] 2 (17%) Hispanic/Latino Intervention women had <=20% energy from fat at year 5.

[8] 3 (27%) 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: August 27, 2000

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFO 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	8.2	0.7	0.00
FFQ Year 2[4]	78	26.8	7.4	121	37.3	7.0	10.5	1.0	0.00
FFQ Year 3[5]	23	27.6	7.8	36	38.3	8.0	10.7	2.1	0.00
FFQ Year 4[6]	20	28.5	8.0	27	37.4	7.1	8.9	2.2	0.00
FFQ Year 5[7]	1	24.2	N/A	10	35.5	9.3	11.3	N/A	N/A
FFQ Year 6[8]	3	30.7	4.9	6	34.1	5.5	3.4	3.8	0.39
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
24 Hr Recall, Post-baseline	1	18.9	N/A	1	27.6	N/A	8.7	N/A	N/A
24 Hr Recall, Year 1	3	22.9	8.8	9	33.0	5.3	10.1	4.1	0.03
24 Hr Recall, Year 2	3	32.3	13.0	1	8.3	N/A	24.0	N/A	N/A
24 Hr Recall, Year 3	2	29.8	13.5	1	36.1	N/A	6.3	N/A	N/A
24 Hr Recall, Year 3 Cohort	11	25.0	9.2	20	33.3	9.0	8.3	3.4	0.02
24 Hr Recall, Year 4	2	16.8	8.8	0	N/A	N/A	N/A	N/A	N/A
Total Energy (kcal)									
FFO Baseline	265	1796	775	393	1725	770	71	61.4	0.22
FFQ Year 1	240	1506	628	353	1500	639	6	53.1	0.64
FFQ Year 2	78	1430	503	121	1577	688	147	90.4	0.23
FFQ Year 3	23	1405	585	36	1532	775	127	188.9	0.52
FFQ Year 4	20	1346	562	27	1488	523	142	159.3	0.27
FFQ Year 5	1	1439	N/A	10	1164	529	275	N/A	N/A
FFQ Year 6	3	1944	309	6	1379	385	565	258.0	0.08
4DFR Baseline	17	1504	288	28	1665	381	161	107.4	0.16
4DFR Year 1	13	1334	469	23	1531	338	197	135.1	0.10
24 Hr Recall, Post-baseline	1	1683	N/A	1	1749	N/A	66	N/A	N/A
24 Hr Recall, Year 1	3	1833	119	9	1643	466	190	280.1	0.46
24 Hr Recall, Year 2	3	1860	920	1	1532	N/A	328	N/A	N/A
24 Hr Recall, Year 3	2	1907	842	1	2006	N/A	99	N/A	N/A
24 Hr Recall, Year 3 Cohort	11	1197	292	20	1496	486	299	161.1	0.11
24 Hr Recall, Year 4	2	1984	265	0	N/A	N/A	N/A	N/A	N/A
Total Fat (g)									
FFO Baseline	265	79.0	39.4	393	75.9	38.5	3.1	3.1	0.30
FFQ Year 1	240	46.7	28.0	353	60.7	31.6	14.0	2.5	0.00
FFQ Year 2	78	42.5	19.5	121	66.8	35.6	24.3	4.4	0.00
FFQ Year 3	23	41.4	16.5	36	65.6	38.5	24.2	8.5	0.00
FFQ Year 4	20	41.0	17.7	27	63.5	28.8	22.5	7.3	0.00
FFQ Year 5	1	38.7	N/A	10	48.2	29.9	9.5	N/A	N/A
FFQ Year 6	3	67.3	21.6	6	54.0	23.1	13.3	16.0	0.38
4DFR Baseline	17	54.4	16.8	28	60.8	16.8	6.4	5.2	0.23
4DFR Year 1	13	33.7	19.1	23	58.3	17.6	24.6	6.3	0.00
24 Hr Recall, Post-baseline	1	35.3	N/A	1	53.9	N/A	18.6	N/A	N/A
24 Hr Recall, Year 1	3	46.0	16.2	9	59.8	19.6	13.8	12.6	0.29
24 Hr Recall, Year 2	3	69.7	49.0	1	14.2	N/A	55.5	N/A	N/A
24 Hr Recall, Year 3	2	56.9	0.5	1	81.1	N/A	24.2	N/A	N/A
24 Hr Recall, Year 3 Cohort	11	31.5	8.8	20	58.5	30.0	27.0	9.3	0.01
24 Hr Recall, Year 4	2	38.3	24.3	0	N/A	N/A	N/A	N/A	N/A

[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 (21%) Other/Unspecified Intervention women had <=20% energy from fat at year 2.

[5] 4 (17%) Other/Unspecified Intervention women had <=20% energy from fat at year 3

[6] 3 (15%) Other/Unspecified Intervention women had <=20% energy from fat at year 4.

[7] 0 (0%) 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: August 27, 2000

	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	15.4	9.4	353	20.9	11.7	5.5	0.9	0.00
FFQ Year 2[4]	78	14.4	7.5	121	23.1	12.7	8.7	1.6	0.00
FFQ Year 3[5]	23	14.2	6.8	36	21.7	14.4	7.5	3.2	0.01
FFQ Year 4[6]	20	13.4	6.4	27	22.7	11.1	9.3	2.8	0.00
FFQ Year 5[7]	1	13.6	N/A	10	17.7	11.9	4.1	N/A	N/A
FFQ Year 6[8]	3	18.9	4.8	6	19.4	9.7	0.5	6.1	0.86
4DFR Baseline	17	17.6	6.7	28	20.6	7.0	3.0	2.1	0.12
4DFR Year 1	13	11.3	8.7	23	19.0	5.8	7.7	2.4	0.00
24 Hr Recall, Post-baseline	1	11.8	N/A	1	18.2	N/A	6.4	N/A	N/A
24 Hr Recall, Year 1	3	19.4	7.6	9	20.2	8.7	0.8	5.7	0.97
24 Hr Recall, Year 2	3	22.8	19.3	1	3.8	N/A	19.0	N/A	N/A
24 Hr Recall, Year 3	2	18.2	5.6	1	30.5	N/A	12.3	N/A	N/A
24 Hr Recall, Year 3 Cohort	11	9.6	4.6	20	18.7	10.4	9.1	3.3	0.01
24 Hr Recall, Year 4	2	15.4	14.1	0	N/A	N/A	N/A	N/A	N/A
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	9.0	6.0	353	11.9	6.8	2.9	0.5	0.00
FFQ Year 2	78	7.9	3.7	121	13.0	8.1	5.1	1.0	0.00
FFQ Year 3	23	7.8	3.0	36	13.8	8.7	6.0	1.9	0.00
FFQ Year 4	20	8.1	3.4	27	11.9	5.7	3.8	1.4	0.02
FFQ Year 5	1	7.8	N/A	10	8.6	5.3	0.8	N/A	N/A
FFQ Year 6	3	17.6	6.3	6	9.7	3.7	7.9	3.2	0.08
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	5.3	1.4	0.00
24 Hr Recall, Post-baseline	1	4.8	N/A	1	8.3	N/A	3.5	N/A	N/A
24 Hr Recall, Year 1	3	7.5	3.9	9	11.5	3.6	4.0	2.4	0.10
24 Hr Recall, Year 2	3	18.5	14.4	1	4.1	N/A	14.4	N/A	N/A
24 Hr Recall, Year 3	2	11.0	6.0	1	18.3	N/A	7.3	N/A	N/A
24 Hr Recall, Year 3 Cohort	11	7.4	3.0	20	12.1	6.2	4.7	2.0	0.08
24 Hr Recall, Year 4	2	7.9	0.6	0	N/A	N/A	N/A	N/A	N/A
Fruits and Vegetables (servings)									
FFQ Baseline	264	3.7	2.0	392	3.4	2.0	0.3	0.2	0.04
FFQ Year 1	239	4.9	2.4	352	3.6	2.0	1.3	0.2	0.00
FFQ Year 2	77	5.0	2.3	121	3.9	2.3	1.1	0.3	0.00
FFQ Year 3	27	4.4	2.0	37	3.7	2.0	0.7	0.5	0.13
FFQ Year 4	19	5.7	3.5	32	4.2	2.1	1.5	0.8	0.47
FFQ Year 5	2	4.3	3.0	11	3.2	1.2	1.1	1.1	0.58
FFQ Year 6	2	8.2	1.5	6	3.4	0.9	4.8	0.8	0.01
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	0.8	0.2	0.00
FFQ Year 2	77	4.6	2.4	121	4.3	2.4	0.3	0.3	0.41
FFQ Year 3	27	4.6	3.0	37	4.4	2.7	0.2	0.7	0.68
FFQ Year 4	19	4.4	2.4	32	3.9	1.9	0.5	0.6	0.46
FFQ Year 5	2	3.3	1.8	11	2.3	1.3	1.0	1.0	0.30
FFQ Year 6	2	7.6	2.5	6	3.5	1.8	4.1	1.6	0.05

[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 (21%) Other/Unspecified Intervention women had <=20% energy from fat at year 2.

[5] 4 (17%) Other/Unspecified Intervention women had <=20% energy from fat at year 3

[6] 3 (15%) Other/Unspecified Intervention women had <=20% energy from fat at year 4.

[7] 0 (0%) 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 FFQ's Collected in the Last Year[1]

Data as of: August 27, 2000

	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			24.7%				24.7%				24.7%	
Age												
60-69	6246				6246				6246			
50-54 vs. 60-69	1669	1.17 **			1669	1.18 **			1669	1.41 **		
55-59 vs. 60-69	2913	0.64			2913	0.62			2913	0.67 *		
70-79 vs. 60-69	2176	-0.78 *			2176	-0.59			2176	-0.63		
Ethnicity												
White	10845				10845				10845			
Black vs. White	1212	-0.41			1212	-0.42			1212	-0.09		
Hispanic vs. White	453	-0.01			453	0.25			453	0.30		
Other Minority vs. White	494	-0.78			494	-0.59			494	-0.87		
Education												
Post H.S.	10244				10244				10244			
0-8 Years vs. Post H.S.	140	-0.41			140	-0.13			140	-0.21		
Some H.S. or Diploma vs. Post H.S.	2620	0.64			2620	0.67 *			2620	0.53		
Family Income												
≥75K	2299				2299				2299			
<20K vs. ≥75K	2291	-0.76			2291	-0.55			2291	-0.30		
20-35K vs. ≥75K	3003	-0.10			3003	0.01			3003	0.16		
35-50K vs. ≥75K	2703	-0.26			2703	-0.06			2703	-0.07		
50-75K vs. ≥75K	2708	0.00			2708	0.17			2708	0.17		
HRT Randomized												
No	10964				10964				10964			
Yes vs. No	2040	0.65			2040	0.76 *			2040	0.66		
Visit			25.3%	(0.6%)			25.3%	(0.6%)			25.3%	(0.6%)
Visit Year												
AV-2	2657				2657				2657			
AV-3 vs. AV-2	3316	-1.58 **			3316	-2.59 **			3316	-1.98 **		
AV-4 vs. AV-2	3682	-1.66 **			3682	-2.81 **			3682	-2.27 **		
AV-5 vs. AV-2	2011	-2.13 **			2011	-3.29 **			2011	-2.64 **		
AV-6 vs. AV-2	1338	-1.75 **			1338	-3.03 **			1338	-2.47 **		
Clinic Effect			30.6%	(5.2%)			30.6%	(5.2%)			30.6%	(5.2%)
Intervention Participation												
# Sessions Attended in Previous 12 Months			34.0%	(3.5%)								
None	9144											
1 vs. None	761	4.22 **										
2 vs. None	1036	5.51 **										
3 vs. None	1175	6.60 **										
4+ vs. None	888	7.38 **										
# Sessions Completed in Previous 12 Months							34.6%	(4.0%)				
None					8690							
1 vs. None					380	2.74 **						
2 vs. None					608	5.51 **						
3 vs. None					1059	6.42 **						
4+ vs. None					2267	8.65 **						
# Fat Scores Provided in Previous 12 Months											35.4%	(4.8%)
None									9189			
1 vs. None									577	3.88 **		
2 vs. None									689	5.30 **		
3 vs. None									926	6.92 **		
4+ vs. None									1623	8.47 **		

[1] Model adjusted for clinic effects.

** P-value < 0.01 from a two-sided test.

* P-value < 0.05 from a two-sided test.

Table 3.6
Body Weight

Data as of: August 27, 2000

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	16.5	-0.1	0.2	0.36
Year 1	18119	74.4	16.8	26661	76.3	16.8	1.9	0.2	0.00
Year 2	16639	75.4	17.2	24954	76.7	16.9	1.3	0.2	0.00
Year 3	13307	75.6	17.1	20209	76.7	16.8	1.1	0.2	0.00
Year 4	7693	76.0	17.0	11774	76.6	16.5	0.6	0.2	0.01
Year 5	3433	75.7	16.5	5288	76.2	16.3	0.5	0.4	0.21
Year 6	1036	74.8	15.7	1572	75.3	15.2	0.5	0.6	0.43
Participants Aged 70-79									
Baseline	3246	73.0	14.7	4870	72.9	14.5	-0.1	0.3	0.82
Year 1	3005	70.7	15.2	4483	72.7	15.4	2.0	0.4	0.00
Year 2	2774	71.1	15.1	4154	72.6	15.3	1.5	0.4	0.00
Year 3	2044	70.7	15.2	3132	71.9	14.7	1.2	0.4	0.01
Year 4	1018	70.4	14.3	1555	71.0	14.2	0.6	0.6	0.28
Year 5	440	69.8	14.7	696	71.4	14.8	1.6	0.9	0.09
Year 6	109	69.6	14.3	178	70.5	15.1	0.9	1.8	0.61
Participants with Revised Fat Gram Goals[3]									
Baseline	15845	77.0	17.0	23739	77.0	16.9	0.0	0.2	0.79
Year 1	14663	74.6	17.1	21593	76.6	17.1	2.0	0.2	0.00
Year 2	13377	75.5	17.4	20112	77.0	17.2	1.5	0.2	0.00
Year 3	10106	75.7	17.4	15379	76.9	17.0	1.2	0.2	0.00
Year 4	4623	76.1	17.1	7073	77.0	16.8	0.9	0.3	0.01
Year 5	513	75.5	17.3	715	76.7	16.7	1.2	1.0	0.20

[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

Data as of: August 27, 2000

Body Weight (kg)[1]	Intervention			Control			Difference		
	N	Mean	S.D.	N	Mean	S.D.	Mean[2]	S.E.	p-value
American Indian/Alaskan Native Participants									
Baseline	87	77.8	14.4	115	80.8	16.9	3.0	2.3	0.19
Year 1	74	75.6	15.0	94	81.1	16.8	5.5	2.5	0.03
Year 2	66	76.9	18.7	91	83.5	18.1	6.6	3.0	0.03
Year 3	61	75.7	15.7	73	83.7	17.9	8.0	2.9	0.01
Year 4	40	76.8	15.2	46	87.1	19.3	10.3	3.8	0.01
Year 5	16	80.0	18.6	18	80.5	18.9	0.5	6.4	0.93
Year 6	5	72.5	10.6	1	63.4	N/A	-9.1	N/A	N/A
Asian/Pacific Islander Participants									
Baseline	431	63.4	13.2	674	63.4	14.4	0.0	0.9	0.94
Year 1	414	62.5	14.7	636	62.8	12.9	0.3	0.9	0.77
Year 2	391	62.7	14.1	615	63.0	12.4	0.3	0.8	0.70
Year 3	290	62.7	13.3	464	64.1	15.3	1.4	1.1	0.22
Year 4	130	62.2	11.7	229	62.4	11.4	0.2	1.3	0.86
Year 5	31	61.8	10.8	44	62.9	10.6	1.1	2.5	0.68
Year 6	9	62.6	6.4	7	60.7	9.7	-1.9	4.0	0.64
Black/African American Participants									
Baseline	2133	85.3	18.2	3126	85.1	18.5	-0.2	0.5	0.79
Year 1	1891	84.3	19.3	2661	84.9	19.0	0.6	0.6	0.27
Year 2	1701	84.8	18.8	2484	85.2	19.0	0.4	0.6	0.50
Year 3	1328	85.3	19.8	1968	85.4	18.6	0.1	0.7	0.90
Year 4	758	85.0	19.0	1152	85.3	18.1	0.3	0.9	0.69
Year 5	315	84.0	18.3	446	84.9	17.8	0.9	1.3	0.48
Year 6	59	84.8	19.1	85	81.3	16.5	-3.5	3.0	0.24
Hispanic/Latino Participants									
Baseline	750	75.2	16.0	1095	73.7	15.2	-1.5	0.7	0.05
Year 1	636	74.2	16.7	934	73.2	15.5	-1.0	0.8	0.23
Year 2	569	74.4	16.1	862	74.0	16.1	-0.4	0.9	0.70
Year 3	430	75.1	16.3	690	74.7	16.1	-0.4	1.0	0.66
Year 4	234	76.8	18.4	362	74.2	14.2	-2.6	1.3	0.06
Year 5	77	74.3	15.8	130	70.2	12.1	-4.1	2.0	0.04
Year 6	23	77.6	15.0	40	69.3	12.2	-8.3	3.5	0.02
Other/Unspecified Participants									
Baseline	265	78.3	18.4	393	76.4	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	204	76.3	18.7	323	77.3	18.6	1.0	1.7	0.56
Year 3	142	76.2	17.7	236	76.9	18.3	0.7	1.9	0.71
Year 4	73	77.1	17.7	117	76.4	16.8	-0.7	2.6	0.77
Year 5	24	80.8	16.9	45	75.6	16.6	-5.2	4.2	0.22
Year 6	8	84.8	19.7	17	76.9	15.4	-7.9	7.2	0.28

[1] Shown for 30 <= weight (kg) <= 220

[2] Control - Intervention

Table 3.7
Blood Specimen Analysis: DM Participants

Data as of: August 27, 2000

	N	Mean[1]	S.D.[1]
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	2396	0.08	0.06
AV-1	2398	0.08	0.06
AV-1 – Baseline	2393	0.00	0.05
Alpha-tocopherol (µg/ml)			
Baseline	2396	16.19	5.65
AV-1	2398	16.95	6.11
AV-1 – Baseline	2393	0.75	4.49
Beta-Carotene (µg/ml)			
Baseline	2396	0.30	0.22
AV-1	2398	0.31	0.23
AV-1 – Baseline	2393	0.01	0.17
Beta-Cryptoxanthine (µg/ml)			
Baseline	2396	0.09	0.05
AV-1	2397	0.09	0.06
AV-1 – Baseline	2392	0.00	0.04
Gamma-tocopherol (µg/ml)			
Baseline	2396	2.20	1.19
AV-1	2397	1.84	1.07
AV-1 – Baseline	2392	-0.36	0.76
Lycopene (µg/ml)			
Baseline	2396	0.41	0.16
AV-1	2398	0.41	0.15
AV-1 – Baseline	2393	-0.01	0.13
Lutein and Zeaxanthin (µg/ml)			
Baseline	2396	0.22	0.09
AV-1	2398	0.22	0.08
AV-1 – Baseline	2393	0.00	0.05
Retinol (µg/ml)			
Baseline	2396	0.61	0.12
AV-1	2398	0.62	0.12
AV-1 – Baseline	2393	0.00	0.08

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

Table 3.7 (Continued)
Blood Specimen Analysis: DM Participants

Data as of: August 27, 2000

	N	Mean[1]	S.D.[1]
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	2323	130.86	27.15
AV-1	2304	130.70	27.23
AV-1 - Baseline	2248	-0.25	18.64
Factor VII C (%)			
Baseline	2280	129.48	25.30
AV-1	2273	127.07	25.18
AV-1 - Baseline	2184	-2.83	18.68
Fibrinogen (mg/dl)			
Baseline	2317	300.17	49.22
AV-1	2298	297.80	48.30
AV-1 - Baseline	2237	-2.32	40.65
Hormones/Other			
Glucose (mg/dl)	2396	100.21	20.94
Baseline	2390	98.94	19.95
AV-1	2385	-1.26	14.76
AV-1 - Baseline			
Insulin (μIU/ml)	2344	11.51	5.72
Baseline	2338	11.23	8.53
AV-1	2290	-0.29	7.35
AV-1 - Baseline			

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

Table 3.7 (Continued)
Blood Specimen Analysis: DM Participants

Data as of: August 27, 2000

	N	Mean[1]	S.D.[1]
Lipoproteins			
HDL-2 (mg/dl)			
Baseline	2335	18.74	6.88
AV-1	2353	19.03	6.95
AV-1 - Baseline	2299	0.30	4.11
HDL-3 (mg/dl)			
Baseline	2337	41.00	7.57
AV-1	2354	40.48	7.16
AV-1 - Baseline	2302	-0.52	4.62
HDL-C (mg/dl)			
Baseline	2389	59.60	13.12
AV-1	2394	59.46	12.75
AV-1 - Baseline	2384	-0.10	7.33
LDL-C (mg/dl)			
Baseline	2352	133.63	28.39
AV-1	2354	126.71	27.69
AV-1 - Baseline	2328	-6.81	19.60
Lp(a) (mg/dl)			
Baseline	2364	25.72	21.77
AV-1	2365	25.13	21.52
AV-1 - Baseline	2335	-0.57	8.18
Total Cholesterol (mg/dl)			
Baseline	2395	224.27	31.03
AV-1	2396	217.74	30.60
AV-1 - Baseline	2391	-6.58	22.17
Triglyceride (mg/dl)			
Baseline	2395	156.02	72.12
AV-1	2396	158.55	72.93
AV-1 - Baseline	2391	2.34	46.56

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

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

Data as of: August 27, 2000

	N	Mean	S.D.
Whole Body Scan			
Baseline	3622	1.03	0.11
AV1	3270	1.03	0.11
AV3	3014	1.04	0.11
AV6	413	1.05	0.12
AV1 % Change from baseline BMD[2]	3243	0.18	2.49
AV3 % Change from baseline BMD[3]	2991	1.34	3.61
AV6 % Change from baseline BMD[4]	412	2.22	4.72
Spine Scan			
Baseline	3545	0.99	0.17
AV1	3205	1.00	0.17
AV3	2958	1.01	0.17
AV6	424	1.00	0.17
AV1 % Change from baseline BMD	3182	0.72	3.84
AV3 % Change from baseline BMD	2937	2.14	5.24
AV6 % Change from baseline BMD	422	2.99	6.31
Hip Scan			
Baseline	3620	0.87	0.14
AV1	3268	0.87	0.14
AV3	3015	0.88	0.14
AV6	437	0.88	0.14
AV1 % Change from baseline BMD	3250	-0.05	2.77
AV3 % Change from baseline BMD	3000	1.03	4.18
AV6 % Change from baseline BMD	437	1.50	5.24

[1] Measured in (g/cm^2).

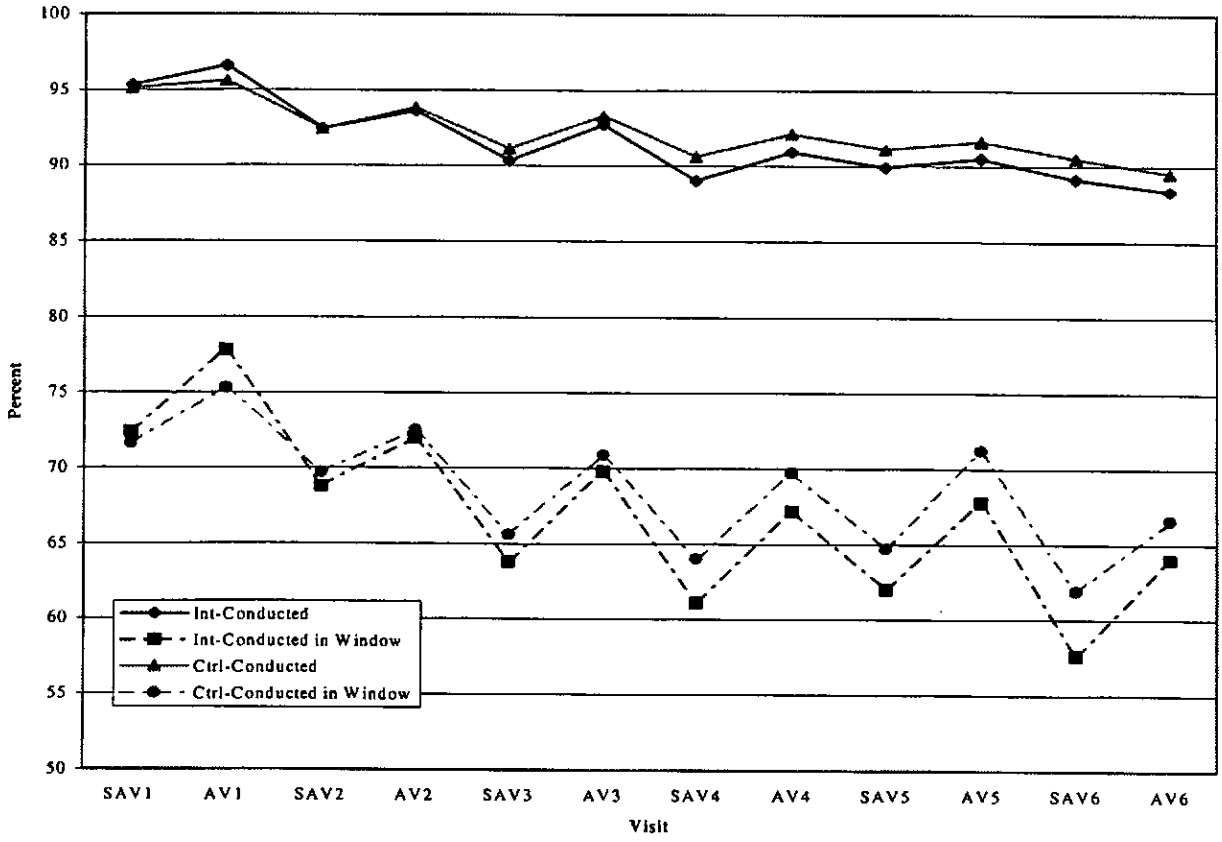
[2] AV1 % Change from baseline BMD is defined as ((AV1-Baseline)/Baseline)x100.

[3] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100.

[4] AV6 % Change from baseline BMD is defined as ((AV6-Baseline)/Baseline)x100.

Table 3.9
Adherence to Follow-up Contacts

Data as of: August 27, 2000



Contact		Due N	Conducted N	Conducted %	Conducted in window N	Conducted in window %
Semi-Annual Contact 1	Intervention	19542	18625	95.3%	14150	72.4%
	Control	29295	27860	95.1%	20986	71.6%
Annual Visit 1	Intervention	19542	18884	96.6%	15197	77.8%
	Control	29295	28014	95.6%	22052	75.3%
Semi-Annual Contact 2	Intervention	19542	18059	92.4%	13440	68.8%
	Control	29295	27067	92.4%	20422	69.7%
Annual Visit 2	Intervention	19538	18292	93.6%	14058	72.0%
	Control	29290	27462	93.8%	21232	72.5%
Semi-Annual Contact 3	Intervention	18067	16323	90.3%	11528	63.8%
	Control	27106	24704	91.1%	17779	65.6%
Annual Visit 3	Intervention	15586	14453	92.7%	10881	69.8%
	Control	23384	21828	93.3%	16590	70.9%
Semi-Annual Contact 4	Intervention	12640	11252	89.0%	7727	61.1%
	Control	18933	17145	90.6%	12114	64.0%
Annual Visit 4	Intervention	9420	8567	90.9%	6332	67.2%
	Control	14155	13035	92.1%	9860	69.7%
Semi-Annual Contact 5	Intervention	6579	5914	89.9%	4080	62.0%
	Control	9832	8955	91.1%	6363	64.7%
Annual Visit 5	Intervention	4334	3922	90.5%	2939	67.8%
	Control	6469	5925	91.6%	4603	71.2%
Semi-Annual Visit 6	Intervention	2667	2377	89.1%	1537	57.6%
	Control	3977	3601	90.5%	2462	61.9%
Annual Visit 6	Intervention	1304	1152	88.3%	834	64.0%
	Control	1975	1768	89.5%	1316	66.6%

Table 3.10
Lost-to-Follow-up and Vital Status: DM Participants

Data as of: August 27, 2000

	DM Participants (N = 48837)	
	N	%
Vital Status/Participation		
Deceased	651	1.3
Alive: Current Participation[1]	45618	93.4
Alive: Recent Participation[2]	1061	2.2
Alive: Past/Unknown Participation[3]	42	0.1
Stopped Follow-Up[4]	770	1.6
Lost to Follow-Up[5]	695	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 3.11
Locally Verified Outcomes (Annualized Percentages) by Age for Dietary Modification

Data as of: August 27, 2000

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	48837	6961	11044	22714	8118
Mean follow-up (months)	44.8	51.1	47.0	42.6	42.4
Cancer					
Breast cancer[1]	773 (0.42%)	87 (0.29%)	182 (0.42%)	354 (0.44%)	150 (0.52%)
Invasive breast cancer	602 (0.33%)	58 (0.20%)	143 (0.33%)	282 (0.35%)	119 (0.41%)
Non-invasive breast cancer	179 (0.10%)	29 (0.10%)	41 (0.09%)	77 (0.10%)	32 (0.11%)
Ovary cancer	79 (0.04%)	14 (0.05%)	16 (0.04%)	31 (0.04%)	18 (0.06%)
Endometrial Cancer[2]	114 (0.11%)	16 (0.10%)	26 (0.10%)	48 (0.11%)	24 (0.15%)
Colorectal cancer	212 (0.12%)	13 (0.04%)	37 (0.09%)	111 (0.14%)	51 (0.18%)
Other cancer[3,4]	770 (0.42%)	67 (0.23%)	130 (0.30%)	385 (0.48%)	188 (0.66%)
Total cancer	1906 (1.05%)	192 (0.65%)	379 (0.88%)	909 (1.13%)	426 (1.48%)
Cardiovascular					
CHD[5]	518 (0.28%)	32 (0.11%)	57 (0.13%)	257 (0.32%)	172 (0.60%)
Coronary death	140 (0.08%)	6 (0.02%)	10 (0.02%)	69 (0.09%)	55 (0.19%)
Total MI[6]	409 (0.22%)	26 (0.09%)	50 (0.12%)	201 (0.25%)	132 (0.46%)
Clinical MI	394 (0.22%)	22 (0.07%)	50 (0.12%)	193 (0.24%)	129 (0.45%)
Definite Silent MI	22 (0.01%)	5 (0.02%)	1 (0.00%)	11 (0.01%)	5 (0.02%)
Possible Silent MI	79 (0.04%)	9 (0.03%)	17 (0.04%)	27 (0.03%)	26 (0.09%)
Angina	726 (0.40%)	48 (0.16%)	93 (0.21%)	373 (0.46%)	212 (0.74%)
CABG/PTCA	603 (0.33%)	32 (0.11%)	73 (0.17%)	311 (0.39%)	187 (0.65%)
Carotid artery disease	125 (0.07%)	5 (0.02%)	12 (0.03%)	59 (0.07%)	49 (0.17%)
Congestive heart failure	328 (0.18%)	18 (0.06%)	35 (0.08%)	149 (0.18%)	126 (0.44%)
Stroke	351 (0.19%)	15 (0.05%)	34 (0.08%)	159 (0.20%)	143 (0.50%)
PVD	89 (0.05%)	3 (0.01%)	9 (0.02%)	43 (0.05%)	34 (0.12%)
DVT	48 (0.03%)	2 (0.01%)	7 (0.02%)	24 (0.03%)	15 (0.05%)
PE	28 (0.02%)	0 (0.00%)	5 (0.01%)	13 (0.02%)	10 (0.03%)
CHD[5]/Possible Silent MI	584 (0.32%)	41 (0.14%)	70 (0.16%)	279 (0.35%)	194 (0.68%)
Coronary disease[7]	1457 (0.80%)	93 (0.31%)	176 (0.41%)	722 (0.89%)	466 (1.62%)
DVT/PE	62 (0.03%)	2 (0.01%)	8 (0.02%)	31 (0.04%)	21 (0.07%)
Total CVD	1939 (1.06%)	112 (0.38%)	226 (0.52%)	950 (1.18%)	651 (2.27%)
Fractures					
Hip fracture	147 (0.08%)	6 (0.02%)	13 (0.03%)	60 (0.07%)	68 (0.24%)
Vertebral fracture	161 (0.09%)	8 (0.03%)	15 (0.03%)	69 (0.09%)	69 (0.24%)
Other fracture[3,8]	2259 (1.24%)	287 (0.97%)	452 (1.04%)	1070 (1.33%)	450 (1.57%)
Total fracture	2501 (1.37%)	298 (1.00%)	476 (1.10%)	1171 (1.45%)	556 (1.94%)
Deaths					
Cardiovascular deaths	184 (0.10%)	7 (0.02%)	15 (0.03%)	87 (0.11%)	75 (0.26%)
Cancer deaths	285 (0.16%)	21 (0.07%)	34 (0.08%)	145 (0.18%)	85 (0.30%)
Deaths: other known cause	67 (0.04%)	5 (0.02%)	10 (0.02%)	28 (0.03%)	24 (0.08%)
Deaths: unknown cause	27 (0.01%)	2 (0.01%)	1 (0.00%)	14 (0.02%)	10 (0.03%)
Deaths: not yet adjudicated	88 (0.05%)	5 (0.02%)	4 (0.01%)	40 (0.05%)	39 (0.14%)
Total death	651 (0.36%)	40 (0.13%)	64 (0.15%)	314 (0.39%)	233 (0.81%)

[1] Excludes five cases with borderline malignancy.

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

[3] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated.

[4] Excludes non-melanoma skin cancer

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

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

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

[8] "Other fracture" excludes fractures indicated as pathological.

Table 3.12
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Dietary Modification

Data as of: August 27, 2000

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)	44.5	40.8	43.3	42.5	45.3	40.8
Cancer						
Breast cancer[1]	2 (0.27%)	15 (0.40%)	44 (0.23%)	20 (0.31%)	687 (0.46%)	5 (0.22%)
Invasive breast cancer	2 (0.27%)	13 (0.35%)	32 (0.17%)	15 (0.23%)	538 (0.36%)	2 (0.09%)
Non-invasive breast cancer	0 (0.00%)	2 (0.05%)	12 (0.06%)	5 (0.08%)	157 (0.10%)	3 (0.13%)
Ovary cancer	1 (0.13%)	0 (0.00%)	8 (0.04%)	1 (0.02%)	69 (0.05%)	0 (0.00%)
Endometrial Cancer[2]	0 (0.00%)	1 (0.04%)	9 (0.11%)	6 (0.17%)	96 (0.11%)	2 (0.16%)
Colorectal cancer	2 (0.27%)	3 (0.08%)	26 (0.14%)	10 (0.15%)	167 (0.11%)	4 (0.18%)
Other cancer[3,4]	2 (0.27%)	7 (0.19%)	56 (0.30%)	16 (0.24%)	680 (0.45%)	9 (0.40%)
Total cancer	7 (0.93%)	26 (0.69%)	140 (0.74%)	51 (0.78%)	1663 (1.11%)	19 (0.85%)
Cardiovascular						
CHD[5]	1 (0.13%)	1 (0.03%)	52 (0.27%)	5 (0.08%)	453 (0.30%)	6 (0.27%)
Coronary death	1 (0.13%)	0 (0.00%)	16 (0.08%)	1 (0.02%)	119 (0.08%)	3 (0.13%)
Total MI[6]	0 (0.00%)	1 (0.03%)	41 (0.22%)	4 (0.06%)	358 (0.24%)	5 (0.22%)
Clinical MI	0 (0.00%)	1 (0.03%)	37 (0.20%)	4 (0.06%)	348 (0.23%)	4 (0.18%)
Definite Silent MI	0 (0.00%)	0 (0.00%)	4 (0.02%)	0 (0.00%)	17 (0.01%)	1 (0.04%)
Possible Silent MI	0 (0.00%)	2 (0.05%)	9 (0.05%)	2 (0.03%)	66 (0.04%)	0 (0.00%)
Angina	2 (0.27%)	9 (0.24%)	99 (0.52%)	15 (0.23%)	592 (0.39%)	9 (0.40%)
CABG/PTCA	0 (0.00%)	5 (0.13%)	61 (0.32%)	8 (0.12%)	526 (0.35%)	3 (0.13%)
Carotid artery disease	2 (0.27%)	2 (0.05%)	11 (0.06%)	1 (0.02%)	107 (0.07%)	2 (0.09%)
Congestive heart failure	0 (0.00%)	0 (0.00%)	57 (0.30%)	3 (0.05%)	264 (0.18%)	4 (0.18%)
Stroke	2 (0.27%)	7 (0.19%)	42 (0.22%)	8 (0.12%)	287 (0.19%)	5 (0.22%)
PVD	1 (0.13%)	0 (0.00%)	18 (0.09%)	1 (0.02%)	69 (0.05%)	0 (0.00%)
DVT	0 (0.00%)	0 (0.00%)	5 (0.03%)	0 (0.00%)	43 (0.03%)	0 (0.00%)
PE	0 (0.00%)	0 (0.00%)	3 (0.02%)	0 (0.00%)	25 (0.02%)	0 (0.00%)
CHD[5]/Possible Silent MI	1 (0.13%)	3 (0.08%)	61 (0.32%)	7 (0.11%)	506 (0.34%)	6 (0.27%)
Coronary disease[7]	3 (0.40%)	12 (0.32%)	194 (1.02%)	22 (0.34%)	1208 (0.81%)	18 (0.81%)
DVT/PE	0 (0.00%)	0 (0.00%)	6 (0.03%)	0 (0.00%)	56 (0.04%)	0 (0.00%)
Total CVD	7 (0.93%)	20 (0.53%)	242 (1.28%)	31 (0.47%)	1616 (1.08%)	23 (1.03%)
Fractures						
Hip fracture	0 (0.00%)	0 (0.00%)	6 (0.03%)	1 (0.02%)	138 (0.09%)	2 (0.09%)
Vertebral fracture	0 (0.00%)	4 (0.11%)	1 (0.01%)	4 (0.06%)	151 (0.10%)	1 (0.04%)
Other fracture[3,8]	9 (1.19%)	35 (0.93%)	117 (0.62%)	50 (0.76%)	2026 (1.35%)	22 (0.98%)
Total fracture	9 (1.19%)	39 (1.04%)	123 (0.65%)	54 (0.83%)	2251 (1.50%)	25 (1.12%)
Deaths						
Cardiovascular deaths	1 (0.13%)	1 (0.03%)	21 (0.11%)	1 (0.02%)	157 (0.10%)	3 (0.13%)
Cancer deaths	1 (0.13%)	1 (0.03%)	26 (0.14%)	6 (0.09%)	249 (0.17%)	2 (0.09%)
Deaths: other known cause	3 (0.40%)	0 (0.00%)	8 (0.04%)	2 (0.03%)	53 (0.04%)	1 (0.04%)
Deaths: unknown cause	0 (0.00%)	0 (0.00%)	5 (0.03%)	1 (0.02%)	21 (0.01%)	0 (0.00%)
Deaths: not yet adjudicated	0 (0.00%)	2 (0.05%)	10 (0.05%)	1 (0.02%)	74 (0.05%)	1 (0.04%)
Total death	5 (0.66%)	4 (0.11%)	70 (0.37%)	11 (0.17%)	554 (0.37%)	7 (0.31%)

[1] Excludes five cases with borderline malignancy.

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

[3] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated.

[4] Excludes non-melanoma skin cancer

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

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

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

[8] "Other fracture" excludes fractures indicated as pathological.

Table 3.13
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for Dietary Modification

Data as of: August 27, 2000

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	48837		6961		11044		22714		8118	
Mean follow-up (months)	44.8		51.1		47.0		42.6		42.4	
Hospitalizations										
Ever	13358	(7.33%)	1471	(4.96%)	2519	(5.82%)	6368	(7.89%)	3000	(10.46%)
Two or more	5120	(2.81%)	494	(1.67%)	866	(2.00%)	2415	(2.99%)	1345	(4.69%)
Other										
DVT[1]	279	(0.15%)	24	(0.08%)	49	(0.11%)	127	(0.16%)	79	(0.28%)
PE	138	(0.08%)	9	(0.03%)	25	(0.06%)	62	(0.08%)	42	(0.15%)
Diabetes (treated)	3167	(1.74%)	356	(1.20%)	682	(1.58%)	1527	(1.89%)	602	(2.10%)
Gallbladder disease[2]	2188	(1.20%)	331	(1.12%)	517	(1.19%)	1011	(1.25%)	329	(1.15%)
Hysterectomy[3]	849	(0.82%)	132	(0.79%)	195	(0.74%)	373	(0.83%)	149	(0.96%)
Glaucoma	2590	(1.42%)	236	(0.80%)	448	(1.04%)	1277	(1.58%)	629	(2.19%)
Osteoporosis	5376	(2.95%)	481	(1.62%)	916	(2.12%)	2655	(3.29%)	1324	(4.61%)
Osteoarthritis[4]	8704	(2.69%)	892	(3.33%)	1690	(4.23%)	4227	(5.60%)	1895	(7.04%)
Rheumatoid arthritis	1744	(0.96%)	238	(0.80%)	390	(0.90%)	799	(0.99%)	317	(1.10%)
Intestinal polyps	3609	(1.98%)	408	(1.38%)	742	(1.71%)	1771	(2.19%)	688	(2.40%)
Lupus	285	(0.16%)	44	(0.15%)	67	(0.15%)	141	(0.17%)	33	(0.12%)
Kidney Stones[4]	666	(0.51%)	87	(0.44%)	153	(0.51%)	320	(0.54%)	106	(0.50%)
Cataracts[4]	8270	(6.33%)	351	(1.78%)	1047	(3.47%)	4475	(7.52%)	2397	(11.35%)
Pills for hypertension	16155	(8.86%)	1739	(5.86%)	3189	(7.37%)	7766	(9.62%)	3461	(12.06%)

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)	44.5		40.8		43.3		42.5		45.3		40.8	
Hospitalizations												
Ever	51	(6.77%)	176	(4.69%)	1396	(7.36%)	415	(6.35%)	11168	(7.44%)	152	(6.80%)
Two or more	27	(3.58%)	54	(1.44%)	537	(2.83%)	128	(1.96%)	4326	(2.88%)	48	(2.15%)
Other												
DVT[1]	0	(0.00%)	1	(0.03%)	29	(0.15%)	3	(0.05%)	243	(0.16%)	3	(0.13%)
PE	0	(0.00%)	1	(0.03%)	10	(0.05%)	2	(0.03%)	121	(0.08%)	4	(0.18%)
Diabetes (treated)	26	(3.45%)	91	(2.42%)	779	(4.11%)	171	(2.62%)	2052	(1.37%)	48	(2.15%)
Gallbladder disease[2]	9	(1.19%)	34	(0.91%)	182	(0.96%)	103	(1.58%)	1825	(1.22%)	35	(1.57%)
Hysterectomy[3]	2	(0.56%)	19	(0.80%)	57	(0.68%)	32	(0.92%)	734	(0.84%)	5	(0.40%)
Glaucoma	14	(1.86%)	58	(1.54%)	428	(2.26%)	89	(1.36%)	1967	(1.31%)	34	(1.52%)
Osteoporosis	23	(3.05%)	118	(3.14%)	269	(1.42%)	217	(3.32%)	4667	(3.11%)	82	(3.67%)
Osteoarthritis[4]	50	(3.87%)	168	(2.44%)	1031	(3.10%)	379	(3.49%)	6938	(2.60%)	138	(3.46%)
Rheumatoid arthritis	18	(2.39%)	32	(0.85%)	337	(1.78%)	156	(2.39%)	1178	(0.79%)	23	(1.03%)
Intestinal polyps	18	(2.39%)	82	(2.18%)	401	(2.11%)	108	(1.65%)	2942	(1.96%)	58	(2.60%)
Lupus	5	(0.66%)	3	(0.08%)	42	(0.22%)	11	(0.17%)	219	(0.15%)	5	(0.22%)
Kidney Stones[4]	5	(0.93%)	15	(0.54%)	69	(0.51%)	34	(0.70%)	532	(0.50%)	11	(0.66%)
Cataracts[4]	39	(7.25%)	194	(6.97%)	843	(6.29%)	293	(6.05%)	6778	(6.31%)	123	(7.41%)
Pills for hypertension	70	(9.29%)	410	(10.92%)	2670	(14.08%)	594	(9.09%)	12186	(8.12%)	225	(10.07%)

[1] Inpatient DVT only.

[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

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

[4] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

4. CaD Component

4.1 Recruitment

Table 4.1 presents the number of women randomized in the Calcium and Vitamin D component of the WHI Clinical Trial as of August 27, 2000. A total of 36,282 women have been randomized which is 80.6% of the overall goal of 45,000. The age distribution of the CaD trial participants is somewhat younger than anticipated in the design assumptions for the trial. Thus far, 17% 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, CaD participants randomized at AV-1, and CaD participants randomized at AV-2, respectively. 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 held steady since the last report and is now about 55%-63% (adherence summary was 55%-60% in the last progress report). Note that the adherence summary for AV-1 randomized CaD participants is somewhat higher at AV-3 compared to participants randomized at AV-2 (60% vs. 52%), but this difference diminishes at AV-4 and reverses at AV-5. 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 and AV-5. 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 (26.6% vs. 28.5%).

Figure 4.1 shows the CaD adherence summary over six month periods from the present period ending in August 2000 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-3 whereas the adherence summary held steady at AV-4.

Table 4.5 summarizes the frequency of reported reasons for stopping CaD. The majority of women stopping study supplements do so of their own accord. Only 7.3% have indicated that they were advised by their physician to discontinue these supplements. 823 women (12.2%) reported health problems or symptoms not related to the intervention. Symptoms or health problems associated with the intervention (20%) was the most frequently reported intervention-related reason followed by not liking to take the pills (11.2%).

We also monitor the number of women who have begun alternative anti-osteoporosis therapies within the CaD trial. As of August 27, 2000, 1216 (3.4%) women were taking alendronate, 172 (0.5%) were taking calcitonin, and 328 (0.9%) were taking raloxifene.

4.3 Bone Mineral Density

Table 4.6 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 twice as large as those observed at AV-3 ranging from 2.5% at the hip to 3.2% at the whole body and spine.

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 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, 1.2% of the participants are lost-to-follow-up or have stopped follow-up, and 1.0% 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 CaD participants is about 2.6 years, suggesting that approximately 7.6% 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. Approximately 7% 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, we have only observed about 30% (71 cases) of the number of hip fractures that we expected in the power calculations to have observed with the current follow-up. The number of observed colorectal and breast cancer cases is approximately 80-90% of what was expected (111 cases). The number of CHD events is about 70% of what was expected (280 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 since the last report, 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 all clinical fractures is high under most scenarios, especially if moderate adherence is achieved.

4.7 Issues

We continue to direct efforts towards improving adherence to Calcium-Vitamin D study medication. On May 19th-20th, 2000 a workshop took place to address adherence and safety issues in the HRT and CaD trials. This workshop included training to enhance interpersonal skills (e.g., motivational interviewing skills) to re-motivate participants in both medication trials; instruction on the use of a new triaging system to improve participant adherence; practical management strategies to assist with adherence programs, such as use of WHILMA reports and symptom management in the CaD trial; discussion of safety issues related to CaD; relevant scientific updates; and use of available forms and data related to adherence and retention.

The BMD UCSF Coordinating Center was asked to investigate the positive changes in BMD being observed in the WHI program, especially in the Observational Study where no systematic intervention to improve BMD is taking place. Issues of quality assurance, calibration and potential drift were investigated with collaborative oversight by the CaD/Osteoporosis Advisory Committee and the CCC. These analyses did not indicate that systematic bias from any of these sources had occurred. To determine if BMD loss had taken place in selected subgroups of WHI-OS women at especially high risk for BMD loss, percent change in BMD was evaluated among women who had lost weight (> 5%), maintained a stable weight (+/- 5%) or gained weight (> 5%) excluding those who were taking anti-osteoporosis therapies. BMD loss was apparent among women who lost weight, as expected. Further analysis of factors associated with BMD gain among WHI-OS women is planned. No corrective action for the BMD measurements is recommended at this time.

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

Data as of: August 27, 2000

	Total Randomized	% of Overall Goal	Distribution	Design Assumption
Age	**36,282**			
50-54	5158	118%	14%	10
55-59	8265	94%	23%	20
60-69	16520	84%	46%	45
70-79	6339	58%	17%	25
Race/Ethnicity	**36,282**			
American Indian	149		<1%	
Asian	721		2%	
Black	3316		9%	
Hispanic	1502		4%	
White	30155		83%	
Other/Unspecified	439		1%	

Table 4.2
CaD Adherence Summary
All CaD Participants

Data as of: August 27, 2000

	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	33046	32201	97	26165	79	2087	6	4179	13	28839	87	4072	14	5784	20	18983	66	58
Annual Visit-2	33010	32200	98	25828	78	1432	4	2205	7	28056	93	2895	10	4819	17	20342	73	62
Annual Visit -3	28624	27598	96	21499	75	1880	7	2438	10	22946	90	2011	9	3960	17	16975	74	60
Annual Visit -4	16381	15550	95	11966	73	799	5	1193	9	12256	91	940	8	1931	16	9385	77	58
Annual Visit -5	7228	6815	94	5371	74	336	5	455	8	5172	92	356	7	768	15	4048	78	57
Annual Visit -6	1936	1789	92	1344	69	62	3	111	8	1367	93	97	7	184	14	1086	79	57

[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 4.2 (continued)
CaD Adherence Summary
Participants Randomized to CaD at Annual Visit 1 (AV-1)

Data as of: August 27, 2000

	Due	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	%	%
Annual Visit-2	32900	1432	4	2204	7	28049	93	2894	10	4818	17	20337	73	62
Annual Visit -3	25907	1552	6	2025	9	20796	91	1704	8	3463	17	15629	75	60
Annual Visit -4	14556	702	5	1059	9	10989	91	804	7	1712	16	8473	77	58
Annual Visit -5	5880	278	5	393	9	4207	92	281	7	634	15	3292	78	56
Annual Visit -6	798	26	3	62	11	520	89	45	9	69	13	406	78	51

[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 4.2 (continued)
CaD Adherence Summary
Participants Randomized to CaD at Annual Visit 2 (AV-2)

Data as of: August 27, 2000

	Due	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	%	%
Annual Visit -3	2465	318	13	404	16	2055	84	297	15	478	23	1280	62	52
Annual Visit -4	1645	97	6	129	9	1252	91	135	11	218	17	899	72	55
Annual Visit -5	1252	58	5	62	6	965	94	75	8	134	14	756	78	60
Annual Visit -6	1113	36	3	49	6	847	94	52	6	115	14	680	80	61

[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: August 27, 2000

	Total			
	Interval[1]		Cumulative[2]	
Drop-Outs[3]				
AV-2	10.4%	(8.8)	10.4%	(8.8)
AV-3	6.6%	(5.9)	16.3%	(14.2)
AV-4	4.9%	(5.9)	20.4%	(19.2)
AV-5	4.7%	(5.9)	24.2%	(24.0)
AV-6	3.2%	(5.9)	26.6%	(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: August 27, 2000

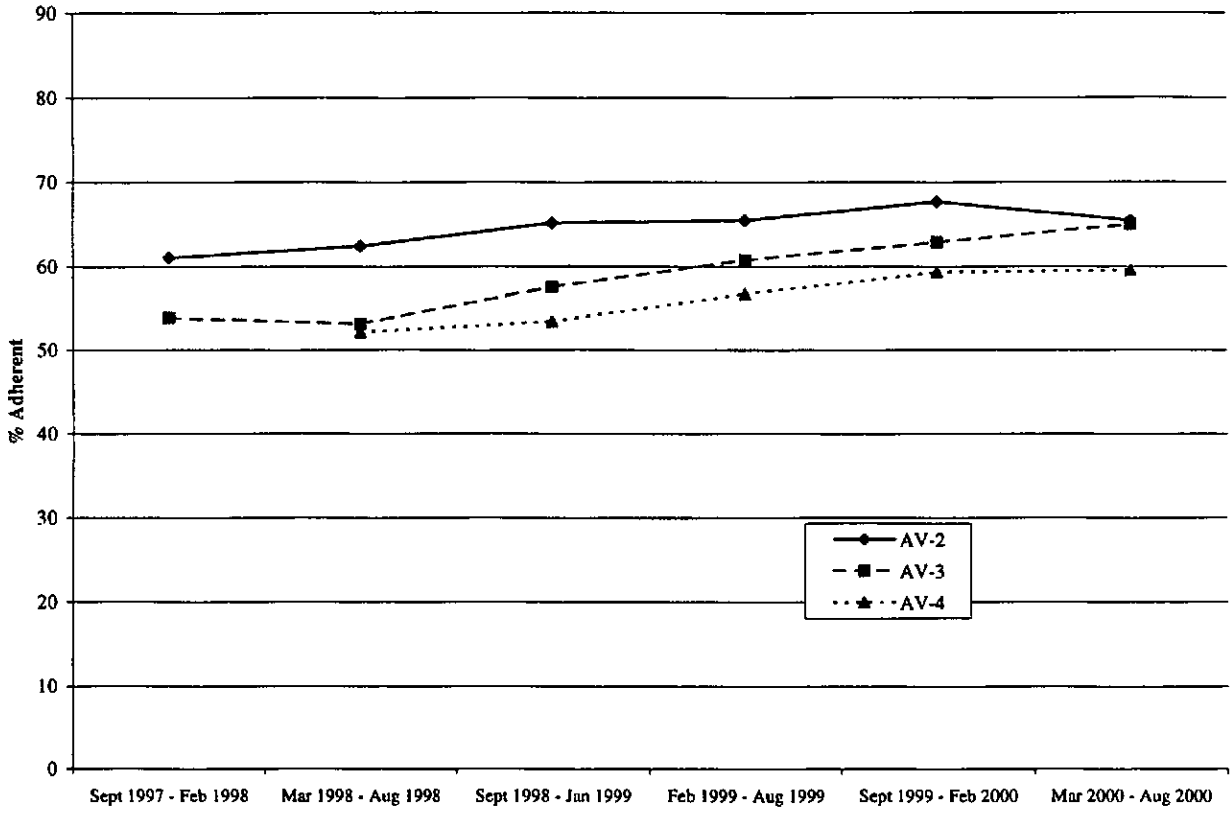


Table 4.5
Reasons for Stopping CaD

Data as of: August 27, 2000

Reasons[1]	(N = 6725)	
Personal		
Demands of work	146	(2.2%)
Death in family[2]	8	(0.1%)
Family illness, emergency or other family demands	215	(3.2%)
Caregiving responsibilities[2]	22	(0.3%)
Conflicting priorites	113	(1.7%)
Financial problems	6	(0.1%)
Lack of cooperation/support from family /friends	27	(0.4%)
Family/friends request withdraw[2]	4	(0.1%)
Living in nursing home	8	(0.1%)
Feels discouraged regarding participation overall[2]	8	(0.1%)
Loss of interest, boredom[2]	21	(0.3%)
Feels it is not an important study[2]	3	(<0.1%)
In another study in conflict with WHI[2]	0	(0.0%)
Travel		
Too far to CC	137	(2.0%)
Transportation problems	36	(0.5%)
Traffic	16	(0.2%)
Parking at CC	4	(0.1%)
CC neighborhood/safety	4	(0.1%)
Moved out of area[2]	18	(0.3%)
Visits and Procedures		
Doesn't like visits, calls	60	(0.9%)
Doesn't like having blood drawn	3	(<0.1%)
Doesn't like ECG	0	(0.0%)
Doesn't like mammograms[2]	1	(<0.1%)
Cost of mammograms[2]	0	(0.0%)
Doesn't like gynecologic procedures	4	(0.1%)
Doesn't like required safety forms and/or procedures	49	(0.7%)
Doesn't like filling out forms	16	(0.2%)
Doesn't like other procedures (non-safety)	14	(0.2%)
Worried about health effects of medical tests/procedures	28	(0.4%)
Wants results of blood analyses[2]	0	(0.0%)
Wants results of bone mineral density[2]	0	(0.0%)
Problem with CC	30	(0.5%)
Problem with CC staff person (other than DM Nutritionist)	7	(0.1%)
Staff change/turnover[2]	1	(<0.1%)

(continues)

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

[2] Version 3 only.

Table 4.5 (continued)
Reasons for Stopping CaD

Data as of: August 27, 2000

Reasons[1]	(N = 6725)	
Symptoms		
Vaginal bleeding	17	(0.3%)
Breast tenderness	14	(0.2%)
Other breast changes[2]	4	(0.1%)
Bloating/gas[2]	71	(1.1%)
Constipation[2]	91	(1.4%)
Other gastrointestinal problems[2]	84	(1.3%)
Headaches[2]	1	(<0.1%)
Vaginal changes[2]	3	(<0.1%)
Hair/skin changes[2]	2	(<0.1%)
Hot flashes/night sweats[2]	0	(0.0%)
Weight loss/gain[2]	4	(0.1%)
Low energy/too tired[2]	5	(0.1%)
Possible allergic reaction[2]	5	(0.1%)
Other symptoms [2]	55	(0.8%)
Health problems or symptoms not due to intervention[3]	823	(12.2%)
Health Conditions		
Breast cancer[2]	8	(0.1%)
Complex or atypical hyperplasia[2]	0	(0.0%)
Endometrial cancer[2]	0	(0.0%)
Deep vein thrombosis[2]	4	(0.1%)
Pulmonary embolism[2]	2	(<0.1%)
Gallbladder disease[2]	1	(<0.1%)
Hypercalcemia[2]	22	(0.3%)
Kidney failure/dialysis[2]	5	(0.1%)
Renal calculi[2]	36	(0.5%)
High triglycerides[2]	0	(0.0%)
Malignant melanoma[2]	0	(0.0%)
Meningioma[2]	1	(<0.1%)
Heart attack[2]	4	(0.1%)
Stroke[2]	14	(0.2%)
Arthritis[2]	1	(<0.1%)
Diabetes[2]	5	(0.1%)
Depresssion[2]	6	(0.1%)
Cholesterol[2]	0	(0.0%)
Osteoporosis[2]	22	(0.3%)
Loss of vision and/or hearing[2]	0	(0.0%)
Communication problem	17	(0.3%)
Cognitive/memory changes[2]	7	(0.1%)
Other health conditions[2]	105	(1.6%)
Other health problems or symptoms from the WHI intervention[3]	1345	(20.0%)
Intervention-General		
Doesn't like randomized nature of intervention	291	(4.3%)
Expected some benefit from intervention	47	(0.7%)
Feels guilty, unhappy or like a failure for not meeting study goals[2]	7	(0.1%)
Removed from intervention due to WHI symptom management[3]	60	(0.9%)
Removed from intervention due to adverse health event[3]	160	(2.4%)

(continues)

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

[2] Version 3 only.

[3] Version 1 & 2 only.

Table 4.5 (continued)
Reasons for Stopping CaD

Data as of: August 27, 2000

Reasons[1]	(N = 6725)	
HRT/CaD Intervention		
Doesn't like taking pills	754	(11.2%)
Doesn't like taste of pills[2]	18	(0.3%)
Unable to swallow pills[2]	22	(0.3%)
Takes too many pills[2]	68	(1.0%)
Has made a personal decision to go on active HRT[2]	2	(<0.1%)
Has made a personal decision that she doesn not want to be on HRT[2]	16	(0.2%)
Advised to go on active HRT by health care provider[2]	7	(0.1%)
Advised to not be on active HRT by health care provider[2]	10	(0.2%)
Has made a personal decision to go on SERM[2]	1	(<0.1%)
Advised to go on SERM by health care provider[2]	1	(<0.1%)
Wants to take her own calcium[2]	100	(1.5%)
Feels diet is already sufficient in calcium/Vit D[2]	15	(0.2%)
Taking more than the max allowable IU of Vit D[2]	11	(0.2%)
Taking Calcitriol[2]	2	(<0.1%)
Taking testosterone medications[2]	0	(0.0%)
DM Intervention		
Problem with DM Group Nutritionist or group members	5	(0.1%)
Doesn't like attending DM intervention classes[2]	0	(0.0%)
Doesn't like self-monitoring[2]	1	(<0.1%)
Doesn't like budgeting fat grams[2]	0	(0.0%)
Has concerns regarding long-term risks/benefits of low-fat diet[2]	0	(0.0%)
Unhappy that not losing weight[2]	1	(<0.1%)
Not in control of meal preparation[2]	0	(0.0%)
Too difficult to meet or maintain dietary goals[2]	0	(0.0%)
Doesn't like eating low fat diet[2]	0	(0.0%)
Doesn't like eating 5 veg/fruits per day[2]	0	(0.0%)
Doesn't like eating 6 grains per day[2]	1	(<0.1%)
Feels fat gram goal is unrealistic[2]	0	(0.0%)
Eating pattern conflicts with personal health[2]	2	(<0.1%)
Doesn't like DM requirements[3]	12	(0.2%)
Doesn't like DM eating pattern[3]	5	(0.1%)
Other Health Issues		
Worried about costs if adverse effects occur	11	(0.2%)
Expected more health care	17	(0.3%)
Advised not to participate by health care provider for other reason[2]	83	(1.2%)
Study conflicts with other health issues[2]	58	(0.9%)
Advised not to participate by health care provider[3]	490	(7.3%)
Study conflicts with health care needs[3]	373	(5.6%)
Other		
Other reason not listed above	1724	(25.6%)
Refuses to give a reason	112	(1.7%)

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

[2] Version 3 only.

[3] Version 1 & 2 only.

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

Data as of: August 27, 2000

	N	Mean	S.D.
Whole Body Scan			
AV1	2435	1.02	0.11
AV3	2145	1.03	0.11
AV6	290	1.05	0.12
AV3 % Change from AV1 BMD[2]	2071	1.43	3.36
AV6 % Change from AV1 BMD[3]	284	3.19	4.47
Spine Scan			
AV1	2369	0.99	0.17
AV3	2111	1.01	0.17
AV6	301	1.01	0.16
AV3 % Change from AV1 BMD[2]	2039	1.57	4.29
AV6 % Change from AV1 BMD[3]	293	3.18	5.68
Hip Scan			
AV1	2427	0.86	0.14
AV3	2153	0.88	0.14
AV6	309	0.87	0.14
AV3 % Change from AV1 BMD[2]	2082	1.30	3.56
AV6 % Change from AV1 BMD[3]	303	2.48	5.09

[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: August 27, 2000

	CaD Participants (N=36282)	
	N	%
Vital Status/Participation		
Deceased	357	1.0
Alive: Current Participation[1]	34889	96.2
Alive: Recent Participation[2]	567	1.6
Alive: Past/Unknown Participation[3]	22	0.1
Stopped Follow-Up[4]	223	0.6
Lost to Follow-Up[5]	224	0.6

[1] Participants who have filled in a Form 33 within the last 9 months.
[2] Participants who last filled in a Form 33 between 9 and 18 months ago.
[3] 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: August 27, 2000

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number of participants	36282	5125	8232	16353	6282
Mean follow-up (months)	31.6	37.3	33.5	29.9	29.2
Fractures					
Hip fracture	71 (0.07%)	3 (0.02%)	7 (0.03%)	26 (0.06%)	35 (0.23%)
Vertebral fracture	85 (0.09%)	3 (0.02%)	9 (0.04%)	35 (0.09%)	38 (0.25%)
Other fracture[1,4]	1238 (1.30%)	167 (1.05%)	257 (1.12%)	571 (1.40%)	243 (1.59%)
Total fracture	1358 (1.42%)	172 (1.08%)	271 (1.18%)	618 (1.52%)	297 (1.94%)
Cancer					
Colorectal cancer	111 (0.12%)	8 (0.05%)	22 (0.10%)	49 (0.12%)	32 (0.21%)
Breast cancer[2]	399 (0.42%)	51 (0.32%)	98 (0.43%)	176 (0.43%)	74 (0.48%)
Invasive breast cancer	310 (0.32%)	39 (0.25%)	76 (0.33%)	138 (0.34%)	57 (0.37%)
Non-invasive breast cancer	90 (0.09%)	12 (0.08%)	22 (0.10%)	39 (0.10%)	17 (0.11%)
Ovary cancer	38 (0.04%)	6 (0.04%)	9 (0.04%)	14 (0.03%)	9 (0.06%)
Endometrial Cancer[3]	59 (0.11%)	9 (0.10%)	14 (0.10%)	28 (0.12%)	8 (0.09%)
Other cancer[4,5]	400 (0.42%)	35 (0.22%)	76 (0.33%)	186 (0.46%)	103 (0.67%)
Total cancer	991 (1.04%)	109 (0.68%)	214 (0.93%)	445 (1.09%)	223 (1.46%)
Cardiovascular					
CHD[6]	280 (0.29%)	21 (0.13%)	29 (0.13%)	137 (0.34%)	93 (0.61%)
Coronary death	79 (0.08%)	5 (0.03%)	8 (0.03%)	38 (0.09%)	28 (0.18%)
Total MI[7]	219 (0.23%)	17 (0.11%)	21 (0.09%)	108 (0.27%)	73 (0.48%)
Clinical MI	206 (0.22%)	14 (0.09%)	21 (0.09%)	101 (0.25%)	70 (0.46%)
Silent MI	19 (0.02%)	4 (0.03%)	0 (0.00%)	10 (0.02%)	5 (0.03%)
Possible Silent MI	68 (0.07%)	9 (0.06%)	16 (0.07%)	20 (0.05%)	23 (0.15%)
Angina	379 (0.40%)	25 (0.16%)	47 (0.20%)	181 (0.44%)	126 (0.82%)
CABG/PTCA	315 (0.33%)	19 (0.12%)	33 (0.14%)	149 (0.37%)	114 (0.75%)
Carotid artery disease	66 (0.07%)	2 (0.01%)	5 (0.02%)	29 (0.07%)	30 (0.20%)
Congestive heart failure	194 (0.20%)	7 (0.04%)	26 (0.11%)	87 (0.21%)	74 (0.48%)
Stroke	179 (0.19%)	6 (0.04%)	24 (0.10%)	75 (0.18%)	74 (0.48%)
PVD	49 (0.05%)	2 (0.01%)	4 (0.02%)	20 (0.05%)	23 (0.15%)
CHD[6]/Possible Silent MI	343 (0.36%)	30 (0.19%)	44 (0.19%)	157 (0.39%)	112 (0.73%)
Coronary disease[8]	818 (0.86%)	53 (0.33%)	107 (0.47%)	377 (0.93%)	281 (1.84%)
Total CVD	1103 (1.15%)	65 (0.41%)	143 (0.62%)	515 (1.26%)	380 (2.49%)
Deaths					
Cardiovascular deaths	100 (0.10%)	6 (0.04%)	9 (0.04%)	45 (0.11%)	40 (0.26%)
Cancer deaths	145 (0.15%)	10 (0.06%)	20 (0.09%)	65 (0.16%)	50 (0.33%)
Deaths: other known cause	32 (0.03%)	2 (0.01%)	6 (0.03%)	14 (0.03%)	10 (0.07%)
Deaths: unknown cause	15 (0.02%)	1 (0.01%)	1 (0.00%)	5 (0.01%)	8 (0.05%)
Deaths: not yet adjudicated	65 (0.07%)	4 (0.03%)	5 (0.02%)	27 (0.07%)	29 (0.19%)
Total death	357 (0.37%)	23 (0.14%)	41 (0.18%)	156 (0.38%)	137 (0.90%)

[1] "Other fracture" excludes 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] 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.

[5] Excludes non-melanoma skin cancer

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

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

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

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

Data as of: August 27, 2000

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		30155		439	
Mean follow-up (months)	31.5		28.1		30.6		30.6		32.0		28.0	
Fractures												
Hip fracture	0	(0.00%)	1	(0.06%)	1	(0.01%)	1	(0.03%)	68	(0.08%)	0	(0.00%)
Vertebral fracture	0	(0.00%)	2	(0.12%)	0	(0.00%)	3	(0.08%)	79	(0.10%)	1	(0.10%)
Other fracture[1,4]	6	(1.53%)	16	(0.95%)	60	(0.71%)	32	(0.84%)	1117	(1.39%)	7	(0.68%)
Total fracture	6	(1.53%)	18	(1.07%)	61	(0.72%)	36	(0.94%)	1229	(1.53%)	8	(0.78%)
Cancer												
Colorectal cancer	2	(0.51%)	1	(0.06%)	11	(0.13%)	6	(0.16%)	90	(0.11%)	1	(0.10%)
Breast cancer[2]	1	(0.26%)	7	(0.42%)	19	(0,23%)	12	(0.31%)	360	(0.45%)	0	(0.00%)
Invasive breast cancer	1	(0.26%)	7	(0.42%)	15	(0.18%)	10	(0.26%)	277	(0.35%)	0	(0.00%)
Non-invasive breast cancer	0	(0.00%)	0	(0.00%)	4	(0.05%)	2	(0.05%)	84	(0.10%)	0	(0.00%)
Ovary cancer	0	(0.00%)	0	(0.00%)	4	(0.05%)	0	(0.00%)	34	(0.04%)	0	(0.00%)
Endometrial Cancer[3]	1	(0.62%)	0	(0.00%)	2	(0.06%)	1	(0.05%)	54	(0.11%)	1	(0.17%)
Other cancer[4,5]	2	(0.51%)	6	(0.36%)	23	(0.27%)	7	(0.18%)	358	(0.45%)	4	(0.39%)
Total cancer	6	(1.53%)	14	(0.83%)	59	(0.70%)	25	(0.65%)	881	(1.10%)	6	(0.59%)
Cardiovascular												
CHD[6]	0	(0.00%)	0	(0.00%)	29	(0.34%)	5	(0.13%)	245	(0.31%)	1	(0.10%)
Coronary death	0	(0.00%)	0	(0.00%)	12	(0.14%)	1	(0.03%)	65	(0.08%)	1	(0.10%)
Total MI[7]	0	(0.00%)	0	(0.00%)	17	(0.20%)	4	(0.10%)	197	(0.25%)	1	(0.10%)
Clinical MI	0	(0.00%)	0	(0.00%)	14	(0.17%)	4	(0.10%)	187	(0.23%)	1	(0.10%)
Silent MI	0	(0.00%)	0	(0.00%)	3	(0.04%)	0	(0.00%)	16	(0.02%)	0	(0.00%)
Possible Silent MI	0	(0.00%)	2	(0.12%)	9	(0.11%)	3	(0.08%)	54	(0.07%)	0	(0.00%)
Angina	1	(0.26%)	2	(0.12%)	36	(0.43%)	11	(0.29%)	326	(0.41%)	3	(0.29%)
CABG/PTCA	0	(0.00%)	2	(0.12%)	25	(0.30%)	11	(0.29%)	274	(0.34%)	3	(0.29%)
Carotid artery disease	1	(0.26%)	0	(0.00%)	3	(0.04%)	0	(0.00%)	62	(0.08%)	0	(0.00%)
Congestive heart failure	0	(0.00%)	0	(0.00%)	25	(0.30%)	6	(0.16%)	160	(0.20%)	3	(0.29%)
Stroke	2	(0.51%)	4	(0.24%)	15	(0.18%)	5	(0.13%)	150	(0.19%)	3	(0.29%)
PVD	1	(0.26%)	0	(0.00%)	9	(0.11%)	0	(0.00%)	39	(0.05%)	0	(0.00%)
CHD[6]/Possible Silent MI	0	(0.00%)	2	(0.12%)	38	(0.45%)	8	(0.21%)	294	(0.37%)	1	(0.10%)
Coronary disease[8]	1	(0.26%)	6	(0.36%)	88	(1.04%)	20	(0.52%)	697	(0.87%)	6	(0.59%)
Total CVD	6	(1.53%)	10	(0.59%)	111	(1.31%)	26	(0.68%)	941	(1.17%)	9	(0.88%)
Deaths												
Cardiovascular deaths	0	(0.00%)	0	(0.00%)	16	(0.19%)	1	(0.03%)	82	(0.10%)	1	(0.10%)
Cancer deaths	0	(0.00%)	4	(0.24%)	13	(0.15%)	2	(0.05%)	125	(0.16%)	1	(0.10%)
Deaths: other known cause	1	(0.26%)	0	(0.00%)	2	(0.02%)	0	(0.00%)	28	(0.03%)	1	(0.10%)
Deaths: unknown cause	1	(0.26%)	0	(0.00%)	5	(0.06%)	0	(0.00%)	9	(0.01%)	0	(0.00%)
Deaths: not yet adjudicated	0	(0.00%)	5	(0.30%)	6	(0.07%)	1	(0.03%)	53	(0.07%)	0	(0.00%)
Total death	2	(0.51%)	9	(0.53%)	42	(0.50%)	4	(0.10%)	297	(0.37%)	3	(0.29%)

[1] "Other fracture" excludes 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] 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.

[5] Excludes non-melanoma skin cancer

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

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

[8] "Coronary disease" includes clinical MI, definite silent MI, possible silent MI, coronary 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

Data as of: August 27, 2000

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	36282		5158		8265		16520		6339	
Mean follow-up (months)	31.6		37.3		33.5		29.9		29.2	
Hospitalizations										
Ever	7455	(7.80%)	849	(5.30%)	1443	(6.25%)	3459	(8.41%)	1704	(11.05%)
Two or more	2380	(2.49%)	250	(1.56%)	403	(1.74%)	1088	(2.64%)	639	(4.14%)
Other										
DVT[1]	165	(0.17%)	11	(0.07%)	34	(0.15%)	74	(0.18%)	46	(0.30%)
PE	72	(0.08%)	5	(0.03%)	17	(0.07%)	34	(0.08%)	16	(0.10%)
Diabetes (treated)	1982	(2.07%)	270	(1.69%)	463	(2.00%)	881	(2.14%)	368	(2.39%)
Gallbladder disease[2]	1172	(1.23%)	175	(1.09%)	294	(1.27%)	533	(1.30%)	170	(1.10%)
Hysterectomy[3]	410	(0.73%)	62	(0.68%)	99	(0.70%)	188	(0.79%)	61	(0.71%)
Glaucoma	1419	(1.49%)	145	(0.91%)	254	(1.10%)	668	(1.62%)	352	(2.28%)
Osteoporosis	2852	(2.99%)	244	(1.52%)	498	(2.16%)	1378	(3.35%)	732	(4.75%)
Osteoarthritis[4]	4994	(5.59%)	546	(3.72%)	1014	(4.72%)	2317	(6.00%)	1117	(7.64%)
Rheumatoid arthritis	882	(0.92%)	125	(0.78%)	217	(0.94%)	382	(0.93%)	158	(1.02%)
Intestinal polyps	1927	(2.02%)	227	(1.42%)	405	(1.75%)	923	(2.24%)	372	(2.41%)
Lupus	180	(0.19%)	30	(0.19%)	42	(0.18%)	81	(0.20%)	27	(0.18%)
Kidney Stones[4]	297	(0.43%)	36	(0.34%)	79	(0.49%)	135	(0.44%)	47	(0.41%)
Cataracts[4]	5099	(7.42%)	249	(2.34%)	701	(4.32%)	2634	(8.64%)	1515	(13.25%)
Pills for hypertension	9722	(10.18%)	1089	(6.80%)	1957	(8.47%)	4503	(10.95%)	2173	(14.09%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native		Asian/Pacific Islander		Black/African Am		Hispanic/ Latino		White		Other/ Unspecified	
Number randomized	149		721		3316		1502		30155		439	
Mean follow-up (months)	31.5		28.1		30.6		30.6		32.0		28.0	
Hospitalizations												
Ever	32	(8.17%)	95	(5.63%)	692	(8.20%)	246	(6.42%)	6317	(7.87%)	73	(7.13%)
Two or more	16	(4.09%)	26	(1.54%)	214	(2.53%)	69	(1.80%)	2037	(2.54%)	18	(1.76%)
Other												
DVT[1]	1	(0.26%)	0	(0.00%)	11	(0.13%)	2	(0.05%)	150	(0.19%)	1	(0.10%)
PE	1	(0.26%)	0	(0.00%)	6	(0.07%)	2	(0.05%)	61	(0.08%)	2	(0.20%)
Diabetes (treated)	15	(3.83%)	60	(3.56%)	410	(4.86%)	146	(3.81%)	1320	(1.64%)	31	(3.03%)
Gallbladder disease[2]	4	(1.02%)	24	(1.42%)	81	(0.96%)	63	(1.64%)	984	(1.23%)	16	(1.56%)
Hysterectomy[3]	1	(0.62%)	5	(0.46%)	19	(0.53%)	13	(0.62%)	367	(0.76%)	5	(0.87%)
Glaucoma	9	(2.30%)	28	(1.66%)	208	(2.46%)	71	(1.85%)	1094	(1.36%)	9	(0.88%)
Osteoporosis	10	(2.55%)	56	(3.32%)	123	(1.46%)	126	(3.29%)	2494	(3.11%)	43	(4.20%)
Osteoarthritis[4]	26	(7.06%)	102	(6.24%)	511	(6.40%)	248	(6.88%)	4042	(5.40%)	65	(6.67%)
Rheumatoid arthritis	11	(2.81%)	18	(1.07%)	170	(2.01%)	84	(2.19%)	588	(0.73%)	11	(1.07%)
Intestinal polyps	10	(2.55%)	32	(1.90%)	179	(2.12%)	65	(1.70%)	1620	(2.02%)	21	(2.05%)
Lupus	3	(0.77%)	2	(0.12%)	17	(0.20%)	7	(0.18%)	148	(0.18%)	3	(0.29%)
Kidney Stones[4]	1	(0.35%)	5	(0.40%)	20	(0.34%)	23	(0.82%)	243	(0.42%)	5	(0.66%)
Cataracts[4]	26	(9.12%)	99	(7.86%)	442	(7.42%)	214	(7.62%)	4258	(7.37%)	60	(7.88%)
Pills for hypertension	48	(12.26%)	224	(13.28%)	1451	(17.19%)	402	(10.49%)	7457	(9.29%)	140	(13.68%)

[1] Inpatient DVT only.

[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

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

[4] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

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] Control	Percentage of Cases[2] Intervention	Design[3]	Revised Assumptions[4]
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						
	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. 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 and 4, the rates of 93.1% and 91.4% fall slightly short of the 94% (Y2) and 92% (Y4) goals for the Exposure Update, at least in part because CC follow-up of non-responders is not required in even numbered follow-up years.

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 10/27/99, 95% overall completed medical history updates (*Form 33*) and 83% 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.

Table 5.4 shows 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 AV3 bone scan, as nearly 3,000 of the women with a baseline do not have an AV3 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 be a measurement problem. Further investigation of this issue is underway, as was described in *Section 4.7*.

5.6 Vital Status

Table 5.5 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 2.1% of the participants are lost to follow-up, and an additional 0.8% of the participants have stopped follow-up. About 1.5% 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 increased by 0.4%. Over that period, the participation of alive participants has improved, as now 92.2% of the participants are current, while 3.4% have either recent or past participation. In contrast, six months ago 91.5% were current and 4.8% had recent or past participation.

5.7 Outcomes

Table 5.6 contains counts of the number of locally verified major WHI outcomes for OS participants by age and race/ethnicity. As approximately 10% 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 110% of the expected number of breast cancers, 60% of the expected number of colorectal cancers, about 45% of the expected number of CHD events, and about 30% of the expected number hip fractures.

Table 5.7 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: August 27, 2000

	Total Enrolled	Distribution
Age	**93,720**	
50-54	12388	13%
55-59	17323	18%
60-69	41215	44%
70-79	22794	24%
Race/Ethnicity	**93,720**	
American Indian	422	<1%
Asian	2671	3%
Black	7636	8%
Hispanic	3642	4%
White	78028	83%
Other/Unspecified	1321	1%

Table 5.2
Response Rates to OS Follow-up Procedures

Data as of: August 27, 2000

	# 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	92700	92517	99.8	85968	92.7	2765	42.2	88733	95.7
VCC	41594	41561	99.9	38383	92.3	1686	53.1	40069	96.3
NCC	51106	50956	99.7	47585	93.1	1079	32.0	48664	95.2
Year 2	65439	63920	97.7	60205	92.0	N/A		60912	93.1
VCC	30607	29891	97.7	28197	92.1	N/A		28589	93.4
NCC	34832	34029	97.7	32008	91.9	N/A		32323	92.8
Year 4	13377	12853	96.1	11959	89.4	N/A		12225	91.4
VCC	8552	8172	95.6	7588	88.7	N/A		7723	90.3
NCC	4825	4681	97.0	4371	90.6	N/A		4502	93.3

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

Table 5.3
OS Annual Visit 3 Task Completeness

Data as of: August 27, 2000

Task	# Due[1]	# Done[2]	% Done
Form 33 – Medical History Update	47188	44912	95%
Form 38 – Daily Life	47188	41600	88%
Form 44 – Current Medications	47188	40148	85%
Form 45 – Current Supplements	47188	40073	85%
Form 60 – Food Frequency Quest	47188	41405	88%
Form 80 – Physical Measures	47188	39468	84%
Form 100 – Blood Collection	47188	39084	83%
Form 143 – Follow-up	47188	41405	88%

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

Data as of: August 27, 2000

	N	Mean	S.D.
Whole Body Scan			
Baseline	6418	1.01	0.11
Baseline (for ppts. with an AV3 scan)	4535	1.01	0.11
AV3	4566	1.02	0.11
AV3 % Change from baseline BMD[2]	4535	1.15	3.66
Spine Scan			
Baseline	6307	0.98	0.17
Baseline (for ppts. with an AV3 scan)	4474	0.97	0.17
AV3	4496	0.99	0.18
AV3 % Change from baseline BMD	4474	1.76	5.16
Hip Scan			
Baseline	6418	0.84	0.14
Baseline (for ppts. with an AV3 scan)	4571	0.84	0.14
AV3	4589	0.85	0.14
AV3 % Change from baseline BMD	4571	0.84	4.28

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

Table 5.5
Lost-to-Follow-up and Vital Status: OS Participants

Data as of: August 27, 2000

	OS Participants (N=93720)	
	N	%
Vital Status/Participation		
Deceased	1437	1.5
Alive: Current Participation[1]	86440	92.2
Alive: Recent Participation[2]	2980	3.2
Alive: Past/Unknown Participation[3]	152	0.2
Stopped Follow-Up[4]	762	0.8
Lost to Follow-Up[5]	1949	2.1

[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 5.6
Locally Verified Outcomes (Annualized Percentages) by Age for Observational Study

Data as of: August 27, 2000

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number enrolled	93720	12388	17323	41215	22794
Mean follow-up (months)	38.4	41.9	40.5	37.2	37.1
Cardiovascular					
CHD[1]	650 (0.22%)	17 (0.04%)	60 (0.10%)	243 (0.19%)	330 (0.47%)
Coronary death	148 (0.05%)	2 (0.00%)	6 (0.01%)	47 (0.04%)	93 (0.13%)
Clinical MI	545 (0.18%)	15 (0.03%)	55 (0.09%)	206 (0.16%)	269 (0.38%)
Angina	1233 (0.41%)	58 (0.13%)	121 (0.21%)	548 (0.43%)	506 (0.72%)
CABG/PTCA	1004 (0.33%)	28 (0.06%)	102 (0.17%)	445 (0.35%)	429 (0.61%)
Carotid artery disease	235 (0.08%)	18 (0.04%)	16 (0.03%)	90 (0.07%)	111 (0.16%)
Congestive heart failure	620 (0.21%)	18 (0.04%)	49 (0.08%)	247 (0.19%)	306 (0.43%)
Stroke	505 (0.17%)	11 (0.03%)	39 (0.07%)	187 (0.15%)	268 (0.38%)
PVD	158 (0.05%)	5 (0.01%)	15 (0.03%)	54 (0.04%)	84 (0.12%)
Coronary disease[2]	2235 (0.74%)	86 (0.20%)	207 (0.35%)	940 (0.74%)	1002 (1.42%)
Total CVD	2915 (0.97%)	112 (0.26%)	263 (0.45%)	1193 (0.93%)	1347 (1.91%)
Cancer					
Breast cancer[3]	1437 (0.48%)	166 (0.38%)	254 (0.43%)	645 (0.50%)	372 (0.53%)
Invasive breast cancer	1190 (0.40%)	140 (0.32%)	212 (0.36%)	525 (0.41%)	313 (0.44%)
Non-invasive breast cancer	261 (0.09%)	29 (0.07%)	46 (0.08%)	125 (0.10%)	61 (0.09%)
Ovary cancer	123 (0.04%)	9 (0.02%)	22 (0.04%)	55 (0.04%)	37 (0.05%)
Endometrial Cancer[4]	181 (0.10%)	16 (0.06%)	22 (0.06%)	87 (0.12%)	56 (0.14%)
Colorectal cancer	306 (0.10%)	16 (0.04%)	35 (0.06%)	132 (0.10%)	123 (0.17%)
Other cancer[5,6]	1250 (0.42%)	94 (0.22%)	162 (0.28%)	571 (0.45%)	423 (0.60%)
Total cancer	3242 (1.08%)	297 (0.69%)	487 (0.83%)	1469 (1.15%)	989 (1.40%)
Fractures					
Hip fracture	266 (0.09%)	6 (0.01%)	27 (0.05%)	88 (0.07%)	145 (0.21%)
Vertebral fracture[7]	46 (0.17%)	2 (0.05%)	4 (0.08%)	13 (0.11%)	27 (0.42%)
Other fracture[5,7,8]	353 (1.32%)	43 (1.14%)	54 (1.11%)	147 (1.27%)	109 (1.69%)
Total fracture[9]	651 (0.22%)	50 (0.12%)	85 (0.15%)	242 (0.19%)	274 (0.39%)
Deaths					
Cardiovascular deaths	325 (0.11%)	6 (0.01%)	16 (0.03%)	108 (0.08%)	195 (0.28%)
Cancer deaths	572 (0.19%)	32 (0.07%)	65 (0.11%)	239 (0.19%)	236 (0.33%)
Deaths: other known cause	194 (0.06%)	9 (0.02%)	22 (0.04%)	80 (0.06%)	83 (0.12%)
Deaths: unknown cause	79 (0.03%)	4 (0.01%)	7 (0.01%)	35 (0.03%)	33 (0.05%)
Deaths: not yet adjudicated	267 (0.09%)	15 (0.03%)	23 (0.04%)	106 (0.08%)	123 (0.17%)
Total death	1437 (0.48%)	66 (0.15%)	133 (0.23%)	568 (0.44%)	670 (0.95%)

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

[2] "Coronary disease" includes clinical MI, coronary death, angina, congestive heart failure, and CABG/PTCA.

[3] Excludes four cases with borderline malignancy.

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

[5] 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.

[6] Excludes non-melanoma skin cancer

[7] Only women from three bone density clinics.

[8] "Other fracture" excludes fractures indicated as pathological.

[9] 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 5.6 (Continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Observational Study

Data as of: August 27, 2000

Outcomes	Ethnicity: American Indian/Alaskan Native	Asian/Pacific Islander	Black/African American	Hispanic/ Latino	White	Other/ Unspecified
Number enrolled	422	2671	7636	3642	78028	1321
Mean follow-up (months)	36.0	37.1	35.6	33.6	39.0	36.7
Cardiovascular						
CHD[1]	3 (0.24%)	13 (0.16%)	48 (0.21%)	9 (0.09%)	562 (0.22%)	15 (0.37%)
Coronary death	0 (0.00%)	3 (0.04%)	18 (0.08%)	0 (0.00%)	123 (0.05%)	4 (0.10%)
Clinical MI	3 (0.24%)	11 (0.13%)	38 (0.17%)	9 (0.09%)	472 (0.19%)	12 (0.30%)
Angina	8 (0.63%)	21 (0.25%)	93 (0.41%)	31 (0.30%)	1070 (0.42%)	10 (0.25%)
CABG/PTCA	5 (0.40%)	19 (0.23%)	56 (0.25%)	22 (0.22%)	886 (0.35%)	16 (0.40%)
Carotid artery disease	1 (0.08%)	3 (0.04%)	12 (0.05%)	6 (0.06%)	206 (0.08%)	7 (0.17%)
Congestive heart failure	4 (0.32%)	10 (0.12%)	65 (0.29%)	12 (0.12%)	520 (0.21%)	9 (0.22%)
Stroke	3 (0.24%)	20 (0.24%)	48 (0.21%)	8 (0.08%)	414 (0.16%)	12 (0.30%)
PVD	1 (0.08%)	1 (0.01%)	14 (0.06%)	2 (0.02%)	138 (0.05%)	2 (0.05%)
Coronary disease[2]	12 (0.95%)	39 (0.47%)	181 (0.80%)	46 (0.45%)	1929 (0.76%)	28 (0.69%)
Total CVD	16 (1.26%)	59 (0.72%)	239 (1.05%)	59 (0.58%)	2497 (0.99%)	45 (1.11%)
Cancer						
Breast cancer[3]	2 (0.16%)	27 (0.33%)	80 (0.35%)	42 (0.41%)	1273 (0.50%)	13 (0.32%)
Invasive breast cancer	2 (0.16%)	20 (0.24%)	63 (0.28%)	31 (0.30%)	1063 (0.42%)	11 (0.27%)
Non-invasive breast cancer	0 (0.00%)	7 (0.08%)	18 (0.08%)	11 (0.11%)	223 (0.09%)	2 (0.05%)
Ovary cancer	0 (0.00%)	2 (0.02%)	6 (0.03%)	4 (0.04%)	111 (0.04%)	0 (0.00%)
Endometrial Cancer[4]	0 (0.00%)	5 (0.09%)	3 (0.03%)	4 (0.07%)	164 (0.11%)	5 (0.21%)
Colorectal cancer	1 (0.08%)	6 (0.07%)	39 (0.17%)	4 (0.04%)	254 (0.10%)	2 (0.05%)
Other cancer[5,6]	4 (0.32%)	21 (0.25%)	62 (0.27%)	24 (0.24%)	1125 (0.44%)	14 (0.35%)
Total cancer	7 (0.55%)	59 (0.72%)	185 (0.82%)	77 (0.76%)	2880 (1.14%)	34 (0.84%)
Fractures						
Hip fracture	1 (0.08%)	3 (0.04%)	1 <0.00%	3 (0.03%)	257 (0.10%)	1 (0.02%)
Vertebral fracture[7]	1 (0.28%)	0 (0.00%)	0 (0.00%)	2 (0.11%)	43 (0.21%)	0 (0.00%)
Other fracture[5,7,8]	5 (1.39%)	1 (0.87%)	16 (0.49%)	16 (0.88%)	312 (1.49%)	3 (1.73%)
Total fracture[9]	7 (0.55%)	4 (0.05%)	17 (0.08%)	21 (0.21%)	598 (0.24%)	4 (0.10%)
Deaths						
Cardiovascular deaths	3 (0.24%)	7 (0.08%)	27 (0.12%)	2 (0.02%)	280 (0.11%)	6 (0.15%)
Cancer deaths	2 (0.16%)	8 (0.10%)	33 (0.15%)	16 (0.16%)	507 (0.20%)	6 (0.15%)
Deaths: other known cause	3 (0.24%)	3 (0.04%)	9 (0.04%)	7 (0.07%)	167 (0.07%)	5 (0.12%)
Deaths: unknown cause	0 (0.00%)	2 (0.02%)	12 (0.05%)	4 (0.04%)	61 (0.02%)	0 (0.00%)
Deaths: not yet adjudicated	1 (0.08%)	5 (0.06%)	34 (0.15%)	11 (0.11%)	212 (0.08%)	4 (0.10%)
Total death	9 (0.71%)	25 (0.30%)	115 (0.51%)	40 (0.39%)	1227 (0.48%)	21 (0.52%)

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

[2] "Coronary disease" includes clinical MI, coronary death, angina, congestive heart failure, and CABG/PTCA.

[3] Excludes four cases with borderline malignancy.

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

[5] 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.

[6] Excludes non-melanoma skin cancer

[7] Only women from three bone density clinics.

[8] "Other fracture" excludes fractures indicated as pathological.

[9] 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
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for Observational Study

Data as of: August 27, 2000

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	93720		12388		17323		41215		22794	
Mean follow-up (months)	38.4		41.9		40.5		37.2		37.1	
Hospitalizations										
Ever	21361	(7.12%)	1999	(4.62%)	3086	(5.27%)	9362	(7.33%)	6914	(9.81%)
Two or more	7145	(2.38%)	581	(1.34%)	874	(1.49%)	3089	(2.42%)	2601	(3.69%)
Other										
DVT[1]	322	(0.11%)	22	(0.05%)	35	(0.06%)	141	(0.11%)	124	(0.18%)
PE	166	(0.06%)	18	(0.04%)	14	(0.02%)	73	(0.06%)	61	(0.09%)
Diabetes (treated)	4660	(1.55%)	473	(1.09%)	759	(1.30%)	2161	(1.69%)	1267	(1.80%)
Gallbladder disease[2]	3112	(1.04%)	468	(1.08%)	576	(0.98%)	1381	(1.08%)	687	(0.97%)
Hysterectomy[3]	1529	(0.87%)	225	(0.87%)	291	(0.80%)	681	(0.92%)	332	(0.84%)
Glaucoma	3953	(1.32%)	338	(0.78%)	523	(0.89%)	1753	(1.37%)	1339	(1.90%)
Osteoporosis	11793	(3.93%)	997	(2.30%)	1638	(2.80%)	5410	(4.23%)	3748	(5.32%)
Osteoarthritis[4]	16491	(5.50%)	1473	(3.40%)	2417	(4.13%)	7319	(5.73%)	5282	(7.50%)
Rheumatoid arthritis	2687	(0.90%)	377	(0.87%)	491	(0.84%)	1079	(0.84%)	740	(1.05%)
Intestinal polyps	6156	(2.05%)	628	(1.45%)	1062	(1.82%)	2821	(2.21%)	1645	(2.33%)
Lupus	507	(0.17%)	85	(0.20%)	106	(0.18%)	214	(0.17%)	102	(0.14%)
Kidney Stones[4]	967	(0.45%)	121	(0.42%)	189	(0.47%)	421	(0.45%)	236	(0.46%)
Cataracts[4]	15442	(7.25%)	536	(1.88%)	1421	(3.55%)	7518	(8.09%)	5967	(11.59%)
Pills for hypertension	28333	(9.44%)	2493	(5.76%)	4313	(7.37%)	12694	(9.93%)	8833	(12.53%)

Outcomes	Race/Ethnicity: Am Indian/ Alaskan Native		Asian/Pacific Islander		Black/African Am		Hispanic/ Latino		White		Other/ Unspecified	
Number randomized	422		2671		7636		3642		78028		1321	
Mean follow-up (months)	36.0		37.1		35.6		33.6		39.0		36.7	
Hospitalizations												
Ever	105	(8.30%)	367	(4.45%)	1594	(7.03%)	568	(5.58%)	18456	(7.28%)	271	(6.70%)
Two or more	42	(3.32%)	113	(1.37%)	533	(2.35%)	157	(1.54%)	6208	(2.45%)	92	(2.28%)
Other												
DVT[1]	1	(0.08%)	1	(0.01%)	24	(0.11%)	2	(0.02%)	290	(0.11%)	4	(0.10%)
PE	0	(0.00%)	2	(0.02%)	8	(0.04%)	1	(0.01%)	154	(0.06%)	1	(0.02%)
Diabetes (treated)	64	(5.06%)	169	(2.05%)	939	(4.14%)	315	(3.09%)	3098	(1.22%)	75	(1.86%)
Gallbladder disease[2]	16	(1.26%)	47	(0.57%)	210	(0.93%)	141	(1.38%)	2656	(1.05%)	42	(1.04%)
Hysterectomy[3]	7	(1.13%)	31	(0.57%)	100	(0.97%)	61	(1.09%)	1303	(0.86%)	27	(1.15%)
Glaucoma	29	(2.29%)	132	(1.60%)	561	(2.48%)	168	(1.65%)	2998	(1.18%)	65	(1.61%)
Osteoporosis	46	(3.64%)	363	(4.40%)	471	(2.08%)	412	(4.05%)	10305	(4.07%)	196	(4.85%)
Osteoarthritis[4]	94	(7.44%)	416	(5.04%)	1351	(5.96%)	677	(6.66%)	13685	(5.40%)	268	(6.63%)
Rheumatoid arthritis	28	(2.21%)	70	(0.85%)	460	(2.03%)	241	(2.37%)	1822	(0.72%)	66	(1.63%)
Intestinal polyps	26	(2.05%)	166	(2.01%)	481	(2.12%)	185	(1.82%)	5212	(2.06%)	86	(2.13%)
Lupus	5	(0.40%)	13	(0.16%)	54	(0.24%)	24	(0.24%)	402	(0.16%)	9	(0.22%)
Kidney Stones[4]	11	(1.20%)	15	(0.25%)	94	(0.57%)	57	(0.73%)	773	(0.43%)	17	(0.57%)
Cataracts[4]	66	(7.19%)	461	(7.73%)	1186	(7.22%)	517	(6.65%)	12978	(7.25%)	234	(7.91%)
Pills for hypertension	136	(10.75%)	840	(10.18%)	3611	(15.94%)	1011	(9.93%)	22326	(8.81%)	409	(10.12%)

[1] Inpatient DVT only.

[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

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

[4] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

6. Outcomes Processing

6.1 Overview

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

After these forms are completed and entered into the database, the CCs identify adjudication cases based on the *Form 33D* information. CCs then request hospital and related records. Once the cases are documented, clinic staff 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. Currently, WHI requires central adjudication of all such events. 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 92% 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. For cardiovascular outcomes, central adjudication results, while offering a higher degree of standardization, will eventually be available only on a subsample, and even then only after a lag time of several months. This part of the central adjudication process should therefore be viewed primarily as a quality assurance effort.

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 of *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 93% of self-reported outcomes in the CT and 90% of the self-reported outcomes in the OS requiring adjudication have been closed. In particular, 48% of the outcomes in the CT and 52% of the outcomes in the OS have been closed within 90 days of self-report and 65% (CT) and 69% (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 early 1998, the percentage of forms that were adjudicated within 90 days has increased from about 40% to about 65%, and the percentage of forms that were adjudicated within 180 days has increased from about 60% to about 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 1.6%. Currently 28 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. In particular, 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.

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

The accuracy of self-reports varies considerably by outcome. For many outcomes the agreement rates for the CT are a few percentage points higher than for the OS. The accuracy of cancer and fracture self-reports may be higher than that for cardiovascular disease because more cardiovascular self-reports result in a related outcome. If those related outcomes are included with the confirmed self-reports, cardiovascular outcomes have a 76% agreement rate between self-reports and locally confirmed outcomes (85% if we exclude angina, which is probably the softest cardiovascular outcome), cancer outcomes have an agreement rate of 86% (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. Since the previous DSMB report, the cancer coders at the CCC have made it their top priority to reduce the backlog in cancer central adjudication. As of August 31, 1999, only 25% of the locally confirmed cancer outcomes had been centrally adjudicated; by February 29, 2000 this percentage had increased to 45%, right now it is up to 79%. *Tables 6.5* and *6.6* 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. Since we see the central adjudication process primarily as a quality assurance activity, data regarding such cross-classification is not shown.

6.4 Outcomes Data Summary

Table 6.7 – Locally Verified Outcomes (Annualized Percentages) by Ethnicity and by Age for CT contains the number of locally verified outcomes for the major WHI outcomes. Since about 8% 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 80% of the invasive breast and colorectal cancer cases of what was assumed for the power calculations. The observed rate of CHD is approximately 80% 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 slightly higher than what was assumed. Only in the oldest age category, 70-79 at baseline, are the current observed rates considerably lower (about 50%) than design assumptions. The participants in the oldest age category were among the latest to be recruited, so the "healthy volunteer effect" may still be an important factor for these women. When we combine the four age categories, the observed CHD rate is about 70% of what was assumed in the design. The rates of hip fractures are currently only about 30% of what was assumed for all age categories.

Table 6.8 – Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Ethnicity and Age for CT contains counts of the number of self-reports for some of the WHI outcomes that are not verified. 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 has 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 rates of cancer and fractures in the OS and CT are very similar. The rate of cardiovascular events is somewhat higher in the CT than in the OS. One possible explanation is that the eligibility criteria for the DM, which excluded women who were eating a low percentage of fat from calories, may have moved a group at lower risk of cardiovascular disease from the CT to the OS.

Tables 6.9 – Locally Confirmed Other Cancers and *6.10 – 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 30% 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 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 August 27, 2000, the CCC had received serial analysis on 43,501 CT participants, whose year 3 ECGs and/or their year 6 ECGs had been analyzed by EPICARE.

Table 6.11 – 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 32 evolving Q-wave MIs have been identified. We note that 12 of these MIs were also identified by the regular outcomes reporting process. The remaining 20 evolving Q-wave MIs are thus the "definite silent MIs." *Table 5.6* also gives the number of possible silent MIs.

6.6 Vital Status

Table 6.12 – 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, death adjudication procedures were changed in April 1999 to encourage clinics to report a "temporary" cause of death for those participants for whom some, but not all, documentation related to the death has been collected. This change in procedures was made in recognition of the fact that it is often more difficult to obtain documents for death cases than for self-reports, for which participants can sign a release themselves. 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 August 27, 2000 database, there were 974 deaths in the CT and 1437 in the OS. Of the 974 CT deaths, there were 778 (80%) for which a final adjudication was available, and an additional 63 (6%) for which a temporary adjudication was available. These 974 CT deaths include 54 that were first reported between July 1 and August 25 of this year. Of the 920 that were first reported before July 1, 2000, 772 have a final adjudication and 61 have a temporary one, giving us cause of death information on 91% of the CT deaths. For the OS there is cause of death information on 81% of all deaths, and 85% of all deaths that were reported before July 1, 2000.

Table 6.13 – Lost-to-Follow-up and Vital Status by Clinic: CT Participants displays information about the follow-up and vital status by clinic. Since June 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 will carry out a National Death Index (NDI) search.

About 1.4% of the CT participants are deceased, we do not know the vital status of about 1.4% of the CT participants, and 1.5% 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 3.7 years, we note that the follow-up is much better than what was assumed in the design.

There is considerable clinic-to-clinic variation in the vital status data. The percentage of participants who are lost-to-follow-up ranges from 0.1 to 6.5% per clinic. The percentage of participants who stopped follow-up ranges from less than 0.1 to 6.6%.

Table 6.14 – Lost-to-Follow-up and Vital Status by Clinic: OS Participants contains the same information as *Table 6.13* 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 2.9% of the OS participants is either lost-to-follow-up or has stopped follow-up.

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

Data as of: August 27, 2000

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	3918	267	7	777	20	3883	99	35	1
1996 July - December	1381	309	22	721	52	1370	99	11	1
1997 January-June	2172	765	35	1335	61	2162	100	10	0
1997 July-December	2540	978	39	1516	60	2522	99	18	1
1998 January-June	3575	1669	47	2787	78	3552	99	23	1
1998 July-December	4153	2369	57	3348	81	4101	99	52	1
1999 January-June	4594	2846	62	3831	83	4449	97	145	3
1999 July	727	483	66	611	84	697	96	30	4
1999 August	763	475	62	631	83	720	94	43	6
1999 September	723	470	65	603	83	683	94	40	6
1999 October	773	477	62	641	83	721	93	52	7
1999 November	744	475	64	625	84	692	93	52	7
1999 December	713	505	71	617	87	652	91	61	9
2000 January	778	535	69	658	85	699	90	79	10
2000 February	734	496	68	637	87	650	89	84	11
2000 March	817	536	66	687	84			130	16
2000 April	751	494	66	609	81			142	19
2000 May	782	557	71	608	78			174	22
2000 June	783	478	61					305	39
2000 July	623	240	39					383	61
2000 August	459	42	9					417	91
Total	32503	15466	48	21242	65	27553	85	2286	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

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

Data as of: August 27, 2000

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	236	86	36	130	55	236	100	0	0
1996 July - December	1309	310	24	705	54	1299	99	10	1
1997 January-June	2151	848	39	1406	65	2127	99	24	1
1997 July-December	2294	715	31	1367	60	2271	99	23	1
1998 January-June	2830	1278	45	2048	72	2802	99	28	1
1998 July-December	3793	2016	53	2918	77	3728	98	65	2
1999 January-June	4748	2872	60	3968	84	4631	98	117	2
1999 July	719	428	60	594	83	694	97	25	3
1999 August	812	518	64	681	84	767	94	45	6
1999 September	763	468	61	641	84	727	95	36	5
1999 October	682	387	57	565	83	651	95	31	5
1999 November	704	420	60	571	81	651	92	53	8
1999 December	521	340	65	424	81	461	88	60	12
2000 January	682	428	63	553	81	587	86	95	14
2000 February	786	494	63	659	84	676	86	110	14
2000 March	1276	878	69	1096	86			180	14
2000 April	1049	696	66	835	80			214	20
2000 May	1078	733	68	789	73			289	27
2000 June	1007	580	58					427	42
2000 July	771	270	35					501	65
2000 August	510	40	8					470	92
Total	28721	14805	52	19950	69	22308	78	2803	10

[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

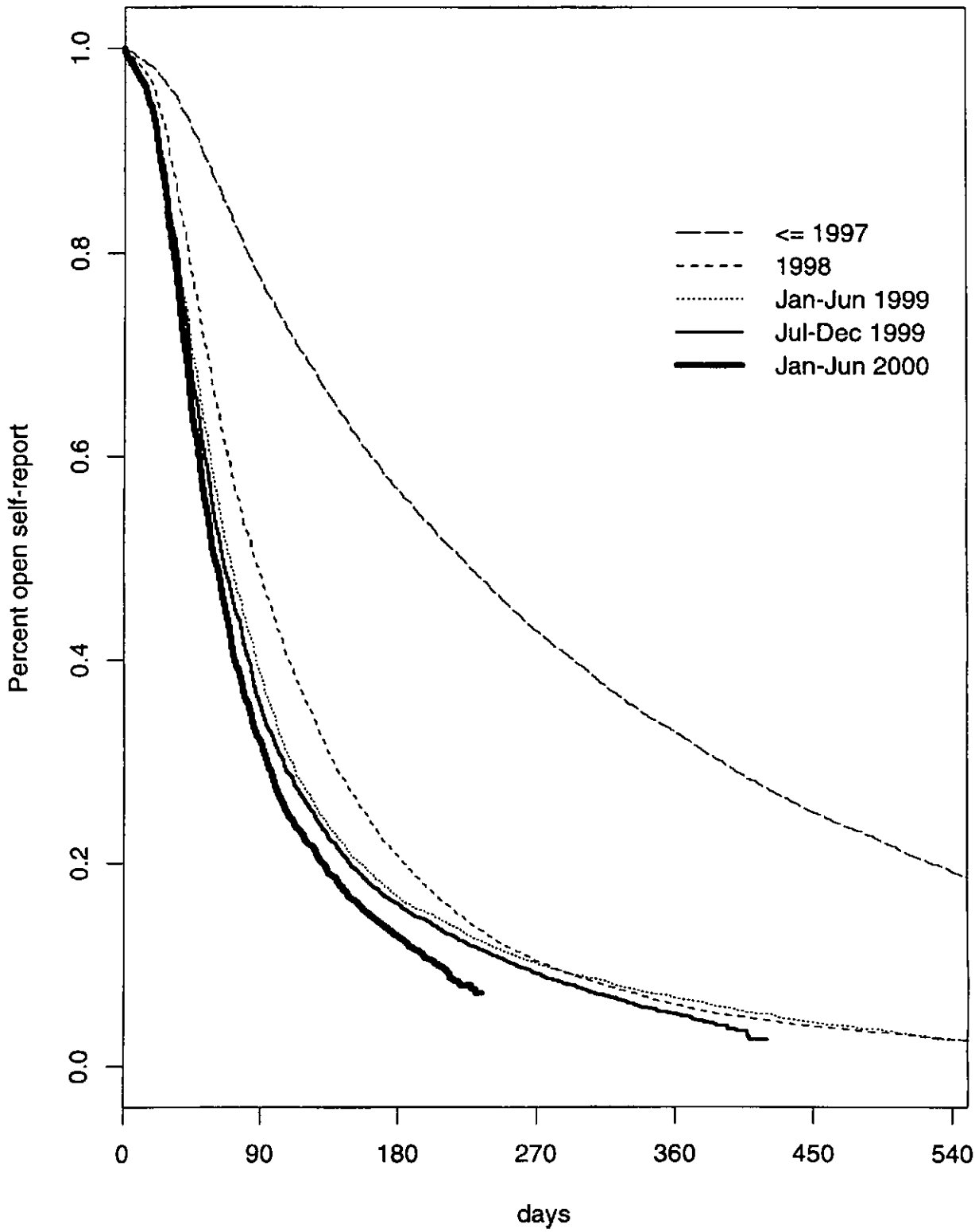


Figure 6.2 Observational Study Timeliness per Period of Self-Report

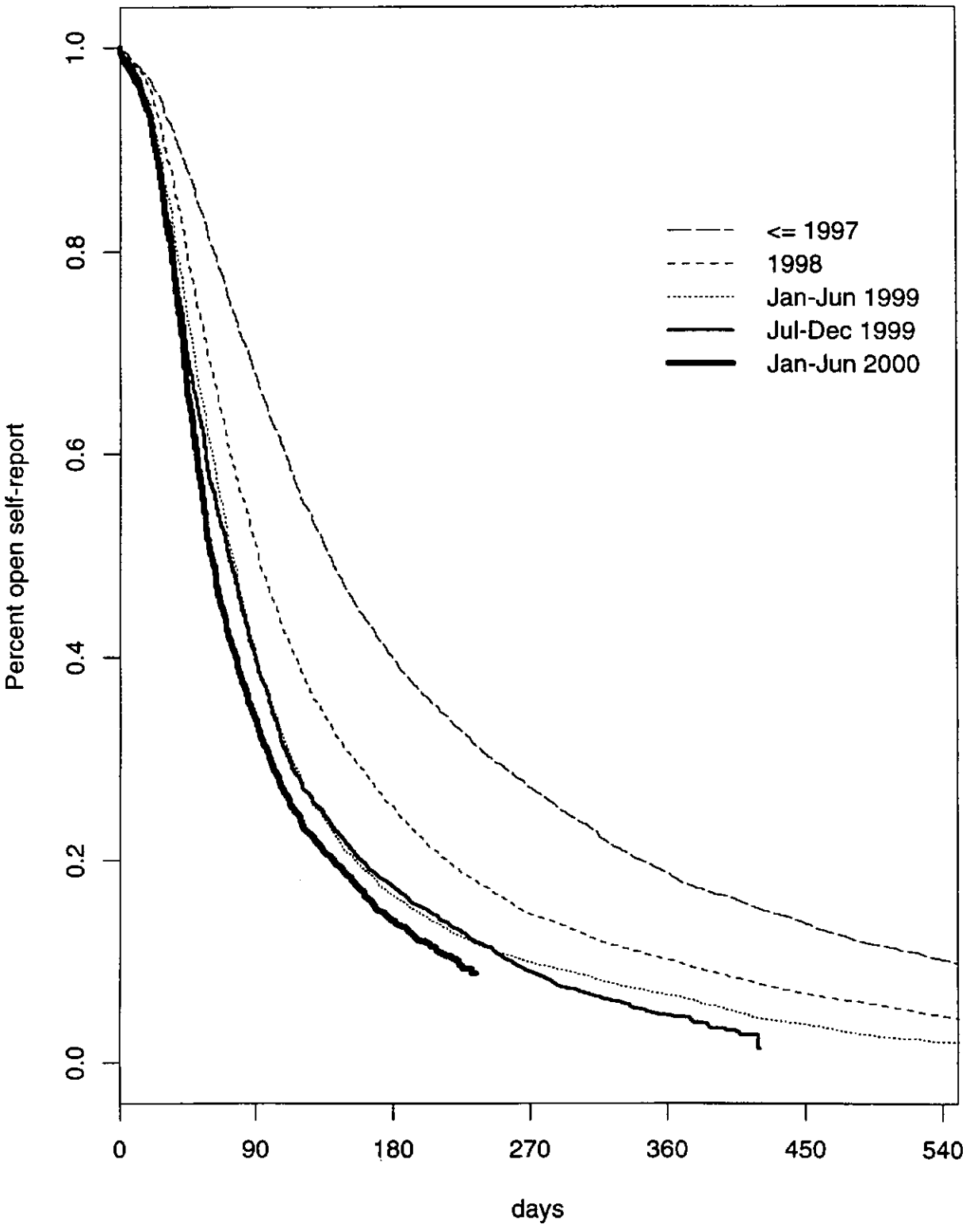


Table 6.3
Agreement of the Local Adjudications with Self-Reports — CT

Data as of: August 27, 2000

	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	597	542	(91%)	392	(72%)	78	(14%)	66	(12%)	6	(1%)
Angina[2]	1222	1088	(89%)	511	(47%)	58	(5%)	493	(45%)	26	(2%)
Congestive heart failure	365	321	(88%)	227	(71%)	23	(7%)	66	(21%)	5	(2%)
CABG/PTCA	1084	960	(89%)	833	(87%)	76	(8%)	41	(4%)	10	(1%)
Carotid artery disease[3]	175	160	(91%)	132	(83%)	17	(11%)	8	(5%)	3	(2%)
Stroke/TIA[4]	910	808	(89%)	618	(76%)	40	(5%)	137	(17%)	13	(2%)
PVD	119	102	(86%)	65	(64%)	13	(13%)	22	(22%)	2	(2%)
DVT[5]	191	180	(94%)	126	(70%)	26	(14%)	24	(13%)	4	(2%)
PE[5]	85	76	(89%)	66	(87%)	4	(5%)	6	(8%)	0	(0%)
Cancers											
Breast cancer	1148	1009	(88%)	958[6]	(95%)	1	(0%)	46	(5%)	4	(0%)
Ovary cancer	125	108	(86%)	79	(73%)	24	(22%)	3	(3%)	2	(2%)
Endometrial cancer	150	141	(94%)	102	(72%)	23	(16%)	14	(10%)	2	(1%)
Colorectal	335	296	(88%)	263	(89%)	16	(5%)	15	(5%)	2	(1%)
Other cancer[7]	1318	1171	(89%)	883	(75%)	71	(6%)	188	(16%)	29	(2%)
Fractures											
Hip fracture	239	220	(92%)	180	(82%)	10	(5%)	27	(12%)	3	(1%)
Vertebral fracture	427	376	(88%)	192	(51%)	13	(3%)	155	(41%)	16	(4%)
Other fracture	4244	3880	(91%)	3127	(81%)	31	(1%)	610	(16%)	112	(3%)

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

[2] Angina that is self-reported after a confirmed MI, is not adjudicated. In particular, 140 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, 2 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 177 participants who reported stroke/TIA for whom only TIA was confirmed.

[5] HRT Participants only

[6] There were 742 cases of invasive breast cancer and 216 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: August 27, 2000

	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	523	435	(83%)	287	(66%)	83	(19%)	60	(14%)	5	(1%)
Angina[2]	1481	1215	(82%)	550	(45%)	64	(5%)	574	(47%)	27	(2%)
Congestive heart failure	412	358	(87%)	249	(70%)	23	(6%)	79	(22%)	7	(2%)
CABG/PTCA	1217	1042	(86%)	871	(84%)	88	(8%)	67	(6%)	16	(2%)
Carotid artery disease[3]	210	191	(91%)	150	(79%)	24	(13%)	14	(7%)	3	(2%)
Stroke/TIA[4]	1035	889	(86%)	649	(73%)	39	(4%)	178	(20%)	23	(3%)
PVD	169	144	(85%)	83	(58%)	18	(13%)	40	(28%)	3	(2%)
Cancers											
Breast cancer	1715	1487	(87%)	1348[5]	(91%)	7	(0%)	116	(8%)	16	(1%)
Ovary cancer	149	129	(87%)	86	(67%)	19	(15%)	23	(18%)	1	(1%)
Endometrial cancer	177	153	(86%)	117	(76%)	22	(14%)	11	(7%)	3	(2%)
Colorectal	355	309	(87%)	259	(84%)	18	(6%)	25	(8%)	7	(2%)
Other cancer[6]	1743	1461	(84%)	1009	(69%)	109	(7%)	299	(20%)	44	(3%)
Fractures											
Hip fracture	322	279	(87%)	219	(78%)	8	(3%)	45	(16%)	7	(3%)
Vertebral fracture	63	58	(92%)	36	(62%)	5	(9%)	14	(24%)	3	(5%)
Other fracture	466	433	(93%)	328	(76%)	8	(2%)	84	(19%)	13	(3%)

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

[2] Angina that is self-reported after a confirmed MI, is not adjudicated. In particular, 82 such self-reports of angina are excluded from this table.

[3] Carotid artery disease that is self-reported after a confirmed Stroke, is not adjudicated. In particular, 6 such self-reports of Carotid artery disease are excluded from this table.

[4] Stroke and TIA have a combined self-report. Only stroke is monitored. There were 222 participants who reported stroke/TIA for whom only TIA was confirmed.

[5] There were 1108 cases of invasive breast cancer and 233 confirmed 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: August 27, 2000

	Locally confirmed N	Centrally adjudicated N	%	In agreement N	%[1]
Cardiovascular					
MI	590	401	68%	344	86%
Angina[2]	1049	753	72%	595	79%
Congestive heart failure	494	336	68%	248	74%
CABG/PTCA	920	662	72%	642	97%
DVT[3]	156	105	67%	93	89%
PE[3]	83	56	67%	51	91%
Cancers					
Breast cancer	975	811	83%	806	99%
Invasive	753	623	83%	610	96%
Non Invasive	222	188	87%	158	82%
Ovary cancer	97	77	79%	62	81%
Endometrial cancer	133	111	83%	106	95%
Colorectal cancer	292	236	81%	232	98%
Fractures					
Hip fracture	219	170	78%	163	96%

[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: August 27, 2000

	Locally confirmed N	Centrally adjudicated N	%	In agreement N	%[1]
Cardiovascular					
MI	545	343	63%	275	80%
Angina[2]	1181	792	67%	657	83%
Congestive heart failure	620	398	64%	324	81%
CABG/PTCA	1004	652	65%	629	96%
Cancers					
Breast cancer	1393	1051	76%	1027	98%
Invasive	1146	851	74%	807	94%
Non Invasive	247	200	81%	162	78%
Ovary cancer	112	90	80%	70	78%
Endometrial cancer	173	133	77%	122	92%
Colorectal cancer	289	217	75%	200	92%
Fractures					
Hip fracture	266	209	79%	203	97%

[1] Percentage is relative to centrally adjudicated cases

[2] Participants with a confirmed MI no longer require adjudication of angina

Table 6.7
Locally Verified Outcomes (Annualized Percentages) by Age for Clinical Trial

Data as of: August 27, 2000

Outcome	Total	Age 50-54	55-59	60-69	70-79
Number randomized	68135	9191	14665	31392	12887
Mean follow-up (months)	44.0	50.2	46.3	42.1	41.4
Cardiovascular					
CHD[1]	782 (0.31%)	48 (0.12%)	80 (0.14%)	378 (0.34%)	276 (0.62%)
Coronary death	223 (0.09%)	11 (0.03%)	17 (0.03%)	107 (0.10%)	88 (0.20%)
Total MI[2]	610 (0.24%)	38 (0.10%)	66 (0.12%)	291 (0.26%)	215 (0.48%)
Clinical MI	590 (0.24%)	34 (0.09%)	66 (0.12%)	279 (0.25%)	211 (0.47%)
Definite Silent MI	34 (0.01%)	6 (0.02%)	2 (0.00%)	18 (0.02%)	8 (0.02%)
Possible Silent MI	123 (0.05%)	13 (0.03%)	22 (0.04%)	43 (0.04%)	45 (0.10%)
Angina	1097 (0.44%)	57 (0.15%)	143 (0.25%)	542 (0.49%)	355 (0.80%)
CABG/PTCA	920 (0.37%)	43 (0.11%)	110 (0.19%)	456 (0.41%)	311 (0.70%)
Carotid artery disease	202 (0.08%)	5 (0.01%)	22 (0.04%)	91 (0.08%)	84 (0.19%)
Congestive heart failure	494 (0.20%)	22 (0.06%)	53 (0.09%)	215 (0.20%)	204 (0.46%)
Stroke	510 (0.20%)	17 (0.04%)	47 (0.08%)	230 (0.21%)	216 (0.49%)
PVD	135 (0.05%)	6 (0.02%)	14 (0.02%)	64 (0.06%)	51 (0.11%)
DVT	156 (0.06%)	10 (0.03%)	18 (0.03%)	78 (0.07%)	50 (0.11%)
PE	83 (0.03%)	4 (0.01%)	12 (0.02%)	36 (0.03%)	31 (0.07%)
CHD[1]/Possible Silent MI	890 (0.36%)	61 (0.16%)	97 (0.17%)	416 (0.38%)	316 (0.71%)
Coronary disease[3]	2207 (0.88%)	122 (0.32%)	260 (0.46%)	1055 (0.96%)	770 (1.73%)
DVT/PE	201 (0.08%)	11 (0.03%)	24 (0.04%)	99 (0.09%)	67 (0.15%)
Total CVD	3009 (1.20%)	155 (0.40%)	341 (0.60%)	1434 (1.30%)	1079 (2.43%)
Cancer					
Breast cancer[4]	975 (0.39%)	110 (0.29%)	202 (0.36%)	459 (0.42%)	204 (0.46%)
Invasive breast cancer	754 (0.30%)	76 (0.20%)	160 (0.28%)	356 (0.32%)	162 (0.36%)
Non-invasive breast cancer	230 (0.09%)	34 (0.09%)	44 (0.08%)	109 (0.10%)	43 (0.10%)
Ovary cancer	102 (0.04%)	14 (0.04%)	19 (0.03%)	45 (0.04%)	24 (0.05%)
Endometrial Cancer[5]	133 (0.09%)	16 (0.07%)	28 (0.08%)	59 (0.09%)	30 (0.12%)
Colorectal cancer	296 (0.12%)	17 (0.04%)	45 (0.08%)	152 (0.14%)	82 (0.18%)
Other cancer[6,7]	1050 (0.42%)	86 (0.22%)	165 (0.29%)	508 (0.46%)	291 (0.65%)
Total cancer	2507 (1.00%)	238 (0.62%)	446 (0.79%)	1200 (1.09%)	623 (1.40%)
Fractures					
Hip fracture	219 (0.09%)	9 (0.02%)	15 (0.03%)	80 (0.07%)	115 (0.26%)
Vertebral fracture	234 (0.09%)	11 (0.03%)	23 (0.04%)	99 (0.09%)	101 (0.23%)
Other fracture[6,8]	3275 (1.31%)	396 (1.03%)	602 (1.06%)	1543 (1.40%)	734 (1.65%)
Total fracture	3631 (1.45%)	411 (1.07%)	632 (1.12%)	1687 (1.53%)	901 (2.03%)
Deaths					
Cardiovascular deaths	288 (0.12%)	12 (0.03%)	23 (0.04%)	131 (0.12%)	122 (0.27%)
Cancer deaths	404 (0.16%)	27 (0.07%)	47 (0.08%)	200 (0.18%)	130 (0.29%)
Deaths: other known cause	102 (0.04%)	8 (0.02%)	16 (0.03%)	46 (0.04%)	32 (0.07%)
Deaths: unknown cause	47 (0.02%)	4 (0.01%)	3 (0.01%)	21 (0.02%)	19 (0.04%)
Deaths: not yet adjudicated	133 (0.05%)	7 (0.02%)	10 (0.02%)	56 (0.05%)	60 (0.14%)
Total death	974 (0.39%)	58 (0.15%)	99 (0.17%)	454 (0.41%)	363 (0.82%)

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

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

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

[4] Excludes eight 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.

[7] Excludes non-melanoma skin cancer

[8] "Other fracture" excludes fractures indicated as pathological.

Table 6.7 (Continued)
Locally Verified Outcomes (Annualized Percentages) by Race/Ethnicity for Clinical Trial

Data as of: August 27, 2000

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)	43.1	40.5	42.9	42.0	44.4	40.1
Cardiovascular						
CHD[1]	1 (0.10%)	4 (0.08%)	76 (0.30%)	15 (0.15%)	675 (0.33%)	11 (0.35%)
·Coronary death	1 (0.10%)	2 (0.04%)	32 (0.13%)	3 (0.03%)	181 (0.09%)	4 (0.13%)
Total MI[2]	0 (0.00%)	3 (0.06%)	51 (0.20%)	12 (0.12%)	535 (0.26%)	9 (0.29%)
Clinical MI	0 (0.00%)	3 (0.06%)	47 (0.19%)	12 (0.12%)	520 (0.25%)	8 (0.26%)
Definite Silent MI	0 (0.00%)	0 (0.00%)	4 (0.02%)	0 (0.00%)	28 (0.01%)	2 (0.06%)
Possible Silent MI	0 (0.00%)	3 (0.06%)	15 (0.06%)	4 (0.04%)	101 (0.05%)	0 (0.00%)
Angina	5 (0.48%)	15 (0.29%)	129 (0.52%)	32 (0.32%)	904 (0.44%)	12 (0.38%)
CABG/PTCA	1 (0.10%)	8 (0.16%)	87 (0.35%)	22 (0.22%)	795 (0.39%)	7 (0.22%)
Carotid artery disease	3 (0.29%)	2 (0.04%)	15 (0.06%)	1 (0.01%)	179 (0.09%)	2 (0.06%)
Congestive heart failure	0 (0.00%)	1 (0.02%)	77 (0.31%)	8 (0.08%)	402 (0.20%)	6 (0.19%)
Stroke	3 (0.29%)	11 (0.21%)	59 (0.24%)	16 (0.16%)	416 (0.20%)	5 (0.16%)
PVD	2 (0.19%)	0 (0.00%)	21 (0.08%)	3 (0.03%)	109 (0.05%)	0 (0.00%)
DVT	1 (0.10%)	1 (0.02%)	15 (0.06%)	2 (0.02%)	137 (0.07%)	0 (0.00%)
PE	1 (0.10%)	1 (0.02%)	8 (0.03%)	0 (0.00%)	73 (0.04%)	0 (0.00%)
CHD[1]/Possible Silent MI	1 (0.10%)	7 (0.14%)	90 (0.36%)	19 (0.19%)	762 (0.37%)	11 (0.35%)
Coronary disease[3]	6 (0.57%)	23 (0.45%)	266 (1.07%)	52 (0.52%)	1834 (0.89%)	26 (0.83%)
DVT/PE	2 (0.19%)	1 (0.02%)	19 (0.08%)	2 (0.02%)	177 (0.09%)	0 (0.00%)
Total CVD	14 (1.33%)	36 (0.70%)	341 (1.37%)	71 (0.70%)	2516 (1.23%)	31 (0.99%)
Cancer						
Breast cancer[4]	2 (0.19%)	21 (0.41%)	59 (0.24%)	23 (0.23%)	865 (0.42%)	5 (0.16%)
Invasive breast cancer	2 (0.19%)	18 (0.35%)	45 (0.18%)	17 (0.17%)	670 (0.33%)	2 (0.06%)
Non-invasive breast cancer	0 (0.00%)	3 (0.06%)	14 (0.06%)	6 (0.06%)	204 (0.10%)	3 (0.10%)
Ovary cancer	1 (0.10%)	0 (0.00%)	9 (0.04%)	1 (0.01%)	91 (0.04%)	0 (0.00%)
Endometrial Cancer[5]	1 (0.21%)	1 (0.03%)	9 (0.08%)	6 (0.11%)	114 (0.09%)	2 (0.11%)
Colorectal cancer	2 (0.19%)	5 (0.10%)	34 (0.14%)	14 (0.14%)	237 (0.12%)	4 (0.13%)
Other cancer[6,7]	5 (0.48%)	16 (0.31%)	74 (0.30%)	23 (0.23%)	922 (0.45%)	10 (0.32%)
Total cancer	11 (1.05%)	43 (0.84%)	182 (0.73%)	65 (0.65%)	2186 (1.06%)	20 (0.64%)
Fractures						
Hip fracture	0 (0.00%)	1 (0.02%)	7 (0.03%)	2 (0.02%)	207 (0.10%)	2 (0.06%)
Vertebral fracture	0 (0.00%)	5 (0.10%)	2 (0.01%)	4 (0.04%)	222 (0.11%)	1 (0.03%)
Other fracture[6,8]	12 (1.14%)	53 (1.03%)	164 (0.66%)	86 (0.85%)	2929 (1.43%)	31 (0.99%)
Total fracture	12 (1.14%)	58 (1.13%)	172 (0.69%)	90 (0.89%)	3265 (1.59%)	34 (1.09%)
Deaths						
Cardiovascular deaths	1 (0.10%)	3 (0.06%)	40 (0.16%)	3 (0.03%)	237 (0.12%)	4 (0.13%)
Cancer deaths	2 (0.19%)	7 (0.14%)	35 (0.14%)	9 (0.09%)	349 (0.17%)	2 (0.06%)
Deaths: other known cause	3 (0.29%)	1 (0.02%)	9 (0.04%)	2 (0.02%)	86 (0.04%)	1 (0.03%)
Deaths: unknown cause	1 (0.10%)	0 (0.00%)	8 (0.03%)	1 (0.01%)	37 (0.02%)	0 (0.00%)
Deaths: not yet adjudicated	1 (0.10%)	6 (0.12%)	15 (0.06%)	2 (0.02%)	107 (0.05%)	2 (0.06%)
Total death	8 (0.76%)	17 (0.33%)	107 (0.43%)	17 (0.17%)	816 (0.40%)	9 (0.29%)

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

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

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

[4] Excludes eight 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.

[7] Excludes non-melanoma skin cancer

[8] "Other fracture" excludes fractures indicated as pathological.

Table 6.8
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Age and Race/Ethnicity for Clinical Trial

Data as of: August 27, 2000

Outcome	Total		Age 50-54		55-59		60-69		70-79	
Number randomized	68135		9191		14665		31392		12887	
Mean follow-up (months)	44.0		50.2		46.3		42.1		41.4	
Hospitalizations										
Ever	18548	(7.43%)	1911	(4.97%)	3278	(5.79%)	8709	(7.90%)	4650	(10.46%)
Two or more	7102	(2.84%)	649	(1.69%)	1135	(2.01%)	3308	(3.00%)	2010	(4.52%)
Other										
DVT[1]	414	(0.17%)	34	(0.09%)	64	(0.11%)	190	(0.17%)	126	(0.28%)
PE	194	(0.08%)	13	(0.03%)	29	(0.05%)	86	(0.08%)	66	(0.15%)
Diabetes (treated)	4570	(1.83%)	523	(1.36%)	949	(1.68%)	2162	(1.96%)	936	(2.11%)
Gallbladder disease[2]	2988	(1.20%)	430	(1.12%)	674	(1.19%)	1384	(1.26%)	500	(1.13%)
Hysterectomy[3]	1074	(0.74%)	150	(0.68%)	234	(0.67%)	486	(0.77%)	204	(0.82%)
Glaucoma	3665	(1.47%)	312	(0.81%)	601	(1.06%)	1770	(1.61%)	982	(2.21%)
Osteoporosis	7481	(3.00%)	593	(1.54%)	1181	(2.09%)	3614	(3.28%)	2093	(4.71%)
Osteoarthritis[4]	11871	(5.10%)	1144	(3.26%)	2188	(4.17%)	5612	(5.43%)	2927	(6.96%)
Rheumatoid arthritis	2417	(0.97%)	315	(0.82%)	533	(0.94%)	1070	(0.97%)	499	(1.12%)
Intestinal polyps	4865	(1.95%)	501	(1.30%)	913	(1.61%)	2411	(2.19%)	1040	(2.34%)
Lupus	408	(0.16%)	63	(0.16%)	91	(0.16%)	196	(0.18%)	58	(0.13%)
Kidney Stones[4]	916	(0.51%)	117	(0.46%)	197	(0.50%)	433	(0.53%)	169	(0.51%)
Cataracts[4]	11764	(6.53%)	460	(1.79%)	1375	(3.46%)	6183	(7.57%)	3746	(11.33%)
Pills for hypertension	22215	(8.90%)	2263	(5.88%)	4109	(7.26%)	10498	(9.52%)	5345	(12.03%)

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)	43.1		40.5		42.9		42.0		44.4		40.1	
Hospitalizations												
Ever	79	(7.51%)	255	(4.97%)	1887	(7.57%)	608	(6.04%)	15517	(7.56%)	202	(6.45%)
Two or more	37	(3.52%)	80	(1.56%)	736	(2.95%)	200	(1.99%)	5986	(2.91%)	63	(2.01%)
Other												
DVT[1]	1	(0.10%)	2	(0.04%)	40	(0.16%)	6	(0.06%)	362	(0.18%)	3	(0.10%)
PE	1	(0.10%)	2	(0.04%)	14	(0.06%)	3	(0.03%)	170	(0.08%)	4	(0.13%)
Diabetes (treated)	41	(3.90%)	143	(2.79%)	1059	(4.25%)	303	(3.01%)	2950	(1.44%)	74	(2.36%)
Gallbladder disease[2]	14	(1.33%)	49	(0.96%)	248	(0.99%)	152	(1.51%)	2475	(1.21%)	50	(1.60%)
Hysterectomy[3]	3	(0.64%)	19	(0.57%)	68	(0.63%)	40	(0.71%)	936	(0.76%)	8	(0.44%)
Glaucoma	20	(1.90%)	86	(1.68%)	583	(2.34%)	156	(1.55%)	2769	(1.35%)	51	(1.63%)
Osteoporosis	33	(3.14%)	175	(3.41%)	360	(1.44%)	310	(3.08%)	6489	(3.16%)	114	(3.64%)
Osteoarthritis[4]	68	(6.86%)	238	(4.79%)	1353	(5.75%)	589	(6.23%)	9433	(4.94%)	190	(6.35%)
Rheumatoid arthritis	26	(2.47%)	53	(1.03%)	463	(1.86%)	239	(2.37%)	1600	(0.78%)	36	(1.15%)
Intestinal polyps	21	(2.00%)	105	(2.05%)	514	(2.06%)	169	(1.68%)	3988	(1.94%)	68	(2.17%)
Lupus	5	(0.48%)	7	(0.14%)	57	(0.23%)	19	(0.19%)	315	(0.15%)	5	(0.16%)
Kidney Stones[4]	5	(0.66%)	24	(0.63%)	91	(0.52%)	58	(0.78%)	725	(0.49%)	13	(0.55%)
Cataracts[4]	56	(7.35%)	274	(7.16%)	1151	(6.51%)	454	(6.08%)	9663	(6.52%)	166	(7.08%)
Pills for hypertension	106	(10.07%)	549	(10.70%)	3539	(14.19%)	919	(9.12%)	16777	(8.17%)	325	(10.39%)

[1] Inpatient DVT only.

[2] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

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

[4] These outcomes have not been self-reported on all versions of Form 33. The annualized percentages are corrected for the different amounts of follow-up.

Table 6.9
Locally Confirmed Other Cancers[1]: CT and OS Participants

Data as of: August 27, 2000

	CT		OS	
Number of participants	68135		93720	
Mean follow-up time (months)	44.0		38.4	
Ppts with other cancer	987	(0.40%)	1130	(0.38%)
Adrenal gland	1	(<0.01%)	3	(<0.01%)
Anus	3	(<0.01%)	7	(<0.01%)
Biliary tract, parts of (other/unspecifi	13	(0.01%)	10	(<0.01%)
Bladder	59	(0.02%)	64	(0.02%)
Bones/joints/articular cartilage (limbs)	2	(<0.01%)	2	(<0.01%)
Bones/joints/articular cartilage (other)	2	(<0.01%)	1	(<0.01%)
Brain	32	(0.01%)	35	(0.01%)
Cervix	29	(0.01%)	13	(<0.01%)
Connective/subcutaneous/soft tissues	3	(<0.01%)	6	(<0.01%)
Endocrine glands, related structures	1	(<0.01%)	1	(<0.01%)
Esophagus	6	(<0.01%)	12	(<0.01%)
Eye and adnexa	3	(<0.01%)	3	(<0.01%)
Genital organs	11	(<0.01%)	8	(<0.01%)
Kidney	46	(0.02%)	51	(0.02%)
Larynx	4	(<0.01%)	2	(<0.01%)
Leukemia	45	(0.02%)	42	(0.01%)
Liver	11	(<0.01%)	13	(<0.01%)
Lung (bronchus)	190	(0.08%)	233	(0.08%)
Lymph nodes	6	(<0.01%)	2	(<0.01%)
Lymphoma, Hodgkins Disease	5	(<0.01%)	5	(<0.01%)
Lymphoma, Non-Hodgkins	82	(0.03%)	105	(0.03%)
Melanoma of the skin	128	(0.05%)	161	(0.05%)
Multiple myeloma	39	(0.02%)	35	(0.01%)
Oral (mouth)	7	(<0.01%)	5	(<0.01%)
Palate	2	(<0.01%)	2	(<0.01%)
Pancreas	58	(0.02%)	53	(0.02%)
Parotid gland (Stensen's duct)	2	(<0.01%)	7	(<0.01%)
Peripheral nerves and autonomic nervous system	0	(0.00%)	2	(<0.01%)
Respiratory system, intrathoracic, other	1	(<0.01%)	2	(<0.01%)
Salivary glands, major (other/unspecifie	1	(<0.01%)	2	(<0.01%)
Stomach	9	(<0.01%)	11	(<0.01%)
Thyroid	32	(0.01%)	35	(0.01%)
Tongue, part of (other/unspecified)	10	(<0.01%)	6	(<0.01%)
Urinary organs (other/unspecified)	1	(<0.01%)	9	(<0.01%)
Uterus, not otherwise specified	15	(0.01%)	25	(0.01%)
Other/unknown site of cancer	138	(0.06%)	172	(0.06%)

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

Table 6.10
Locally Confirmed Other Fractures: CT and OS Participants

Data as of: August 27, 2000

	CT		OS[1]	
Locally Confirmed				
Number of participants	68135		7203	
Mean follow-up time (months)	44.0		44.4	
Ppts with other fractures	3274	(1.31%)	351	(1.32%)
Ankle	556	(0.22%)	55	(0.21%)
Carpal bone(s) in wrist	75	(0.03%)	5	(0.02%)
Clavicle or collar bone	47	(0.02%)	9	(0.03%)
Humerus, shaft/unspecified	29	(0.01%)	4	(0.02%)
Humerus, upper end	313	(0.13%)	28	(0.11%)
Humerus, lower end	40	(0.02%)	5	(0.02%)
Metacarpal bone(s)	122	(0.05%)	8	(0.03%)
Patella	135	(0.05%)	20	(0.08%)
Pelvis	98	(0.04%)	20	(0.08%)
Radius or ulna	917	(0.37%)	101	(0.38%)
Sacrum and coccyx	30	(0.01%)	5	(0.02%)
Scapula	15	(0.01%)	4	(0.02%)
Shaft of femur	43	(0.02%)	2	(0.01%)
Tarsal/metatarsal bones	557	(0.22%)	60	(0.23%)
Tibia and fibula	295	(0.12%)	23	(0.09%)
Tibial plateau	60	(0.02%)	4	(0.02%)
Upper radius/ulna	183	(0.07%)	21	(0.08%)
Unknown other fracture	1	(<0.01%)	0	(0.00%)
Self-Reports				
Number of participants			93720	
Mean follow-up time (months)			38.4	
Upper Leg			131	(0.04%)
Pelvis			200	(0.07%)
Knee			309	(0.10%)
Upper Arm			521	(0.17%)
Lower Arm			1413	(0.47%)
Hand			195	(0.06%)
Lower Leg			1150	(0.38%)
Foot			1026	(0.34%)
Tailbone			64	(0.02%)
Elbow			259	(0.09%)
Vertebra			559	(0.19%)
Other Fracture			1379	(0.46%)

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

Table 6.11
Cross-tabulation of ECG Codes Suggesting an Incident MI and Locally Confirmed and Self-Reported MI for all CT participants

Data as of: August 27, 2000

	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]	41136	8	191	41335
Borderline Q-wave change[4]	1238	1	27	1266
Ischemic ST-T evolution[5]	729	1	25	755
Possible evolving Q-wave MI[6]	97[7]	1	15	113
Evolving Q-wave MI[8]	20[9]	0	12	32
Total	43220	11	270	43501
HRT Participants				
No significant Q or ST-T evolution[3]	15965	6	86	16057
Borderline Q-wave change[4]	520	1	11	532
Ischemic ST-T evolution[5]	330	0	8	338
Possible evolving Q-wave MI[6]	45[7]	1	6	52
Evolving Q-wave MI[8]	7[9]	0	7	14
Total	16867	8	118	16993
DM Participants				
No significant Q or ST-T evolution[3]	30153	3	130	30286
Borderline Q-wave change[4]	868	1	19	888
Ischemic ST-T evolution[5]	507	1	18	526
Possible evolving Q-wave MI[6]	59[7]	0	13	72
Evolving Q-wave MI[8]	15[9]	0	5	20
Total	31602	5	185	31792
CaD Participants				
No significant Q or ST-T evolution[3]	23561	4	65	23630
Borderline Q-wave change[4]	727	0	11	738
Ischemic ST-T evolution[5]	380	0	7	387
Possible evolving Q-wave MI[6]	57[7]	1	5	63
Evolving Q-wave MI[8]	13[9]	0	5	18
Total	24738	5	93	24836

[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 6.12
Cause of Death: CT and OS Participants (Annualized Percentages)

Data as of: August 27, 2000

	CT		OS	
Number Randomized	68135		93720	
Mean Follow-up Time (months)	44.0		38.4	
Total death	974	(0.39%)	1437	(0.48%)
Adjudicated death	841	(0.34%)	1170	(0.39%)
Final Adjudicated Death	778	(0.31%)	1064	(0.35%)
Temporary Adjudicated Death	63	(0.03%)	106	(0.04%)
Cardiovascular				
Athereosclerotic cardiac	119	(0.05%)	113	(0.04%)
Cerebrovascular	62	(0.02%)	81	(0.03%)
Other cardiovascular	67	(0.03%)	76	(0.03%)
Unknown cardiovascular	19	(0.01%)	17	(0.01%)
Total cardiovascular deaths	267	(0.11%)	287	(0.10%)
Cancer				
Breast cancer	10	(<0.01%)	64	(0.02%)
Ovarian cancer	27	(0.01%)	37	(0.01%)
Endometrial cancer	3	(<0.01%)	9	(0.01%)
Colorectal cancer	41	(0.02%)	51	(0.02%)
Other cancer	303	(0.12%)	371	(0.12%)
Unknown cancer site	20	(0.01%)	40	(0.01%)
Total cancer deaths	404	(0.16%)	572	(0.19%)
Accident/injury				
Homicide	4	(<0.01%)	4	(<0.01%)
Accident	25	(0.01%)	28	(0.01%)
Suicide	4	(<0.01%)	10	(<0.01%)
Other injury	3	(<0.01%)	2	(<0.01%)
Total accidental deaths	36	(0.01%)	44	(0.01%)
Other				
Other known cause	66	(0.03%)	150	(0.05%)
Unknown cause	46	(0.02%)	79	(0.03%)
Total deaths – other causes	112	(0.04%)	229	(0.08%)

Table 6.13
Lost-to-Follow-up and Vital Status by Clinic: CT Participants

Data as of: August 27, 2000

	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	30	1.7	1601	93.2	37	2.2	0	0.0	15	0.9	35	2.0	1718
Birmingham	42	2.3	1723	94.0	35	1.9	0	0.0	20	1.1	13	0.7	1833
Bowman	18	1.2	1433	94.6	34	2.2	0	0.0	8	0.5	21	1.4	1514
Brigham	30	1.3	2220	96.1	43	1.9	1	<0.1	2	0.1	13	0.6	2309
Buffalo	26	1.6	1563	97.2	3	0.2	1	0.1	11	0.7	4	0.2	1608
Chapel Hill	17	1.1	1486	96.8	9	0.6	0	0.0	22	1.4	1	0.1	1535
Chicago	37	2.3	1487	91.6	32	2.0	8	0.5	50	3.1	9	0.6	1623
Chi-Rush	19	1.4	1244	93.5	15	1.1	0	0.0	25	1.9	27	2.0	1330
Cincinnati	9	0.6	1160	83.2	113	8.1	20	1.4	26	1.9	66	4.7	1394
Columbus	26	1.7	1494	95.8	8	0.5	0	0.0	25	1.6	7	0.4	1560
Detroit	7	0.5	1131	82.0	99	7.2	0	0.0	91	6.6	52	3.8	1380
Gainesville	33	1.6	1961	95.8	7	0.3	0	0.0	36	1.8	11	0.5	2048
GWU-DC	14	0.9	1465	96.8	13	0.9	1	0.1	10	0.7	11	0.7	1514
Honolulu	12	0.9	1330	94.7	15	1.1	1	0.1	30	2.1	17	1.2	1405
Houston	7	0.6	1197	94.5	23	1.8	0	0.0	37	2.9	3	0.2	1267
Iowa City	39	1.6	2358	96.9	15	0.6	0	0.0	10	0.4	11	0.5	2433
Irvine	17	1.1	1487	92.0	34	2.1	3	0.2	30	1.9	45	2.8	1616
L.A.	19	1.1	1604	94.9	33	2.0	0	0.0	25	1.5	10	0.6	1691
La Jolla	35	1.6	1980	92.0	60	2.8	0	0.0	5	0.2	72	3.3	2152
Madison	17	1.1	1503	96.7	8	0.5	1	0.1	19	1.2	7	0.5	1555
Medlantic	26	1.7	1403	93.5	26	1.7	0	0.0	25	1.7	21	1.4	1501
Memphis	36	2.1	1595	91.4	51	2.9	1	0.1	42	2.4	20	1.1	1745
Miami	15	1.0	1246	84.0	97	6.5	0	0.0	28	1.9	97	6.5	1483
Milwaukee	18	1.1	1517	91.9	75	4.5	0	0.0	26	1.6	15	0.9	1651
Minneapolis	31	1.6	1902	95.5	41	2.1	0	0.0	6	0.3	12	0.6	1992
Nevada	32	2.1	1445	96.9	2	0.1	0	0.0	12	0.8	0	0.0	1491
Newark	35	1.4	2281	92.7	56	2.3	0	0.0	66	2.7	23	0.9	2461
NY-City	24	1.3	1754	93.1	33	1.8	2	0.1	28	1.5	44	2.3	1885
Oakland	20	1.3	1504	95.3	34	2.2	0	0.0	14	0.9	7	0.4	1579
Pawtucket	32	1.2	2514	94.8	18	0.7	0	0.0	37	1.4	50	1.9	2651
Pittsburgh	28	1.7	1593	96.1	17	1.0	0	0.0	12	0.7	7	0.4	1657
Portland	25	1.5	1512	93.0	33	2.0	0	0.0	23	1.4	33	2.0	1626
San Antonio	9	0.7	1261	91.2	3	0.2	0	0.0	64	4.6	45	3.3	1382
Seattle	34	1.9	1707	95.3	12	0.7	4	0.2	15	0.8	19	1.1	1791
Stanford	20	1.1	1739	96.5	13	0.7	4	0.2	21	1.2	6	0.3	1803
Stonybrook	17	1.3	1281	94.6	32	2.4	0	0.0	13	1.0	11	0.8	1354
Torrance	15	1.5	890	87.1	65	6.4	2	0.2	23	2.3	27	2.6	1022
Tucson	41	2.0	1873	91.2	32	1.6	0	0.0	44	2.1	63	3.1	2053
U.C. Davis	43	2.3	1747	92.4	62	3.3	6	0.3	25	1.3	8	0.4	1891
Worcester	19	1.2	1541	94.4	49	3.0	0	0.0	3	0.2	20	1.2	1632
Total	974	1.4	63732	93.5	1387	2.0	55	0.1	1024	1.5	963	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] Participants without a Form 33 within the last 18 months, who have been located (as indicated on Form 23) within the last 6 months.

[4] Participants with codes 5 (no follow-up) or 8 (absolutely no follow-up) on Form 7.

[5] Participants not in any of the above categories.

Table 6.14
Lost-to-Follow-up and Vital Status by Clinic: OS Participants

Data as of: August 27, 2000

	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	1.3	2312	93.6	60	2.4	0	0.0	6	0.2	59	2.4	2470
Birmingham	55	2.2	2302	91.0	96	3.8	0	0.0	34	1.3	42	1.7	2529
Bowman	32	1.4	2030	91.3	106	4.8	0	0.0	17	0.8	39	1.8	2224
Brigham	18	0.6	2823	95.8	69	2.3	1	<0.1	0	0.0	35	1.2	2946
Buffalo	63	2.8	2147	95.5	16	0.7	2	0.1	6	0.3	14	0.6	2248
Chapel Hill	26	1.2	2018	96.8	28	1.3	0	0.0	11	0.5	1	<0.1	2084
Chicago	29	1.5	1687	89.2	116	6.1	16	0.8	14	0.7	29	1.5	1891
Chi-Rush	21	1.0	1659	80.7	209	10.2	1	<0.1	23	1.1	142	6.9	2055
Cincinnati	20	0.9	1945	86.4	164	7.3	14	0.6	14	0.6	93	4.1	2250
Columbus	25	1.1	2117	95.2	60	2.7	6	0.3	8	0.4	7	0.3	2223
Detroit	21	1.0	1816	86.0	155	7.3	3	0.1	47	2.2	69	3.3	2111
Gainesville	44	1.6	2658	95.2	15	0.5	6	0.2	48	1.7	22	0.8	2793
GWU-DC	43	1.9	2158	96.0	43	1.9	1	<0.1	1	<0.1	3	0.1	2249
Honolulu	23	1.1	1989	94.1	42	2.0	3	0.1	50	2.4	7	0.3	2114
Houston	43	2.0	2037	95.7	5	0.2	0	0.0	37	1.7	6	0.3	2128
Iowa City	30	1.0	3008	96.4	47	1.5	0	0.0	11	0.4	24	0.8	3120
Irvine	38	1.7	2068	92.8	43	1.9	1	<0.1	36	1.6	42	1.9	2228
L.A.	26	1.2	2118	96.5	21	1.0	0	0.0	19	0.9	10	0.5	2194
La Jolla	51	1.5	3061	88.3	179	5.2	1	<0.1	8	0.2	165	4.8	3465
Madison	39	2.0	1910	96.3	16	0.8	0	0.0	8	0.4	11	0.6	1984
Medlantic	28	1.3	1924	87.8	93	4.2	12	0.5	3	0.1	132	6.0	2192
Memphis	40	1.6	2294	91.1	99	3.9	9	0.4	35	1.4	41	1.6	2518
Miami	22	1.6	1068	76.1	165	11.8	2	0.1	14	1.0	133	9.5	1404
Milwaukee	20	0.9	2117	94.1	67	3.0	2	0.1	9	0.4	34	1.5	2249
Minneapolis	36	1.3	2603	95.6	49	1.8	2	0.1	15	0.6	18	0.7	2723
Nevada	72	3.3	2040	93.7	56	2.6	1	<0.1	7	0.3	1	<0.1	2177
Newark	42	1.2	3072	91.0	109	3.2	8	0.2	28	0.8	115	3.4	3374
NY-City	36	1.2	2541	87.6	103	3.5	2	0.1	23	0.8	197	6.8	2902
Oakland	38	1.9	1951	95.1	37	1.8	2	0.1	14	0.7	9	0.4	2051
Pawtucket	60	1.7	3342	93.1	83	2.3	0	0.0	12	0.3	92	2.6	3589
Pittsburgh	37	1.9	1729	90.2	97	5.1	1	0.1	8	0.4	45	2.3	1917
Portland	25	1.1	2050	91.9	100	4.5	2	0.1	36	1.6	17	0.8	2230
San Antonio	20	1.0	1783	91.9	27	1.4	1	0.1	41	2.1	68	3.5	1940
Seattle	44	2.6	1568	94.4	26	1.6	0	0.0	12	0.7	11	0.7	1661
Stanford	52	1.9	2535	94.4	43	1.6	7	0.3	28	1.0	19	0.7	2684
Stonybrook	27	1.3	1912	94.3	53	2.6	1	<0.1	9	0.4	25	1.2	2027
Torrance	24	1.6	1323	88.0	56	3.7	27	1.8	21	1.4	53	3.5	1504
Tucson	56	2.0	2505	90.4	90	3.2	4	0.1	32	1.2	85	3.1	2772
U.C. Davis	48	2.1	2125	93.9	57	2.5	13	0.6	14	0.6	5	0.2	2262
Worcester	30	1.3	2095	93.6	80	3.6	1	<0.1	3	0.1	29	1.3	2238
Total	1437	1.5	86440	92.2	2980	3.2	152	0.2	762	0.8	1949	2.1	93720

[1] Participants who have filled in a Form 33 within the last 15 months.

[2] Participants who last filled in a Form 33 between 15 and 24 months ago.

[3] Participants without a Form 33 within the last 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. Laboratory Studies

7.1 Overview

Blood samples are collected on all CT participants at baseline and year 1 and on a 6% subsample of participants at years 3, 6, and 9. Blood samples are collected on all OS participants at baseline and year 3. All blood samples are obtained in the fasting state (at least 12 hours), maintained at 4° C until plasma or serum is separated. Plasma/serum aliquots and buffy coats are then frozen at -70° C and sent on dry ice to the central repository (McKesson BioService) where storage at -70° C is maintained.

The analyses of the twenty core analytes are done by Medical Research Laboratories, Highland Heights, Kentucky (MRL). Samples are pulled in pairs (baseline and Year 1) and shipped in monthly batches on dry ice to MRL for analysis in a blinded fashion. MRL has completed the analyses of baseline and Year 1 blood samples on the 6% subsample of CT participants. See *Sections 2.5* and *3.3* in this report for presentation of the results for HRT and DM. MRL has also completed the analyses of the 1% OS-MPS subsample participants. See *Section 5.3* in the Feb. 1, 1999 to August 25, 1999 Semi-Annual Progress Report for the results.

7.2 MRL Laboratory Methods

Micronutrients
Vitamin A, vitamin E, and the carotenoids are measured by high performance liquid chromatography.[1,2] After the addition of an internal standard, serum is extracted into hexane and injected onto a C_{18} reverse phase column. The analytes are measured at wavelengths of 292 nm and 452 nm.

Factor VIIc
Factor VII activity is measured using citrated plasma on a MLA ELECTRA 1400C (Medical Laboratory Instrumentation Inc., Mt. Vernon, New York) using a turbidometric detection system and utilizing Factor VII deficient plasma (George King Bio-Medical, Overland Park, Kansas) in preparation of the standard curve.[3] Monthly interassay coefficients of variation were approximately 7.8%, 5%, and 4% for mean activities of 8%, 45%, and 99%, respectively.

Factor VIIag
Factor VII antigen is measured in citrated plasma using a sandwich ELISA assay (Asserchrom VIIag, Diagnostica Stago, France) in which specific rabbit anti-human Factor VII antibodies are used.[4] Monthly interassay coefficients of variation were 5-10%, 4-6%, and 3-5% at mean concentrations of 8, 45, and 101%.

Fibrinogen
Fibrinogen is measured in citrated plasma on a MLA ELECTRA 1400C (Medical Laboratory Automation Inc., Mt. Vernon, New York) using a clot based turbidometric detection system.[5] Monthly interassay coefficients of variation were 2.3 - 3.5% and 2.6 - 3.6% at mean concentrations of 250 and 140 mg/dl, respectively.

Glucose

Glucose is measured using the hexokinase method on the Hitachi 747 (Boehringer Mannheim Diagnostics, Indianapolis, Indiana).[6,7] An ongoing monthly quality assurance program is maintained with the Diabetes Diagnostic Laboratory (DDL) at the University of Missouri. Monthly interassay coefficients of variation were < 2% for mean concentrations of 84 and 301 mg/dL.

Insulin

Serum insulin is measured in a step-wise sandwich ELISA procedure on an ES 300 (BMD, Indianapolis, Indiana). A monoclonal insulin antibody bound to the tube in turn binds insulin in proportion to its concentration in the sample. The bound insulin is then quantitated using a second monoclonal antibody labeled with peroxidase (POD) which then reacts with a chromogenic substrate to generate a photometrically monitored chromogen.[8] The assay was externally monitored as part of a monthly quality assurance program by the Diabetes Diagnostic Laboratory (DDL) at the University of Missouri, Columbia, which served as the USA reference laboratory for the Diabetes Collaborative Clinical Trial (DCCT). Monthly interassay coefficients of variation (CV) were 4.7 – 9.5% and 3.2 – 7.9% at mean concentrations of 26.6 and 80.6 microIU/ml, respectively.

Lipids, Lipoproteins and Apolipoproteins

Throughout the study, the laboratory participated in, and remained certified by the National Heart Lung and Blood Institute, Centers for Disease Control part III program.[9] All lipid, lipoprotein and apolipoprotein fractions are analyzed using EDTA treated plasma as previously described.[10,11]

Total cholesterol and triglycerides are analyzed by enzymatic methods on a Hitachi 747 analyzer (Boehringer Mannheim Diagnostics, Indianapolis, Indiana) as previously described.[10] High-density lipoprotein cholesterol (HDL-C) is isolated using heparin manganese chloride.[11] HDL_3 is separated directly from whole plasma by precipitation of VLDL, LDL, and HDL_2 with dextran sulfate (MW 50,000) and $MgCl_2$.[12] The supernate is measured enzymatically on the Hitachi 747. The HDL_2 is calculated as the difference in cholesterol between the previously isolated HDL fraction and this HDL_3 fraction.

Lipoprotein (a) [Lp(a)] is quantitated using an isoform independent bi-site ELISA assay procedure based on the linkage of apo(a) to apoB.[13] Standardization and ongoing quality control was established and maintained with Northwest Lipid Research Clinic.

7.3 MRL Quality Control

MRL maintains comprehensive internal as well as external quality assurance programs. In addition to the NHLBI-CDC Lipid and DDL Glycemic Marker Programs already mentioned, MRL participates in CAP and Bio-Rad (Murex) proficiency programs. In addition, a WHI-specific long-term quality control program using two frozen pools to monitor the stability of the assays over time and blinded split samples to monitor assay precision and reproducibility was implemented. Samples of blinded Pools A and B as well as blinded split samples are included in each batch of samples sent to MRL. There are sufficient quality control pool aliquots and split duplicate samples to be used for the duration of the study.

Table 7.1 shows the mean and CV for each of the 20 analytes for the blinded pools A and B and *Table 7.2* shows the % CV from the blinded split duplicates. *Figure 7.1* shows the plot of fibrinogen values for Pool A over time. Values from five Pool A samples were included in each of the first five batches to establish the initial mean and standard deviation for the pool. For these first five batches, one point on the plot represents all the samples with the same value. One sample was included in each subsequent batch. Similar plots for all analytes in both Pool A and Pool B are updated and reviewed after analysis of each batch to monitor for drift in the analyses.

The CCC Laboratory Working Group holds regular conference calls to review ongoing laboratory quality control measures. Membership of the working group includes Andrea LaCroix, CCC, chair; Jacques Rossouw, Project Office; Evan Stein and Judy Miller, MRL; and Chu Chen and Bernedine Lund, CCC. The working group consults with WHI and outside expert advisors for input on biomarkers, DNA extraction and testing, and other issues as needed.

References:

1. Kaplan LA, Miller JA, Stein EA: Simultaneous measurement of serum retinol, tocopherols, carotenes, and carotenoids by High Performance Liquid Chromatography. J of Clin Lab Anal 1: 147-152, 1987.
2. Miller KW, Lorr NA, Yang CS. Simultaneous determination of plasma retinol, ∝-tocopherol, Lycopene, ∝-carotene, and B-carotene in High Performance Liquid Chromatography. Anal Biochemistry 1984: 138: 340-5.
3. Nygaard KK: Hemmorhagic Diseases: Photoelectric study of Blood Coagulability. St. Louis: CV Mosby Co., 1941.
4. Osterud B, Bjorklid E, Brown S F: The interaction of human blood coagulation factor VII and tissue factor: the effect of anti factor VII, anti tissue factor and dilisopropyl-fluorophosphate. Biochem, Biophys. Res. Commun., 88, 59-67, 1979.
5. Clauss A. Gerinnungsphysiologische Schnellmethode sur Bestimmung des Fibrinogens. Acta Haematol 1957; 17: 237.
6. Schmidt FH: Bergmeyer HU, ed. Methods of enzymatic analysis. 2nd Eng ed. New York, NY. Academic Press; 1974: 1196.
7. Peterson JI, Young DS. Anal Biochemistry. 1958; 23: 301.
8. Tietz NW. Fundamentals of Clin Chem. 3rd ed. Philadelphia, PA: WB Saunders Co: 1987: 544.
9. Myers GL, Cooper GR, Winn CL, Smith SJ. The Centers for Disease Control-National Heart, Lung, and Blood Institute Lipid Standardization Program: an approach to accurate and precise lipid measurements. Clin Lab Med 1989; 9 (1): 105-35.
10. Steiner P, Freidel J, Bremner W, Stein E. Standardization of micromethods for plasma cholesterol, triglyceride and HDL-cholesterol with the lipid clinics' methodology. J Clin Chem 1981; 19: 850.
11. Warnick G, Albers J. A comprehensive evaluation of the heparin manganese precipitation procedure for estimating high-density lipoprotein cholesterol. J lipid Res 1978; 19: 65-76.
12. Warnick G Russell. Measurement and clinical significance of high-density lipoprotein cholesterol subclasses. Laboratory Measurement of Lipids, Lipoproteins, and Apolipoproteins. Edited by Rifai/Warnick, pp. 207-222, 1994.
13. Vu Dac N, Mezdour H, Parra H J, Luc G, Luyeye I, Fruchart JC. A selective bi-site immunoenzymatic procedure for human Lp(a) lipoprotein quantification using monoclonal antibodies against apo[a] and apo B. J. Lipid Res 1989, 30 (9) 1437-43.

Table 7.1

Blood Specimen Analysis: Mean and CV[1] of QC Pools

Data as of: August 27, 2000

	Pool A			Pool B		
	N	Mean	CV	N	Mean	CV
Micronutrients						
Alpha-Carotene (µg/ml)	44	0.096	12.1	57	0.030	22.6
Alpha-tocopherol (µg/ml)	44	20.8	4.7	57	15.3	7.0
Beta-Carotene (µg/ml)	44	0.264	11.4	57	0.119	17.7
Beta-Cryptoxanthine (µg/ml)	44	0.094	10.2	57	0.049	13.8
Gamma-tocopherol (µg/ml)	44	1.79	4.6	57	2.84	7.7
Lycopene (µg/ml)	44	0.409	16.2	57	0.317	14.4
Lutein and Zeaxanthin (µg/ml)	44	0.198	7.9	57	0.217	12.4
Retinol (µg/ml)	44	0.633	5.6	57	0.621	7.1
Clotting Factors						
Factor VII Activity, Antigen (%)	44	114.6	9.2	70	131.9	7.0
Factor VII C (%)	44	121.7	5.2	70	126.1	5.2
Fibrinogen (mg/dl)	44	258.1	3.2	70	243.6	3.5
Hormones/Other						
Glucose (mg/dl)	44	83.2	2.3	57	91.0	2.0
Insulin (µIU/ml)	43	10.8	8.8	57	41.8	5.3
Lipoproteins						
HDL-2 (mg/dl)	41	15.5	13.7	61	14.0	15.6
HDL-3 (mg/dl)	41	39.9	4.8	61	39.1	4.7
HDL-C (mg/dl)	43	55.4	2.6	71	53.1	2.4
LDL-C (mg/dl)	43	124.9	2.2	71	152.9	1.5
Lp(a) (mg/dl)	18	89.8	6.2	70	43.7	12.4
Total Cholesterol (mg/dl)	43	207.3	1.3	71	238.8	0.8
Triglyceride (mg/dl)	43	134.8	2.0	71	164.1	1.8

[1] Coefficient of variation

Table 7.2

Blood Specimen Analysis: CV[1] (%) of Blinded Duplicates

Data as of: August 27, 2000

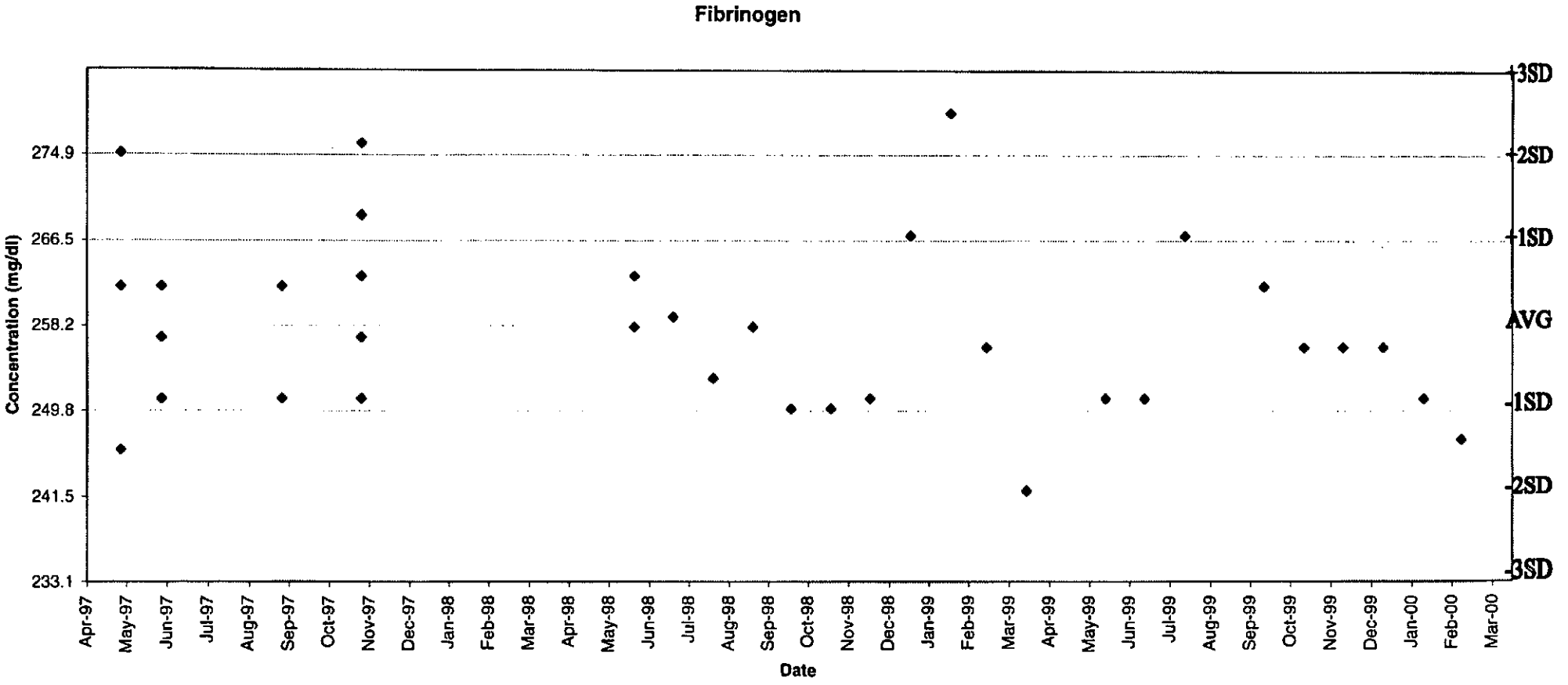
	N	CV% Mean	S.D.
Micronutrients			
Alpha-Carotene (µg/ml)	256	10.9	12.1
Alpha-tocopherol (µg/ml)	256	3.67	3.21
Beta-Carotene (µg/ml)	256	9.08	9.29
Beta-Cryptoxanthine (µg/ml)	256	6.91	6.60
Gamma-tocopherol (µg/ml)	256	5.12	5.87
Lycopene (µg/ml)	256	8.47	7.27
Lutein and Zeaxanthin (µg/ml)	256	6.33	5.87
Retinol (µg/ml)	256	3.76	3.12
Clotting Factors			
Factor VII Activity, Antigen (%)	237	4.63	3.91
Factor VII C (%)	232	3.57	3.98
Fibrinogen (mg/dl)	238	2.78	3.29
Hormones/Other			
Glucose (mg/dl)	251	1.37	1.50
Insulin (µIU/ml)	238	10.1	10.9
Lipoproteins			
HDL-2 (mg/dl)	243	7.92	8.72
HDL-3 (mg/dl)	243	2.64	2.50
HDL-C (mg/dl)	254	1.98	2.00
LDL-C (mg/dl)	248	1.81	1.49
Lp(a) (mg/dl)	244	15.0	17.3
Total Cholesterol (mg/dl)	255	0.92	0.94
Triglyceride (mg/dl)	255	1.45	1.85

[1] Coefficient of variation of duplicate results.

Figure 7.1

Cumulative Pool A Results

Data as of: August 27, 2000



8. Clinical Center Performance Monitoring

8.1 Performance Monitoring

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

8.2 PMC Committee Activity

The Performance Monitoring Committee (PMC) provides an overall monitoring of 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; Shirley Beresford, Seattle Clinical Center PI; Judith Hsia, George Washington Clinical Center PI; Linda Pottern and Shari Ludlum, Project Office; 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 March 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 also compared to study goals as well as Clinical Center averages. During this period, the following additional data was added for review on each Clinical Center: 1) cumulative task completeness and completeness in the previous six months for selected tasks in both the CT and at OS Year 3 visit, and 2) percentage of participants in each follow-up status category, such as no follow-up and lost-to-follow-up.

The A&R PMC conducted three Level 4 visits to Clinical Centers between March and August. To assist Clinic Center staff who participant on PMC visits, guidelines for conducting visits were drafted. After the most recent PMC visits were completed, the PMC began discussions on how to best follow-up with Clinical Centers that had been visited. The PMC assembled and distributed a compendium of adherence and retention tips, including those assembled from previous PMC A&R visit reports and feedback from Clinical Centers.

At the recommendation of the CCC, the PMC report was revised and shortened to focus on 3-5 performance measures in six areas: DM, HRT, CaD, OS, outcomes, and data quality. This reduced the report from over 100 measures in 10 tables to 25 measures in 6 tables. The revised report emphasizes the previous 6-month period or cumulative results rather than by contact type. Reviewing data for previous six months allows both the PMC and Clinical Centers to more easily monitor the effects of changes in clinic procedures. See *Tables 8.2-8.5.*

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.

Since March 1, the Outcomes PMC conducted targeted or specific conference calls with three Clinical Centers to discuss lagging outcomes processing. A CC outcomes staff person was to participant in the A&R PMC visit to one CC, and an CCC outcomes staff person made an informal visit to one Clinical Center to meet with outcomes staff and review their outcomes operations. The Outcomes PMC also drafted a congratulatory letter for Dr. Lenfant to send to CCs that had improved their outcomes processing.

Table 8.1
Performance Monitoring Committee Report
Data as of 8/27/00

DM

	Adjusted C-I[1]				Task Completeness Form 60 - FFQ[4]		% Stopped[5]	
	Average[2]		Sept 99-Aug 00[3]		Dec 99-May 00		Cum Aug 00	
	%	Rank	%	Rank	%	Rank	%	Rank
Nevada	13.5	1	12.1	1	93.6	7	3.9	8
Iowa City	11.9	2	10.8	5	100.0	1	2.8	3
Oakland	11.8	3	11.4	2	95.1	4	2.6	1
Madison	11.7	4	10.7	6	93.5	8	3.4	6
Stanford	11.4	5	10.7	7	93.0	9	4.0	9
Columbus	11.4	6	10.2	10	98.7	2	6.7	23
Seattle	11.3	7	10.4	9	89.3	19	5.9	20
Minneapolis	11.3	8	9.7	14	92.3	10	4.0	10
Pittsburgh	11.3	9	10.9	3	87.8	22	2.7	2
Milwaukee	11.1	10	10.1	11	89.0	21	3.8	7
GWU-DC	11.0	11	10.9	4	80.6	32	3.0	4
Gainesville	10.6	12	8.8	19	93.8	5	6.6	22
Irvine	10.5	13	9.5	15	92.3	10	8.1	29
Portland	10.4	14	8.9	18	85.0	27	7.5	28
Worcester	10.1	15	10.0	12	93.8	6	5.3	15
Chicago	9.9	16	10.5	8	89.3	20	8.7	32
Torrance	9.9	17	7.7	29	83.3	29	10.2	35
LA	9.7	18	9.3	17	79.8	34	6.2	21
Chapel Hill	9.5	19	9.9	13	90.9	14	3.1	5
Brigham	9.5	20	7.8	27	90.1	17	4.5	12
Buffalo	9.3	21	8.6	20	87.7	23	4.5	11
Pawtucket	9.3	22	8.3	24	91.5	13	6.8	24
UC Davis	9.2	23	8.5	21	79.6	35	6.9	25
Memphis	9.1	24	6.1	35	65.9	40	8.5	31
Tucson	9.1	25	9.4	16	90.5	15	7.5	27
Newark	9.0	26	7.0	31	83.2	30	8.9	33
Houston	8.8	27	8.5	22	92.0	12	4.6	13
Stony Brook	8.8	28	6.4	34	77.8	36	5.7	19
Bowman	8.7	29	6.7	32	87.3	26	4.8	14
Cincinnati	8.6	30	6.6	33	81.7	31	10.6	36
Honolulu	8.6	31	8.0	25	95.1	3	5.7	18
Atlanta	8.5	32	7.2	30	87.4	25	5.4	16
LaJolla	8.4	33	8.0	26	90.4	16	5.5	17
Chi-Rush	8.3	34	8.3	23	87.5	24	12.1	37
Detroit	7.8	35	7.8	28	69.3	38	13.2	38
NYC	7.5	36	6.1	36	89.7	18	9.3	34
Birmingham	7.1	37	5.6	38	70.9	37	7.0	26
San Antonio	6.6	38	5.6	37	83.5	28	15.4	40
Medlantic	6.1	39	4.6	40	80.6	33	8.4	30
Miami	5.1	40	4.9	39	67.3	39	15.2	39
CC Average	**9.6**		**8.5**		**86.5**		**6.6**	

1. Adjusted C-I defined as C-I = (C-I of collected FFQs) x (FFQ completion rate)
2. Based on FFQs collected at AV1-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 May '00; excludes deaths
5. From *WHIP CCC0751- DM Intervention & F/U Status*, includes stopped intervention, stopped F/U, lost-to-F/U, and deceased participants

Table 8.2
Performance Monitoring Committee Report
Data as of 8/27/00

HRT Intervention

	Adherence Summary				Task Completeness Dec 99-May 00				% Stopped[5]	
	Average[1]		Sept 99-Aug 00[2]		Form 10[3]		Form 85[4]		Cum Aug 00	
	%	Rank	%	Rank	%	Rank	%	Rank	%	Rank
Oakland	83.0	1	80.5	1	97.2	8	94.8	6	17.3	1
Iowa City	77.9	2	73.7	2	97.8	5	98.2	1	20.8	3
Stanford	74.5	3	69.1	4	97.0	10	79.2	38	24.3	5
Chapel Hill	74.1	4	68.0	9	93.7	24	94.0	9	25.9	10
Minneapolis	73.5	5	70.0	3	95.4	18	95.8	4	25.1	7
Madison	73.3	6	68.5	6	97.0	9	94.6	7	28.7	15
Gainesville	72.4	7	67.2	10	97.4	6	92.7	12	32.9	24
Cincinnati	72.1	8	68.5	5	88.2	35	89.9	22	24.9	6
LA	72.0	9	68.2	8	93.1	27	94.9	5	20.7	2
Portland	72.0	10	65.6	13	92.9	28	88.3	25	25.4	9
Milwaukee	71.4	11	67.1	11	91.5	29	92.5	13	25.2	8
Brigham	71.2	12	68.3	7	98.9	1	94.0	8	26.9	11
Pittsburgh	68.5	13	64.2	16	95.7	15	93.4	10	28.6	13
Pawtucket	68.3	14	63.4	17	98.7	2	91.6	14	33.8	26
Worcester	68.3	15	65.0	14	95.6	16	96.6	2	30.7	18
Nevada	68.1	16	66.1	12	98.3	3	96.1	3	28.6	13
Chicago	67.0	17	64.4	15	94.8	21	90.4	20	32.7	23
Birmingham	65.9	18	61.9	20	94.3	22	90.4	21	31.1	19
Newark	65.7	19	59.1	24	96.6	11	90.5	19	28.0	12
Stony Brook	64.8	20	54.9	32	95.9	13	91.6	15	35.4	31
Honolulu	64.7	21	62.0	19	89.2	34	91.3	16	21.4	4
UC Davis	64.6	22	60.3	22	95.5	17	90.6	18	34.1	27
Torrance	64.5	23	62.5	18	96.3	12	87.6	27	32.1	21
Columbus	64.1	24	60.3	23	97.3	7	92.8	11	31.4	20
Chi-Rush	62.2	25	58.6	25	98.1	4	84.2	33	33.0	25
Seattle	62.0	26	57.8	27	94.8	20	85.8	28	36.2	33
Memphis	61.6	27	58.5	26	93.4	25	84.3	32	34.4	28
Irvine	60.3	28	55.2	31	87.1	38	80.9	37	30.5	17
NYC	59.0	29	56.3	28	91.5	30	84.4	31	36.3	34
GWU-DC	58.9	30	53.8	34	93.3	26	88.0	26	32.5	22
Buffalo	58.5	31	55.5	29	95.1	19	88.5	24	34.6	29
Tucson	58.3	32	60.4	21	87.5	37	85.7	29	39.5	38
LaJolla	57.8	33	55.3	30	94.0	23	84.1	34	29.3	16
Houston	57.5	34	50.9	39	88.1	36	83.9	35	43.1	39
Bowman	56.4	35	52.6	38	91.3	31	91.0	17	35.4	31
Detroit	55.9	36	52.7	37	82.6	39	72.6	39	34.9	30
Atlanta	55.9	37	53.5	35	89.7	33	88.7	23	38.2	37
San Antonio	54.4	38	53.4	36	91.0	32	81.8	36	38.1	36
Medlantic	54.3	39	54.3	33	95.8	14	84.9	30	37.0	35
Miami	37.3	40	36.0	40	69.8	40	71.8	40	54.0	40
CC Average	**65.6**		**61.8**		**93.8**		**89.4**		**30.9**	

1. Adherence from randomization through 1) Aug 99, 2) last adherence collection after Aug 99, 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, lost-to-F/U, and deceased participants

Table 8.3
Performance Monitoring Committee Report
Data as of 8/27/00

CaD Intervention

	Adherence Summary				Task Completeness Form 17[3]		% Stopped[4]	
	Average[1]		Sept 99-Aug 00[2]		Dec 99-May 00		Cum Aug 00	
	%	Rank	%	Rank	%	Rank	%	Rank
Oakland	79.7	1	81.9	1	97.9	6	7.0	1
Iowa City	73.6	2	74.8	2	97.8	8	9.5	2
Stanford	71.5	3	72.2	3	98.6	4	14.9	9
Minneapolis	69.4	4	70.6	6	96.8	15	13.4	5
Gainesville	68.1	5	70.6	5	98.3	5	20.0	25
Columbus	68.1	6	67.4	7	98.6	2	17.7	19
Nevada	66.5	7	71.7	4	99.0	1	13.2	4
Chi-Rush	65.6	8	66.6	8	97.0	14	21.0	27
Honolulu	65.5	9	65.6	9	91.1	33	17.7	19
Milwaukee	65.2	10	63.1	15	89.7	37	14.8	8
Chapel Hill	64.6	11	65.2	12	95.6	18	12.6	3
Brigham	62.9	12	65.3	11	97.3	12	21.8	31
Pittsburgh	62.9	13	63.7	14	94.8	24	18.3	22
Portland	62.5	14	61.9	18	92.9	30	17.9	21
Tucson	61.0	15	65.3	10	92.1	31	27.7	39
Pawtucket	60.9	16	62.1	17	98.6	3	21.5	29
Worcester	60.1	17	62.4	16	95.6	19	14.0	6
Madison	59.6	18	59.6	25	97.4	11	17.2	17
Cincinnati	59.3	19	61.6	19	87.6	38	17.5	18
LA	59.1	20	60.4	24	93.3	28	16.8	14
Bowman	58.7	21	59.1	26	90.2	36	16.6	13
Torrance	58.3	22	63.8	13	93.3	29	16.9	15
Seattle	57.9	23	61.1	21	94.0	25	21.8	31
Buffalo	56.8	24	61.2	20	97.9	7	15.8	11
UC Davis	56.6	25	60.6	22	96.8	16	20.0	25
Stony Brook	56.4	26	57.3	28	96.5	17	21.5	29
LaJolla	55.1	27	56.8	30	95.6	20	16.4	12
GWU-DC	55.0	28	53.5	35	95.3	21	17.1	16
Houston	53.3	29	52.7	37	90.3	35	24.3	36
Detroit	53.1	30	53.3	36	85.3	39	19.8	24
Birmingham	52.9	31	60.5	23	97.2	13	14.5	7
Chicago	52.7	32	56.8	29	97.6	9	26.2	37
Atlanta	52.4	33	58.2	27	93.9	26	22.1	33
Irvine	51.8	34	54.9	31	90.8	34	19.2	23
NYC	51.4	35	54.0	33	93.7	27	22.4	34
Memphis	50.7	36	54.1	32	91.7	32	26.5	38
San Antonio	49.9	37	53.9	34	95.2	22	23.0	35
Medlantic	45.6	38	49.5	38	97.5	10	15.2	10
Newark	39.6	39	48.6	39	94.9	23	21.1	28
Miami	30.7	40	36.1	40	77.5	40	38.4	40
CC Average	**59.1**		**61.5**		**94.8**		**18.5**	

1. Adherence from randomization through 1) Aug 99, 2) last adherence collection after Aug 99, or 3) death; women off intervention are considered non-adherent
2. Adherence in previous 12 months; excludes deaths; women off intervention are considered non-adherent
3. From *WHIP 1445-Task Completeness*, complete if encounter date on *Form 17 - CaD Management and Safety* is -3/+3 months from target date
4. From *WHIP CCC750-CaD Intervention & F/U Status*; includes stopped intervention, stopped F/U, lost-to-F/U, and deceased participants

Table 8.4
Performance Monitoring Committee Report
Data as of 8/27/00

OS

	Task Completeness - Year 3[1] May 99-Oct 99[2]				% Stopped[3]	
	Form 100		Form 143		Cum Aug 00	
	%	Rank	%	Rank	%	Rank
Columbus	94.7	1	97.4	1	1.9	3
Iowa City	94.1	2	97.0	3	2.2	5
Oakland	92.7	3	96.3	4	3.0	8
GWU-DC	92.2	4	94.5	8	2.1	4
Chapel Hill	92.0	5	95.8	6	1.8	1
Madison	90.9	6	97.2	2	3.0	8
UC Davis	90.7	7	93.6	11	3.0	8
Nevada	89.5	8	92.9	13	3.7	15
Pittsburgh	88.6	9	92.1	16	4.7	26
Portland	88.3	10	91.7	20	3.5	13
Stanford	87.2	11	94.0	10	3.9	18
Brigham	87.2	12	92.2	15	1.8	1
Worcester	86.4	13	92.8	14	3.2	12
Gainesville	86.2	14	95.9	5	4.1	23
Minneapolis	86.1	15	95.7	7	2.6	7
Honolulu	86.0	16	91.9	19	3.8	16
Atlanta	85.1	17	94.0	9	4.0	20
Bowman	84.9	18	91.5	21	4.1	23
Chicago	83.7	19	92.0	17	3.9	18
Buffalo	83.3	20	93.5	12	3.8	16
Seattle	83.1	21	91.3	23	4.0	20
Pawtucket	82.7	22	91.4	22	4.6	25
LA	82.2	23	92.0	18	2.5	6
Torrance	81.0	24	84.8	29	6.7	33
Irvine	80.8	25	86.8	27	5.5	29
Tucson	80.8	26	85.5	28	6.4	31
LaJolla	79.6	27	83.2	30	7.6	36
Stony Brook	79.6	28	87.7	24	3.1	11
San Antonio	76.6	29	87.4	25	7.0	34
Medlantic	75.6	30	78.5	32	9.5	38
Cincinnati	75.0	31	78.1	33	7.1	35
Birmingham	73.4	32	72.0	35	5.2	28
Chi-Rush	70.1	33	70.7	36	9.2	37
Newark	68.6	34	76.2	34	5.6	30
Detroit	66.1	35	82.5	31	6.5	32
Milwaukee	62.3	36	62.3	39	3.5	13
Houston	62.0	37	86.9	26	4.0	20
Memphis	61.7	38	63.1	38	4.7	26
NYC	51.7	39	67.9	37	10.4	39
Miami	51.3	40	57.5	40	12.1	40
CC Average	**81.5**		**87.8**		**4.7**	

1. From *WHIP1445-Task Completeness;* complete if encounter date is -3/+15 months from AV3 target date
2. May 99-Oct 99 used to allow for 10 month lag in completeness
3. From *WHIP CCC752 Intervention & F/U Status*; includes stopped F/U, lost-to-F/U, and deceased participants

Table 8.5
Performance Monitoring Committee Report
Data as of 8/27/00

Outcomes

	Task Completeness						Close Cases < 14 Weeks[4]	
	CT Form 33[1]		OS Form 33[2]		Form 33D[3]			
	Dec 99-May 00		May 99-Oct 99		Cum Aug 00		Cum Aug 00	
	%	Rank	%	Rank	%	Rank	%	Rank
Nevada	98.8	1	98.7	1	99.9	2	55.6	24
Buffalo	97.6	2	97.4	9	100.0	1	83.5	2
Iowa City	97.4	3	97.6	5	99.3	17	71.5	8
Madison	97.2	4	98.2	2	99.7	7	90.5	1
Columbus	96.9	5	97.5	6	98.4	28	64.2	14
Pittsburgh	96.7	6	84.6	38	99.0	23	61.0	18
GWU-DC	96.6	7	96.8	14	99.4	14	69.1	11
Stanford	96.5	8	96.3	18	99.2	18	78.2	5
Brigham	96.3	9	97.0	13	99.7	4	41.9	33
Gainesville	96.3	10	96.5	17	99.4	15	76.7	6
Chapel Hill	95.9	11	97.8	4	99.5	11	64.0	15
Seattle	95.8	12	97.8	3	99.9	2	70.4	9
Minneapolis	95.4	13	97.4	7	98.1	33	59.0	20
Pawtucket	95.1	14	95.4	22	99.1	19	67.0	13
Birmingham	94.7	15	94.0	25	99.7	6	36.3	37
Oakland	94.7	16	96.8	15	98.9	24	32.8	40
Bowman	94.1	17	95.6	21	98.2	30	32.8	39
Stony Brook	94.1	18	97.1	11	99.6	9	82.4	3
Worcester	93.9	19	95.8	20	99.7	7	67.7	12
Medlantic	93.8	20	88.0	36	99.5	10	37.8	35
Chi-Rush	93.6	21	81.2	39	98.1	31	58.6	21
LaJolla	92.8	22	91.0	32	98.4	25	62.5	16
UC Davis	92.6	23	97.1	12	99.5	11	80.4	4
Atlanta	92.3	24	93.1	28	96.9	35	56.8	23
LA	92.1	25	97.1	10	97.2	34	47.7	28
Houston	91.8	26	94.9	23	92.6	39	52.4	26
Chicago	91.7	27	94.9	24	93.7	37	45.3	30
San Antonio	91.7	28	92.7	29	99.7	5	57.2	22
Tucson	91.6	29	93.8	26	98.2	29	60.6	19
Memphis	91.4	30	92.1	30	99.1	20	48.9	27
Newark	91.2	31	91.6	31	99.3	16	61.4	17
Milwaukee	91.2	32	96.8	16	93.6	38	70.1	10
NYC	91.2	33	86.9	37	99.1	20	41.2	34
Honolulu	91.1	34	96.2	19	99.0	22	73.1	7
Irvine	90.8	35	93.7	27	98.1	32	36.0	38
Portland	89.7	36	97.4	8	98.4	26	53.8	25
Torrance	85.8	37	88.9	35	94.0	36	37.7	36
Miami	80.8	38	81.2	40	99.5	13	44.0	31
Cincinnati	79.2	39	90.1	33	87.6	40	47.6	29
Detroit	78.7	40	89.1	34	98.4	26	42.9	32
CC Average	**93.0**		**94.1**		**98.3**		**60.4**	

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 *Form 33D* for CT and OS
4. From *WHIP 1262-Timeliness of Outcomes Processing*; time from receipt of *Form 33, 33D, or 120* to close date

Table 8.6
Performance Monitoring Committee Report
Data as of 8/27/00

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	
Madison	97.5	1	0.019	13	2.3	14	0.00	1	5.4	8	1
Nevada	96.5	3	0.007	7	1.3	3	0.11	19	8.6	15	2
Brigham	78.9	34	0.003	3	1.9	8	0.00	1	3.3	3	3
Pittsburgh	84.8	22	0.064	22	1.1	2	0.00	1	-	-	4
Gainesville	96.4	4	0.010	9	2.6	17	0.44	31	2.7	1	5
Honolulu	90.8	10	0.007	6	1.7	6	0.23	24	9.1	17	6
Stony Brook	96.3	5	0.096	29	2.0	9	0.03	10	6.4	11	7
GWU-DC	96.7	2	0.031	16	2.9	22	0.05	14	-	-	8
Stanford	84.5	24	0.013	11	1.8	7	0.02	6	12.6	25	9
Oakland	83.3	26	0.000	1	3.7	28	0.08	16	4.3	4	10
Chapel Hill	83.6	25	0.010	8	3.0	24	0.00	1	10.0	20	11
Atlanta	89.7	13	0.006	5	2.3	12	0.73	34	-	-	12
Milwaukee	87.9	15	0.088	27	4.1	32	0.00	1	4.4	5	12
San Antonio	92.1	8	0.035	18	2.3	13	1.15	35	4.7	6	12
Buffalo	94.1	7	0.001	2	5.2	38	0.05	13	12.0	23	15
Seattle	81.6	30	0.003	4	2.7	19	0.15	21	5.6	9	15
Bowman	90.5	11	0.018	12	2.8	21	0.14	20	11.9	22	17
Iowa City	94.7	6	0.024	14	3.0	23	0.11	18	13.8	26	18
Worcester	85.8	19	0.032	17	4.9	37	0.03	8	4.9	7	19
Minneapolis	84.8	23	0.101	30	0.1	1	0.17	22	7.2	13	20
Columbus	85.0	21	0.042	19	2.5	15	0.11	17	-	-	21
Pawtucket	82.6	28	0.084	26	2.0	10	0.05	11	-	-	22
Portland	68.1	40	0.012	10	2.5	16	0.03	9	-	-	22
Miami	87.5	16	0.030	15	1.7	5	3.40	40	-	-	24
Newark	85.4	20	0.048	20	2.6	18	0.26	27	7.7	14	25
Tucson	90.3	12	0.074	24	3.2	26	0.23	26	11.2	21	26
LA	82.7	27	0.118	31	4.1	31	0.03	7	8.8	16	27
Chi-Rush	86.3	17	0.080	25	1.7	4	1.46	37	17.9	30	28
Chicago	82.5	29	0.119	32	3.8	29	0.23	25	6.3	10	29
NYC	78.9	33	0.060	21	2.8	20	0.57	32	9.4	19	29
UC Davis	76.9	35	0.072	23	3.4	27	0.05	12	21.7	32	31
Irvine	69.6	38	0.095	28	2.1	11	1.24	36	9.1	17	32
Detroit	81.3	31	0.511	39	4.1	30	0.43	30	2.9	2	33
LaJolla	92.1	9	0.473	38	3.1	25	1.93	38	12.4	24	34
Houston	86.3	18	0.299	36	4.9	36	0.30	28	14.6	27	35
Cincinnati	76.1	36	0.282	35	4.3	33	0.06	15	19.2	31	36
Birmingham	73.8	37	0.138	33	4.4	34	0.19	23	15.8	28	37
Memphis	68.4	39	0.459	37	7.2	40	0.41	29	6.5	12	38
Mediantic	88.3	14	0.258	34	6.0	39	2.28	39	-	-	39
Torrance	80.5	32	0.534	40	4.6	35	0.60	33	16.3	29	40
CC Average	**85.2**		**0.098**		**2.3**		**0.41**		**9.4**		

1. From *WHIP1113 - Timelinesss of Data Entry*; percent of encounters data entered within 14 days of encounter date
2. From *WHIP794-Encounters w/o Data;* excludes screening encounters 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

9. Other Study Activities

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

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

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

These tables represent the current information available to the relevant committees. Updates are clearly needed. Status reports for 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 9.1
Publications

MS ID	Title	Authors	Data Focus	Stage	Reference
1	Informed Consent in the Women's Health Initiative Clinical Trial and Observational Study	**McTiernan,** Rossouw, Manson, Franzi, Taylor, Carleton, Johnson, Nevitt	Gen.	10	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.	10	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.	10	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.	10	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.	10	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	**Unauthored – writing group: Prentice,** Rossouw, Furberg, Johnson, Henderson, Cummings, Manson, Freedman, Oberman, Kuller, Anderson	Gen.	10	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	10	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	10	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.	10	Journal of Women's Health and Gender-Based Medicine, in press
21	Factors Associated with Prevalence, Treatment and Control of Hypertension among Post-menopausal Women: Baseline Data from the Women's Health Initiative	**Wassertheil-Smoller,** Manson, Wong, Lasser, Kotchen, Langer, Grimm, Black, Psaty, Anderson, Francis	OS	10	Hypertension, in press
24	Estimation of the Correlation between Nutrient Intake Measures Under Restricted Sampling	**Wang,** Anderson, Prentice	Gen.	10	Biometrics, in press

MS ID	Title	Authors	Data Focus	Stage	Reference
27	The Effects of Insurance Coverage and Ethnicity on Mammography Utilization in a Postmenopausal Population	**Bush**, Langer	Gen.	10	Western Journal of Medicine 168:236-40, 1998
35	Measurement Characteristics of the WHI Food Frequency Questionnaire	**Patterson**, Kristal, Carter, Inker, Bolton, Agurs-Collins	Gen.	10	Annals of Epidemiology 1999:9:178-197
37	Depression as Mediated by Social Support, Life Events, and Sexual Activity in Postmenopausal Non-Hispanic White and Latina Women	**Larisch**, Talavera, Langer, Velasquez, Elder	Gen.	10	
40	The Health Impact of Domestic Violence in Older Women	**Mouton**, Furniss, Lasser, Rovi	OS	10	Journal of Women's Health & Gender-Based Medicine 1999:8(9):1173-1179
43	Sleep Complaints of Postmenopausal Women	**Kripke**, Freeman, Masaki, Brunner, Jackson, Hendrix, Carter	CT	10	
60	WHIMS: a Trial of the Effect of Estrogen Therapy in Preventing and Slowing the Progression of Dementia	**Shumaker, Bowen**	WHIMS	10	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	10	Preventive Medicine, In Press
69	Correlates of Serum Lypocene in Older Women	**Casso**, White, Patterson, Agurs-Collins, Kooperberg, Haines	CT	10	
70	Correlates of Serum A- and G-Tocopherol in the WHI	**White**, Masaki, Chen, Shikany, Caan, Mares-Perlman, Wilson, Kristal	CT	10	Nutrition and Cancer 2000: 36:163-69
71	The Women's Health Initiative: Goals, Rationale, and Current Status	**Liu**	Gen.	10	Menopausal Medicine, Vol.6(2), p.1-4, 1998
103	The Women's Health Initiative: Recruitment Complete - Looking Back and Looking Forward (Guest Editorial)	**Rossouw**, Hurd	CT	10	Journal of Women's Health 8:3-5, 1999.
108	Cross-Sectional Geometry and Bone Mass in the Proximal Femur in African-American and White Postmenopausal Women	**Nelson**, Hendrix	CT	10	
10	A Comprehensive Data Management System for Multicenter Studies	**Anderson**, Davis, Koch	Gen.	9	
17	Sexual Orientation and Health: Comparisons in the Women's Health Initiative Sample	**Valanis**, Charney, Whitlock, Wassertheil-Smoller, Bassford, Bowen, Carter	CT	9	
30	Completeness of Purchase Mailing Lists for Identifying Older Women	**Falkner**, Wactawski-Wende, Trevisan	CT	9	

MS ID	Title	Authors	Data Focus	Stage	Reference
59	Dietary and Supplemental Calcium Intake and the Occurrence of Kidney Stones in Postmenopausal Women Residing in the Kidney Stone Belt	**Hall,** Pettinger, Oberman, Watts, Johnson, Paskett, Limacher, Hays	Gen.	9	
61	WHI Halfway Paper (100K Paper)	**Langer,** Kotchen, Daugherty, Lewis, Elmer, Trevisan, Noonan, Hendrix, Adams-Campbell	Gen.	9	
72	Post-Menopausal Bone Loss and its Relationship to Oral Bone Loss	**Jeffcoat,** Lewis, Reddy, Wang, Redford	Gen.	9	Periodontics 2000
76	Labeling as a Predictor of Dietary Maintenance	**Hopkins,** Burrows, Bowen, Tinker	CT	9	
88	Estimating Normal Hemogram Values for Postmenopausal Women	**Carleton,** Assaf, Miller	Gen.	9	
93	Fat Intake in Husbands of Women in the Dietary Component of the Women's Health Initiative	**Shikany**	Gen.	9	
19	Body Weight and Anthropometric Measures of Adiposity	**Manson,** Kotchen, Perri, Lewis, Johnson, Freed, Hall, Allen, Foreyt, Tinker, Noonan, Stefanick	Gen.	8	
26	Special Populations Recruitment for the WHI: Success and Limitations	**Fouad,** Corbie-Smith, Curb, Howard, Mouton, Simon, Talavera, Thompson, Wang, White, Young	Gen.	8	
85	Women's Health Initiative: Rationale, Design and Progress Report	**Johnson, Anderson, Barad, Stefanick, McNagy**	CT	10	
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.	8	
105	Retention of Low Income and Minority Women in Clinical Trials: A Focus Group Study	**Johnson,** Williams, Fouad	CT	8	
109	NCI Monograph: Approaches to Research Trials Recruitment in Hispanic Communities: Review and Recommendations	**Larkey**	Gen.	8	
111	Effects of Fat Intake on Fat Hedonics: Cognition or Taste?	**Bowen,** Green, Vizenor, Vu, Kreuter, Rolls	OS	8	
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	8	
126	Influences on Older Women's Adherence to a Low-Fat Diet in the Women's Health Initiative	**Kearney,** Rosal, Ockene, Churchill	CT	8	

MS ID	Title	Authors	Data Focus	Stage	Reference
34	The Relationship between Smoking Status, Body Weight, and Waist-to-Hip Ratio: the WHI	**Johnson,** Klesges, Hays, Noonan, Blaack, Curb, Liu, Manson	Gen.	7	
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	7	
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.	7	
14	Psychosocial and Behavioral Correlates of Moderate Alcohol Consumption in Women	**Powell,** Hymowitz, Criqui, Ockene, Finnegan, Castro, Trevisan, Curb, Hunt, Noonan	CT	6	
22	Prevalence of Pelvic Organ Prolapse and Urinary Incontinence in Women	**Clark,** Harris, Varner, Chang, Hendrix, Barnabei, Mattox, McTiernan, Francis, Nygaard	CT	6	
26	Special Populations Recruitment for the WHI: Success and Limitations	**Fouad,** Howard, Mouton, Talavera, Strickland, Thompson, Young, Lakin, Wang	OS& CT	6	
62	Self-reported Urogenital Symptoms in Postmenopausal Women aged 50-79: WHI	**Pastore,** Hulka, Wells, Carter	Gen.	6	
79	Databased Tracking and Statistical Models of the Clinical Trial Recruitment Process	**Creech**	CT	6	
91	Adherence to NCEP Lifestyle Guidelines by Hyperlipidemic Women in the OS	**Hsia,** Frishman, Rosaal, Stefanick, Howard, Snetselaar, Cochrane	OS	6	
98	Patterns of Antioxidant Supplement Use in Participants in the Women's Health Initiative	**Anderson**, Dunn, Patterson, Agurs-Collins, Shikany	Gen.	6	
13	Cardiovascular and other Physiological Correlates of Depression	**Wasserthell-Smoller,** Talavera, Campbell, Shumaker, Ockene, Robbins, Dunbar, Greenland, Cochrane, Noonan	Gen.	5	
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.	5	
25	Hormone Replacement Therapy Effects on the Resting ECG	**Greenland,** Daugherty, Frishman, Kadish, Limacher, Schwartz	CT	5	

MS ID	Title	Authors	Data Focus	Stage	Reference
31	Comparisons between Never Smokers, Former Smokers, and Current Smokers in the WHI	**Hymowitz,** Ockene, Bowen, Robbins, Brunner, Shikany, Wagenknecht	OS	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	
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	
53	Dietary, Physical Activity, and Exercise Patterns among Diabetics	**Agurs-Collins,** Adams-Campbell, Passaro, Howard	Gen.	5	
57	Regional Differences in Stroke Morbidity at Baseline in the WHI	**Johnson,** Hall, Oberman, Sheps, Hulka, Hays, Baum, Schenken, Burke, Limacher, Anderson, Jeppson	Gen.	5	
66	Physical Activity and CVD in Women: the Role of Moderate vs. Vigorous Exercise	**Manson,** Mouton, LaCroix, Greenland, Oberman, Perri, Siscovick, Sheps, White, Casso, Wang, Stefanick	OS	5	
74	Baseline Characteristics of the WHI-OS Breast Cancer Survivor Cohort	**Paskett,** Sherman, Anderson, Hays, McDonald, Naughton	OS	5	
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.	5	
81	The Prevalence of Urinary Incontinence in WHI Women	**Hendrix,** Clark, Ling, Dugan, Salmieri, Hurtado, McNeeley, Laube, McTiernan, Francis	Gen.	5	

MS ID	Title	Authors	Data Focus	Stage	Reference
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	Adherence Factors in the Dietary Modification Clinical Trial	**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	
99	Risk Factor Clustering in the Insulin Resistance Syndrome and its Relationship to Cardiovascular Disease: Comparison of White and Black Postmenopausal Women	**Howard,** Criqui, Curb, Santoro, Wilson, Wylie-Rosett, Safford, Heber	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	
107	Physical Activity Throughout the Life Course: The Women's Health Initiative	**Evenson,** Wilcox, Heiss, King, Daugherty, McTiernan	OS	5	
113	Prior Use of Oral Contraceptives and Fracture Risk in Menopausal Women	**Barad,** Kooperberg, Wactawski-Wende, Hendrix, Watts, Liu	Gen.	5	
115	Prevalence and 3-year Incidence of Domestic Violence in Older Women	**Mouton,** Hunt, Rodabough, Rovi, Talamantes, Brzyski, Burge	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	
122	HMG Co-A Reductase Inhibitor (Statin) Use and Risk of Fracture In the Women's Health Initiative Observational Study	LaCroix, Jackson, Cauley, Chen, Lewis, McGowan, Hsia, Daugherty, McNeeley, Passaro, Bauer	OS	5	
20	Correlates of Endogenous Sex Hormone Concentrations in WHI	**McTiernan,** Wactawski-Wende, Chen, Meilahn, La Valluer, Cummings, Hiaat, Baum, Hulka, Wang, McNagny	CT	4	

MS ID	Title	Authors	Data Focus	Stage	Reference
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	
39	Interactions among HRT and Dietary Fat Intake on Heart Disease Risk Factors in Postmenopausal Women	**Chlebowski,** Stefanick, Wagenknecht, Frid, Mossavar-Rahmani, Cain	Gen.	4	
68	Reliability and Physiologic Correlates of the Physical Activity Questionnaire in the WHI	**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	Gen.	4	
84	Research Staff Turnover and Participant Adherence in the WHI	**Jackson,** Chlebowski, Huber, Boe, Granek, Snetselaar, Meyer, Milas	CT	4	
95	The Effects of Becoming a Widow on Health Behaviors and Health Status in Postmenopausal Women: The Women's Health Initiative	**Wilcox,** Evenson, Loevinger, Cochrane, Mouton, Wassertheil-Smoller	OS	4	
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.	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	The WHI Sleep Disturbance Scale: Scoring and Psychometric Evaluation	**Levine,** Shumaker, Naughton, Kaplan, Kripke, Bowen	Gen.	3	
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	

MS ID	Title	Authors	Data Focus	Stage	Reference
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, Snetselaar	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	
134	Creative Self-Monitoring Tools in the Dietary Modificiation Component of the Women's Heath Initiative	**Mossavar-Rahmani,** Henry, Brewer, Freed, Kinzel, Pederson, Soule, Vosburg, Bragg	CT	3	

Stage
2= Approved
3= Writing group approved
4= Analysis proposed
5= Analysis in progress
6= Draft manuscript
7= Final manuscript submitted to P&P and PO
8= Final manuscript approved by P&P and PO
9= Submitted
10= In press/published

Table 9.2
Ancillary Studies

AS #	Title	Study's PI(s)	WHI Investigator	Initial D&A Approval	Initial PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
135	Natural History of Pelvic Organ Prolapse in WHI women	Ingrid Nygaard	Robert Wallace	pending	pending	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	pending	pending		OS Blood Comp	400	yes	1/01-12/01	funded
133	Biochemical and Genetic Predictors of Incident Hypertension in White and Black Women	Howard Sesso, JoAnn Manson	JoAnn Manson	pending	pending		OS Blood Comp	1600	yes	1/1/02-12/31/04	pending
132	A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus	Simin Liu, JoAnn Manson	JoAnn Manson	pending	pending		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	pending	pending		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	pending	pending	40	DM, HRT		no	7/01-06/06	pending
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	pending	pending	all	OS Blood Comp	5775	yes	2/02-2/06	pending

AS #	Title	Study's PI(s)	WHI Investigator	Initial D&A Approval	Initial PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
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	pending	pending	all	OS Blood Comp	6500	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	pending	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	pending	all	OS	2100	yes	7/01-7/04	pending
125	Osteoporosis in Caribbean Hispanic Women	Ellen Cohen	S. Wassertheil-Smoller	yes	pending	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	pending	pending	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	pending
122	Feasibility Study of Computerized Tailored Dietary Feedback	Karen Glanz, David Curb	David Curb	yes	yes	none	DM	36	no	3/10/00-9/00	funded
121	Hyperinsulinemia and Ovarian Cancer	Carrie Cottreau, Lewis Kuller	Lew Kuller	yes	yes	all	OS Blood Comp	206	yes	2000-2004	pending

AS #	Title	Study's PI(s)	WHI Investigator	Initial D&A Approval	Initial PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
120	Epidemiology of Cervical and Lumbar Stenosis	Molly T. Vogt	Lew Kuller	yes	yes	Pittsburgh, Arizona	OS	4000	no	12/00 - 11/04	pending
119	The Longevity Consortium	Robert D. Langer	Robert Langer	no			DM, HRT, OS		yes		pending
118	Accuracy of Food Portion Estimation Among Postmenopausal Women	Chrisitine L. Coy		yes	yes	none	DM	191	no	12/1999-4/2000	funded
117	Risk Factors for Dry Eye Syndrome in Postmenopausal Women	Kelley A. Kinney	Rebecca Jackson	yes	yes	none	OS	400	no	9/99-8/02	funded
115	Diabetes In Postmenopausal Women	Barbara V. Howard	Barbara V. Howard	yes	yes	all	OS	93726	yes		pending
114	Effects of Hormone Replacement Therapy on Cardiac Function and Ischemia	Mary Haan	John Robbins	yes		1 other to participate, ID unknown	HRT	300	no	7/1/99-6/30/04	pending
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	pending
111	Role of Inflammation in Acute Myocardial Infarction in Women	David Brown	S. Wassertheil-Smoller	yes	yes	all	OS Blood Comp	750	yes	2/1/00 - 1/31/02	pending
110	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Kathryn Rexrode/JoAnn Manson	JoAnn Manson	yes	yes	33	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	ID#s of Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
108	Gene-environment effects and colorectal cancer	Rowan Chlebowski/Henry Lin	Rowan Chlebowski Harbor UCLA	yes	yes	all	OS Blood Comp	2000	yes	4/1/00 - 3/31/05	pending
107	Hashimoto's Thyroiditis in Postmenopausal Women	Margita Zakarija		yes	yes	51	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	no		none	OS Blood Comp	800	yes	6/1/99 - 5/31/03	pending
105	Xanthophyll Pigments in the Diet, Blood and Ocular Macula and Relationship to Age-Related Eye Disease in the Women's Health Initiative	Julie Mares-Perlman	Catherine Allen	yes	yes	4 others to participate, Ids unknown	OS Blood Comp	2880	yes	4/1/00 - 3/31/04	funded
104	Tamoxifen Prevention: Is it acceptable to women at risk?	John Robbins	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 (Kit) Allen	Catherine Allen	yes	yes	none	DM+HRT +OS	50	no	1/99 - 12/00	funded
100	Genetic, Biochemical and Behavioral Determinants of Obesity	Jennifer Hays	Jennifer Hays	yes	yes		OS	775	yes	4/1/99 - 3/31/01	funded
99	GENNID Study	Rowan Chlebowski		yes	yes	none	ALL	40	yes	12/1/98 - 3/31/00	funded

AS #	Title	Study's PI(s)	WHI Investigator	Initial D&A Approval	Initial PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
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	all	OS	720	yes	4/1/00 - 3/31/04	pending
95	Work organization, psychological distress, and health among minority older women	Beatriz Rodriguez		yes	N/A	none	OS	500	no	till 12/31/00	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	Cummings	yes	yes	none	OS	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	11/1/98 – 12/1/03	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	1300	yes	7/1/99 - 6/30/03	funded

AS #	Title	Study's PI(s)	WHI Investigator	Initial D&A Approval	Initial PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
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	Rowan Chlebowski	yes	yes	none	DM	28	no	9/1/97 - 8/13/98	funded
75	Adherence to Dietary Modification in the WHI	Milagros C. Rosal	Judith Ochene	yes	N/A	6 (does not specify which CC's)	DM	480	no	9/1/97 - 8/30/02	funded
74	The Effectiveness of Individual Versus Group Behavioral Strategies to Increase Participants Adherence	Lois Wodarski	Maurizio Trevisan	yes	yes	none	DM	50	no	7/1/97 - 9/30/97	funded
73	Psychosocial and Cultural Determinants of NIDDM in Latinas	Deborah Parra-Medina	Robert Langer	yes	yes	3	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	David Sheps	David Sheps	yes	yes	10	OS	3200	no	9/1/97 - 8/31/00	funded
68	Coronary artery calcification detected with Ultrafast CT as an indication of CAD in OS participants	Judith Hsia	Judith Hsia	yes	yes	51	OS	782	no	1/1/97 - 12/31/05	funded

AS #	Title	Study's PI(s)	WHI Investigator	Initial D&A Approval	Initial PO Approval	ID#s of Other Participating Clinics	Study Popu-lation	Sample Size	Speci-mens?	Funding Dates	Funding Status
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
65	Incidence of Benign breast disease in the DM CT - Pilot	Tom Rohan	A. McTiernan	yes	yes	all	DM	200	no	4/1/98 - 6/30/99	funded
63	Development and Evaluation of Eating Style Index	Pam Haines		yes	yes		OS	800	no	10/1/96 - 6/30/99	funded
62	Prevention of age-related maculopathy in the WHI HRT CT: WHI-SE	Mary Haan	Mary Haan	yes	no		HRT	3300	no	9 year study	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	pending
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	All	OS	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	ID#s of 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	funded
40	Ethnic and age differences in use of Mammography	S. Wassertheil-Smoller	S. Wassertheil-Smoller	yes	yes	none	All	All	no	N/A	funded
39	The Effects of HRT on the Development and Progression of Dementia	Sally Shumaker	Curt Furberg	yes	yes	all except #18	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	ALL	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
29	HRT and Cardiovascular Biomarkers Related to Oxidation Status and Platelet Function	Michael Gaziano/JoAnn Manson	JoAnn Manson	yes	yes	none	HRT	300	no	9/1/95 - 2/29/96	dropped
28	Perspectives on Aging	S. Wassertheil-Smoller	S. Wassertheil-Smoller	yes	yes	none	OS	NA	no	5 year follow-up	pending
25	Ankle-Arm Blood Pressure Index Measurement	Kamal Masaki	David Curb	yes	yes	none	OS	2700	no	2/96 - 1/98	funded

AS #	Title	Study's PI(s)	WHI Investigator	Initial D&A Approval	Initial PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Specimens?	Funding Dates	Funding Status
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	Lewis Kuller	Lew Kuller	yes	N/A	none	CT	150	no	12 year study	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