Women's Health Initiative
Clinical Trial and Observational Study

Annual Progress Report
September 1, 1997 to August 31, 1998

Prepared by
WHI Clinical Coordinating Center
Fred Hutchinson Cancer Research Center

Ross Prentice, Principal Investigator

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WHI Annual Progress Report

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Executive Summary

This report marks the successful completion of recruitment into the Clinical Trial (CT) components of the Women's Health Initiative (WHI). Through a large and sustained effort over the last five years, the 40 WHI Clinical Centers have enrolled 68,108 women into the CT.

As of August 31, 1998, 27,321 women (99% of goal) had been randomized into the Hormone Replacement Therapy (HRT) component and 48,837 women (105% of goal) into the Dietary Modification (DM) component. Randomizations into the Calcium and Vitamin D (CaD) component, designed to occur at a CT participant's first annual follow-up visit, have reached 28,315 (73% of cumulative goal). This represents a noticeable increase in CaD accrual rates, due in part to the availability of an alternate pill formulation. In addition, 92,914 women have been enrolled in the OS. Recruitment of minority women into the Observational Study (OS) has been extended through December 31, 1998.

The age distribution of the recruited population is close to target, particularly in HRT. This was of particular concern to us as the power for the HRT component was more dependent on the increased event rates expected in older women. WHI has recruited a significant proportion of minorities to the CT (18.3%). Minority enrollment in OS is also strong (currently at 15.8%) and will increase slightly in the next few months.

Adherence to the HRT study is somewhat lower than original projections but improving. Approximately 9.8% of HRT women have discontinued study hormones after one year and 18.1% after 2 years as compared to design assumptions of 8.8% and 14.2% respectively. Year 3 and early Year 4 data indicate the subsequent drop-out rates are somewhat smaller. Power calculations indicate that the adherence pattern suggested by the current data would reduce the power by 8%-10%. Further efforts are underway to understand the factors related to adherence and identify cost-efficient methods to improve it.

Intervention activities in the DM study are progressing well. Process measures of attendance at group sessions, completion of self-monitoring activities and self-reported scores for nutrient intake suggest that the current implementation is generally consistent with feasibility study results. Average baseline percent energy from fat based on food records is lower than anticipated (about 33%) and adherence in the Intervention arm is also somewhat less than expected. Accordingly, the Control minus Intervention (C-I) difference achieved is smaller than anticipated. 11.1% at Year 1, 10% at Year 2 and 9.9% at Year 3. Power calculations based on models of fat intake suggest that we must maintain a C-I of 10% throughout follow-up to achieve 80% power for the breast cancer primary outcome. Multivariate analyses have identified various program factors as well as age and racial/ethnic minorities to be predictors of poorer adherence. The program is examining potential methods for bringing additional improvement in the C-I difference and in strengthening the long-term adherence for all Intervention women, with additional assistance for minority women in particular.

Adherence to CaD supplements is of concern as it is clearly lower than expected, with a drop-out rate of 12.4% at one year of follow-up and 20% at Year 2. The new tablet formulation has

improved these rates significantly from the previous year's report of 15.1% and 26% respectively. The protocol change to add a 4-week phone call is showing a modest effect on adherence. Power for the combined fractures outcome remains high even with the anticipated reductions in adherence and sample size, but improvements in current trends will be needed to preserve adequate power for the designated primary outcome, hip fractures.

OS follow-up is proceeding well with acceptable return rates to mailings. Planned clinic follow-up of non-respondents appears adequate to achieve study goals for completeness of follow-up.

Analyses of the appropriate samples of blood specimens, bone density measures and ECGs are presented in this report by study component. These values serve as intermediate endpoints or, in the case of ECGs, potential outcomes for the CT.

The timeliness and completeness of local outcomes processing has been a major emphasis in the past year. Substantial improvement has been made in reducing the backlog and in processing new reported events in a timely way. Both CHD and fracture rates are currently well below predicted rates. Cancer rates are reasonably close to expected. Central adjudication activities are proceeding. Event rates by study component, age and ethnicity are shown in this report for self-reported and locally adjudicated events. A summary of locally and centrally adjudicated outcomes and the corresponding agreement rate are also provided.

The PMC has been pro-active in addressing program concerns regarding clinic performance, particularly with regard to adherence and outcomes during this past year. Their activities are documented in this report.

Finally, reports on program Publications and Ancillary studies are presented.

1. Preliminary Remarks

This report documents study activities of the Women's Health Initiative (WHI) Clinical Trial (CT) and Observational Study (OS) during the period September 1, 1997 to August 31, 1998 as well as the cumulative experience. Topics include recruitment, follow-up, intervention monitoring, safety, outcomes, data quality, study timeline, design related issues and related scientific efforts. Updates are provided for each study component separately.

During this period, major milestones, emphases, and changes have included:

- Successful completion of HRT and DM recruitment;
- Extending minority recruitment into the OS through December 31, 1998, and allowing CaD randomizations through the second follow-up year;
- Continuing encouragement to improve retention and adherence to all CT components including regional workshops on adherence and retention;
- A broad and concerted effort to improve the timeliness, documentation and adjudication of outcomes;
- Intensive work by the Performance Monitoring Committee (PMC) to review CC performance and provide assistance with some restructuring to place particular emphasis on adherence and outcomes procedures;
- Increasing our emphasis on safety monitoring and related quality assurance;
- Analyses of baseline data, and distribution of the initial baseline data to study investigators;
- Reorganization of the committee structure;
- Monitoring and preparing for external events that impact the program (e.g., raloxifene and tamoxifen studies, HERS).

All reports summarize Clinical Center (CC) data provided to the CCC by August 31, 1998. 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*).

Table 1.1 - Database Abbreviations for WHI CCs displays the abbreviations used in database reports to identify CCs. Other organizations providing data to this report are:

- McKesson (formerly Ogden) BioServices, Rockville, Maryland, CCC subcontractor for specimen repository and drug distribution (Harrison Hoppes, PhD, President).
- Epicare, Bowman Gray School of Medicine, Winston-Salem, North Carolina (formerly Epicore, located at University of Alberta, Alberta, Ontario) CCC subcontractor for central reading of electrocardiograms (Pentti Rautaharju, MD, Principal Investigator).
- University of California, San Francisco, CCC subcontractor for central reading of bone densitometry (Steven Cummings, MD, Principal Investigator).

We note several changes in Clinical Center leadership in the past year. Dr. Dallas Hall, Principal Investigator of the VCC at Emory University, Atlanta has retired. Dr. Sally McNagny has assumed the PI role for this site. Dr. Gregory Burke has stepped down from the Principal Investigator role at Wake Forest University in Winston-Salem, North Carolina. Dr. Electra Paskett has taken over the leadership of this clinic. Dr. Robert Hiatt has left his position at Kaiser Oakland for a new position at NCI. His colleague Dr. Bette Caan is now the PI for this NCC. Dr. Maureen Henderson, Seattle VCC PI and CCC Co-PI, retired from the Fred Hutchinson Cancer Research Center and Dr. Shirley Beresford was named as PI of this Clinical Center. Dr. Cheryl Ritenbaugh, former PI of the Arizona VCC, has relocated to Portland, where she has taken over for Dr. Barbara Valanis as the Principal Investigator. Dr. Mary-Jo O'Sullivan was named Principal Investigator for the Miami NCC replacing Dr. Mariana Baum.

While these retirements represent a loss to the program as a whole and the individual Clinical Centers in particular, many of these positions have been filled by other investigators with considerable expertise and experience in this study. We want to express our sincere appreciation to those who have brought the program forward to this point and express our best wishes in their new endeavors.

Table 1.1
Database Abbreviations for WHI CCs

Abbreviation	CC Institution and Location	Principal Investigator
Vanguard Clinical Centers (VCCs):		
ATLANTA	Emory University Atlanta (Decatur), Georgia	Sally McNagny, MD
BIRMING	University of Alabama at Birmingham Birmingham, Alabama	Albert Oberman, MD MPH
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
CHICAGO	Northwestern University Chicago and Evanston, Illinois	Philip Greenland, MD
IOWACITY	University of Iowa Iowa City and Bettendorf, Iowa	Robert Wallace, MD
LAJOLLA	University of California, San Diego La Jolla and Chula Vista, California	Robert Langer, MD MPH
MEMPHIS	University of Tennessee Memphis, Tennessee	William Applegate, MD
MINNEAPO	University of Minnesota Minneapolis, Minnesota	Richard Grimm, MD
NEWARK	University of Medicine and Dentistry Newark, New Jersey	Norman Lasser, MD PhD
PAWTUCK	Memorial Hospital of Rhode Island Pawtucket, Rhode Island	Annalouise Assaf, PhD
PITTSBUR	University of Pittsburgh Pittsburgh, Pennsylvania	Lewis Kuller, MD DrPH
SEATTLE	Fred Hutchinson Cancer Research Center Seattle, Washington	Shirley Beresford, PhD
TUCSON	University of Arizona Tucson and Phoenix, Arizona	Tamsen Bassford, MD
UCDAVIS	University of California, Davis Sacramento, California	John Robbins, MD

Table 1.1 (continued)
Database Abbreviations for WHI CCs

Abbreviation	CC Institution and Location	Principal Investigator
New Clinical Centers (NCCs):		
CHAPHILL	University of North Carolina at Chapel Hill Chapel Hill, North Carolina	Barbara Hulka, MD, MPH
CHI-RUSH	Rush Presbyterian- St. Luke's Medical Center Chicago, Illinois	Henry Black, MD
CINCINNA	University of Cincinnati Cincinnati, Ohio	James Liu, MD
COLUMBUS	Ohio State University Columbus, Ohio	Rebecca Jackson, MD
DETROIT	Wayne State University Detroit, Michigan	Susan Hendrix, DO
GAINESVI	University of Florida Gainesville and Jacksonville, Florida	Marian Limacher, MD
GWU-DC	George Washington University Washington, DC	Judith Hsia, MD
HONOLULU	University of Hawaii Honolulu, Hawaii	David Curb, MD
HOUSTON	Baylor College of Medicine Houston, Texas	Jennifer Cousins, PhD
IRVINE	University of California, Irvine Irvine, California	Frank Meyskens, Jr., MD
LA	University of California, Los Angeles Los Angeles, California	Howard Judd, MD
MADISON	University of Wisconsin Madison, Wisconsin	Catherine Allen, PhD
MEDLAN	Medlantic Research Institute Washington, D.C.	Barbara Howard, PhD
MIAMI	University of Miami Miami, Florida	Mary-Jo O'Sullivan, MD

Table 1.1 (continued)
Database Abbreviations for WHI CCs

Abbreviation	CC Institution and Location	Principal Investigator
NCCs: (cont.)		
MILWAUKE	Medical College of Wisconsin Milwaukee, Wisconsin	Jane Morley Kotchen MD MPH
NEVADA	University of Nevada Reno, Nevada	Sandra Daugherty, 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
PORTLAND	Kaiser Foundation Research Institute Portland, Oregon	Cheryl Ritenbaugh, PhD
SANANTON	University of Texas San Antonio, Texas	Robert Schenken, MD
STANFORD	Stanford University San Jose, California	Marcia Stefanick, PhD
STONYBRK	Research Foundation of SUNY, Stony Brook Stony Brook, NY	Dorothy Lane, MD
TORRANCE	University of California, Los Angeles Torrance, California	Rowan Chlebowski, MD PhD
WORCESTR	University of Massachusetts Worcester, Massachusetts	Judith Ockene, PhD

2 Enrollment

2.1 Overall CT Recruitment

Table 2.1 – Component-Specific Enrollment Status. WHI Clinical Centers have enrolled 68,108 women into the CT, 6% more than our design projection of 64,500, and 92,914 into the OS. The overlap in DM and HRT participation is about 12%, 5% lower than expected. The additional recruitment was therefore necessary to meet component specific goals. Fortunately this was accomplished with minimal additional time and we have been able to successfully draw recruitment to a close.

2.2 HRT Recruitment

Table 2.1 – Component-Specific Enrollment Status and *Figure 2.1 – Projected and Actual HRT Randomizations at All CCs.* Enrollment in the HRT component is essentially complete. We anticipate the final 20-30 women will be randomized in September. These are women who had unavoidable delays in the screening process. With 27,321 women already participating, these few additional cases will bring us just 150 short of goal. The HRT was clearly the more difficult component for which to recruit. The effort required of these centers to enroll over 27,000 women to a nine year blinded study of hormones was enormous and certainly larger than some anticipated. While we would have liked to have enrolled the full 27,500 women, the cost of restarting recruitment is too high to justify what would be a negligible gain in power.

Approximately 40% of HRT participants have had a prior hysterectomy. With the modification to the protocol in 1994 related to the PEPI results,[1] the projected proportion of women with a prior hysterectomy was set at 45%. At several points in time we considered restricting enrollment to assure that this target would be reached. After noting the greater prevalence in CHD risk factors among hysterectomized women, and the complexity of further targeting recruitment to subsets of postmenopausal women, we elected not to directly address this issue. Power calculations reflecting this final distribution have been conducted (see Section 3). The higher prevalence of CHD risk factors in women without a uterus should partially compensate for the smaller sample size, though these changes are not reflected in the incidence rates used in these power calculations.

2.3 DM Recruitment

Table 2.1 – Component-Specific Enrollment Status and *Figure 2.2 – Projected and Actual DM Randomizations at All CCs.* The DM goal of 48,000 was actually met in May. DM was generally the preferred arm for women and in some cases, the availability of this component was instrumental in recruiting to HRT. For this reason, and to accommodate those women in process, we did not close DM when we reached goal. Women still in process were allowed to continue screening through August 31. At that time, DM was closed to all further recruitment with 48,837 women randomized, 105% of goal.

[1] The Writing Group for the PEPI Trial. Effects of Estrogen or Estrogen/Progestin Regimens on Heart Disease Risk Factors in Postmenopausal Women. JAMA 1995;273:199-208.

2.4 CaD Recruitment

Table 2.1 – Component-Specific Enrollment Status and *Figure 2.3 – Projected and Actual CaD Randomizations at All CCs*. CaD recruitment has improved significantly since we have been able to offer a swallowable formulation. We have now enrolled 28,315 of our CT participants to this component. Over the last 6 months recruitment to this component as been at goal. Assuming that this rate continues for the next year, approximately 40,000 will eventually be enrolled. While this is lower than the original projection of 45,000, this sample size was not selected to assure the power for the study per se, but rather to accommodate all of the HRT and DM women who would be interested in joining. A sample size of 45,000 in fact provided greater power for the primary endpoint than one usually has in randomized trials. A final value of 40,000 will, in fact, provide adequate power for most endpoints under consideration, assuming the other assumptions are reasonable (see Section 5).

2.5 OS Recruitment

Table 2.1 – Component-Specific Enrollment Status and *Figure 2.4 – Projected and Actual OS Randomizations at All CCs*. Recruitment into the OS has continued as a secondary priority for the program. Current enrollment is 92,914, 93% of goal. This sample size was not based on testing a particular hypothesis but rather on the number of women who would likely be captured in screening for the CT. Thus Clinical Centers have been directly encouraged not to target OS recruitment. Nevertheless, the OS is a tremendous resource that will give us an opportunity to examine other questions and extend the results of the CT to other formulations of our interventions. The current sample size is adequate for many of these studies. We have a particular interest in examining some of these questions in minority populations, where the numbers are proportionally smaller. Thus in June, the study leadership approved an extension of OS recruitment only for minority women until December 31, 1998. We anticipate this will yield 800-1000 additional women.

2.6 Age Distribution

Table 2.2 – Age-Specific Recruitment by Study Component. The age distribution for all CT components was specified to be 10%, 20%, 45%, and 25% for the age categories 50-54, 55-59, 60-69, and 70-79. An effort was made to adhere to these goals on a local level by closing recruitment to HRT and/or DM in each age group as the targets were met. This strategy was very successful for HRT. The discrepancies between observed and projected are small and within design tolerance for this component. This approach was instituted at a point when DM was already over-subscribed in the younger age groups at many clinics, however. This has produced a greater divergence between goal and realized values, primarily in the 70-79 year age group. Power calculations for all study components using the observed values are presented in Sections 3, 4, and 5. We note that currently the age distribution for CaD is the farthest from design. CaD recruitment takes place between one and two years after the original randomization so that these numbers are reflecting the early recruiting of younger women. There are no age distribution goals for the OS but the nature of the recruitment process has produced an age profile similar to CT.

2.7 Minorities

Table 2.3 – Ethnic-Specific Recruitment by Study Component. 16.8% of WHI participants are racial or ethnic minorities. Through tremendous effort on the part of Clinical Centers, an even greater percentage of clinical trial participants are minorities (18.3%). This accomplishment is attributed to both very targeted recruitment of minorities and some increased interest by minority women in the interventions and monitoring of the CT, particularly the HRT component. With over 14,000 African American and 6,200 Hispanic women, this program has one of the best resources assembled to examine minority women's health issues.

Table 2.1
Component-Specific Enrollment Status
Data as of: August 31, 1998

Study Component	Enrollment in last 6 months		Cumulative Enrollment		
	N	% of goal	N	% of cumulative goal	% of overall goal
HRT	2263	--	27321	99%	99%
without Uterus	866	--	10724	87%	87%
with Uterus	1397	--	16597	110%	110%
DM	3099	--	48837	105%	105%
CaD	6050	99%	28315	73%	63%
OS	16745	--	92914	93%	93%

Table 2.2
Age - Specific Recruitment by Study Component
Data as of: August 31, 1998

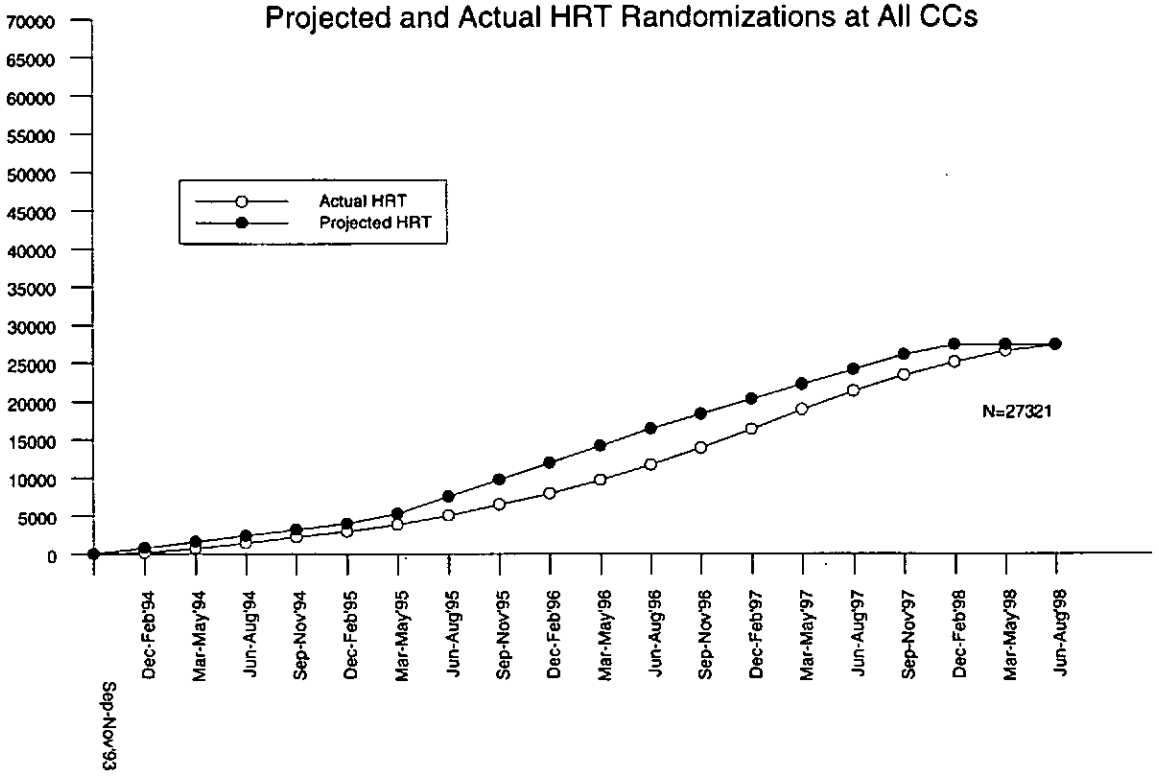
	Total Randomized	% of Cumulative Goal	% of Overall Goal	Age Distribution	Design Assumption
HRT (Overall)					
50-54	3426	125%	125%	13%	10
55-59	5400	99%	99%	20%	20
60-69	12343	100%	100%	45%	45
70-79	6152	90%	90%	23%	25
HRT without Uterus					
50-54	1398	114%	114%	13%	10
55-59	1908	78%	78%	18%	20
60-69	4839	87%	87%	45%	45
70-79	2579	84%	84%	24%	25
HRT with uterus					
50-54	2028	135%	135%	12%	10
55-59	3492	116%	116%	21%	20
60-69	7504	111%	111%	45%	45
70-79	3573	95%	95%	22%	25
DM					
50-54	6958	149%	149%	14%	10
55-59	11042	118%	118%	23%	20
60-69	22714	108%	108%	47%	45
70-79	8123	70%	70%	17%	25
CaD					
50-54	4943	128%	113%	17%	10
55-59	7087	92%	81%	25%	20
60-69	11733	67%	60%	41%	45
70-79	4552	47%	42%	16%	25
OS					
50-54	4664			11%	
55-59	7736			19%	
60-69	18976			46%	
70-79	10290			25%	

Table 2.3
Ethnic-Specific Recruitment by Study Component
Data as of: August 31, 1998

Minorities	CT		OS		Overall	
	N	%	N	%	N	%
American Indian or Eskimo	293	0.4	415	0.4	708	0.4
Asian or Pacific Islander	1520	2.2	2465	2.7	3985	2.5
Black or African American	6984	10.3	7360	7.9	14344	8.9
Hispanic	2883	4.2	3375	3.6	6258	3.9
Other	774	1.1	1028	1.1	1802	1.1
Total Minorities	12454	18.3	14643	15.8	27097	16.8
Whites	55503	81.5	77996	83.9	133499	82.9
Unknown	151	0.2	275	0.3	426	0.3
Total	68108	100	92914	100	161022	100

Figure 2.1

Projected and Actual HRT Randomizations at All CCs



HRT Randomizations per Quarter at All CCs

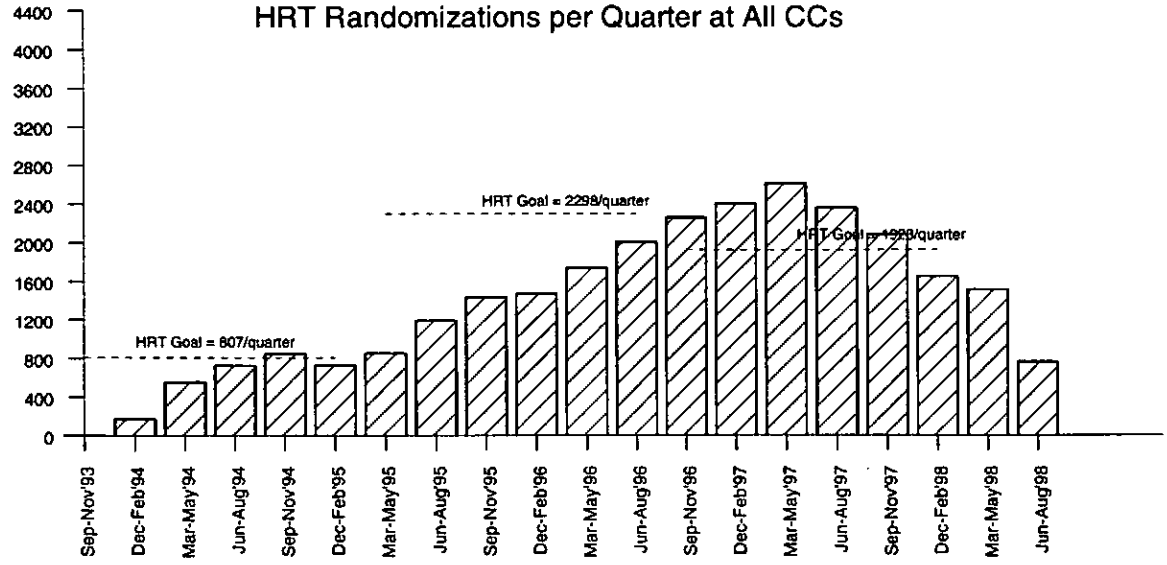
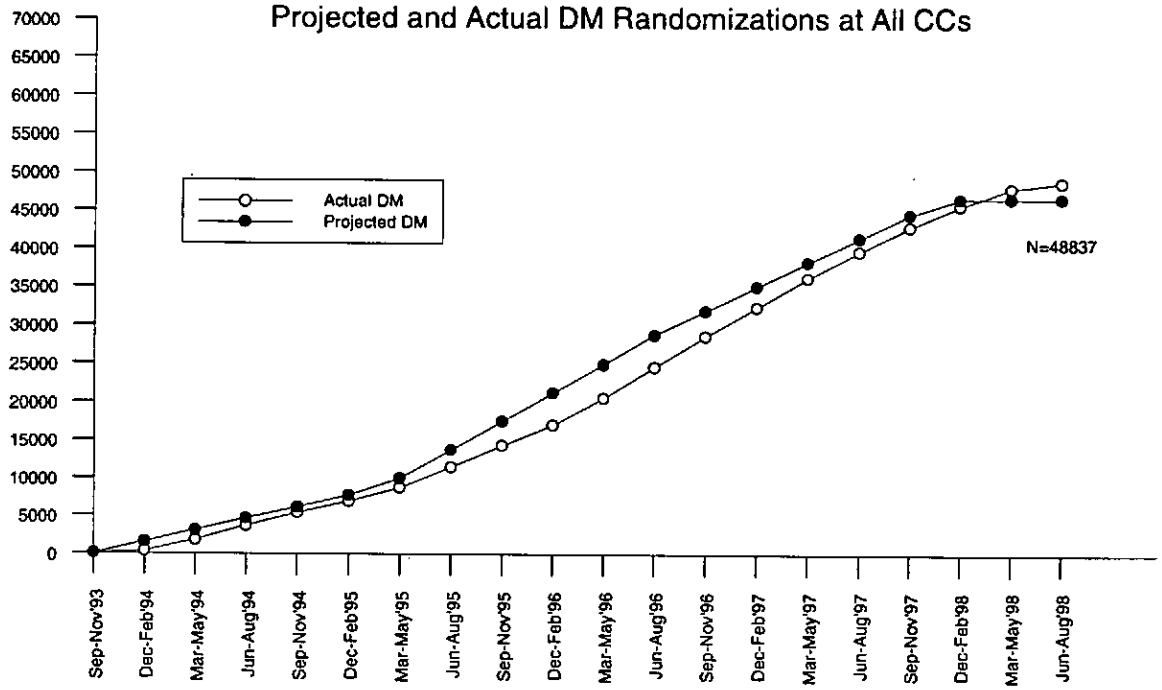


Figure 2.2

Projected and Actual DM Randomizations at All CCs



DM Randomizations per Quarter at All CCs

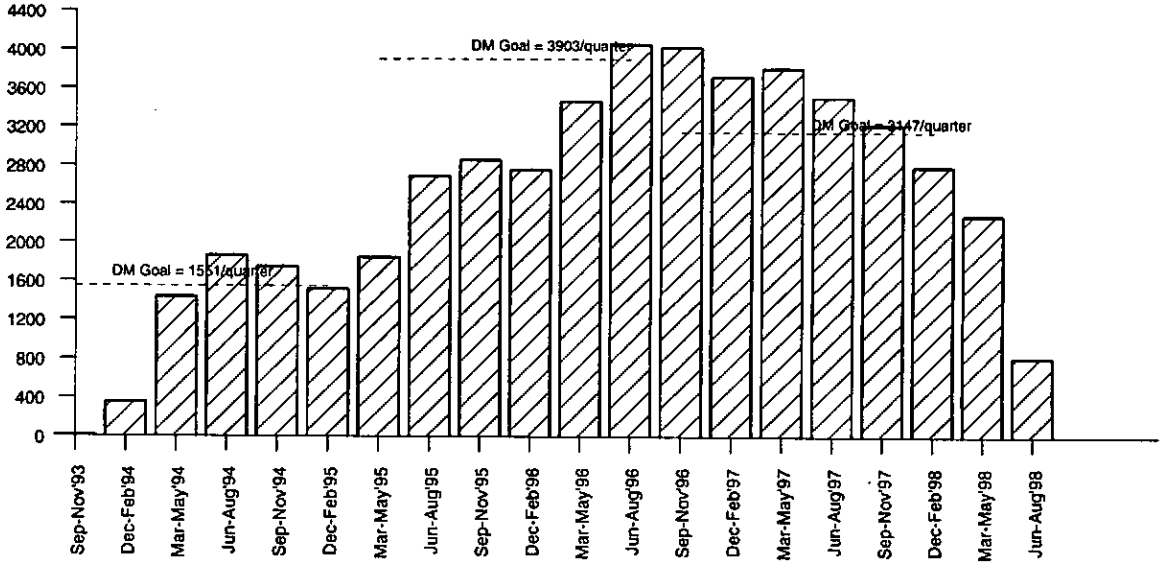
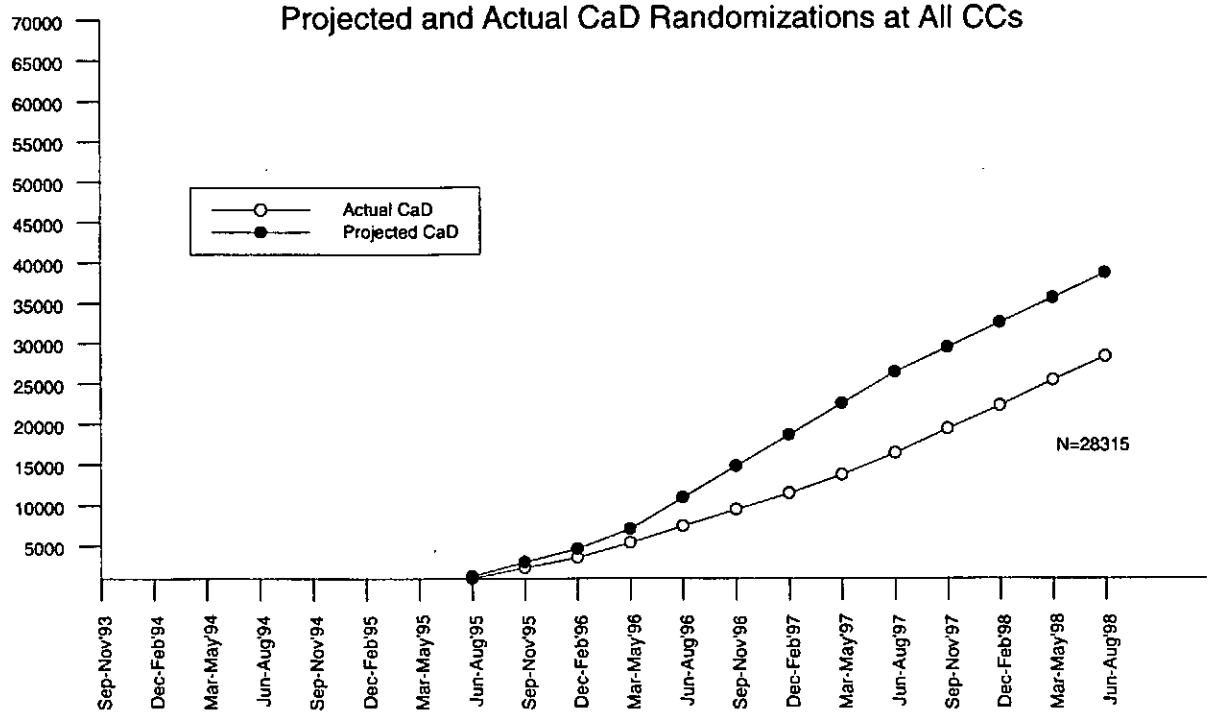


Figure 2.3

Projected and Actual CaD Randomizations at All CCs



CaD Randomizations per Quarter at All CCs

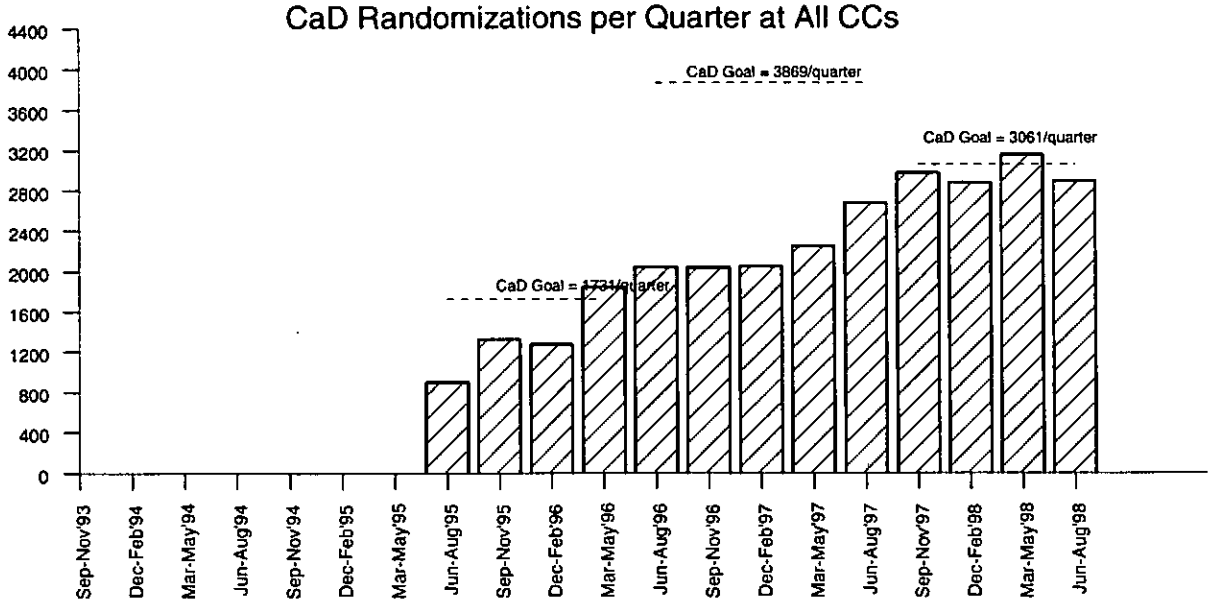
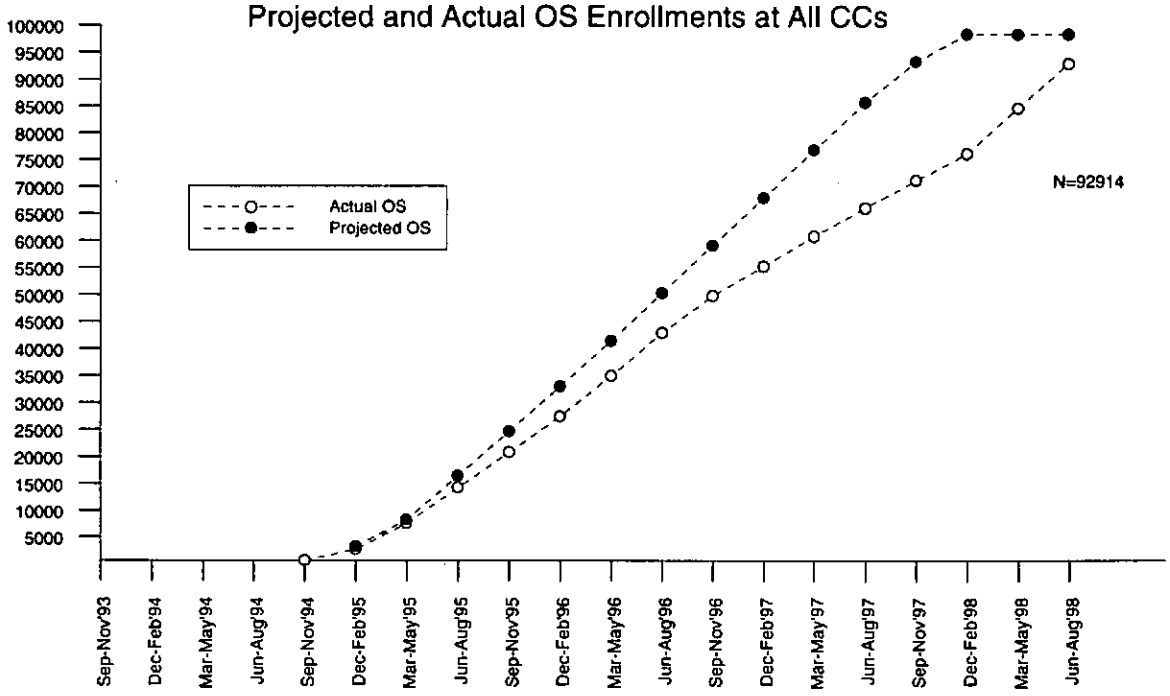
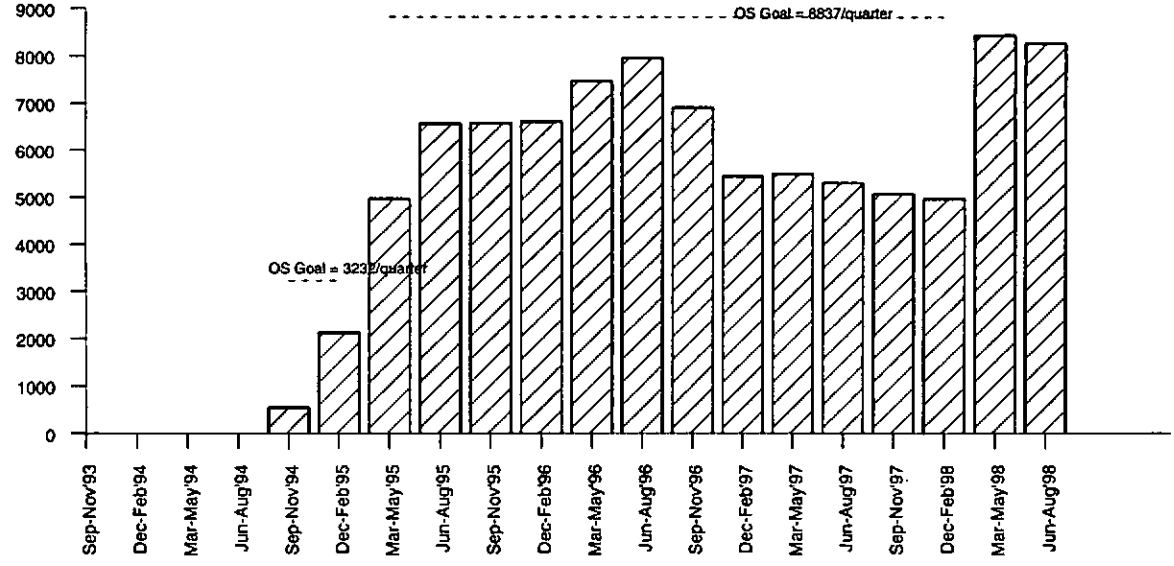


Figure 2.4

Projected and Actual OS Enrollments at All CCs



OS Enrollments per Quarter at All CCs



3. HRT Intervention Status

3.1 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 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 are also required at 6 weeks and on the anniversary of their six month visits. These contacts serve mostly to assure safety, ascertain outcomes and promote bonding. Adherence data from these contacts are limited so we do not report them here.

Table 3.1 - HRT Adherence Summary gives descriptive data on all women who are considered due for each contact by treatment arm. Rates of visits conducted, visits within window, stopping intervention and taking assigned medications are shown by treatment arm for each interval for which we have adherence data. Note that for stopping intervention and medication rates we have excluded the 331 who were moved from ERT to PERT in early 1995 after our protocol change. A large proportion of these women (34%) have stopped intervention. Since their experience is unique in the trial, including their results here would skew these data away from what is being observed in the remaining women. The final column is the adherence summary presenting the proportion of women known to have consumed more than 80% of their assigned HRT pills during that interval. Women with an intact uterus are somewhat more adherent (3%-6%) than hysterectomized women throughout follow-up.

Table 3.2 presents estimated drop-in and drop-out rates based on observed data and the associated design assumptions. The design assumptions underestimated the observed values to date, particularly the first two years of follow-up. The power calculations assumed that 6% of HRT women would stop intervention in the first year with an additional 3% per year thereafter. An independent assumption of 3% per year lost to follow-up or competing risk events gives an overall drop-out rate of 8.8% in year 1, and 5.9% per year thereafter. Our lifetable estimate of the AV-1 drop-out rate is 9.8%, and our estimate for drop-out between AV-1 and AV-2 is 9.2% with small differences between those women with and without a uterus.

The power calculations also assumed that a small proportion (1.5% per year) of the HRT participants would stop study hormone pills and begin taking hormones outside of the trial. Among hysterectomized women this observed rate is about 2.0% per year; in women with a uterus it averages 1.6% per year.

Adherence to HRT was not explicitly modeled in the power calculations with the exception of stopping the intervention entirely or changing from placebo to active. Adherence is incorporated implicitly, though, through the selection of treatment effect size as these values were gleaned from population based studies of hormones and disease incidence. To the extent that the WHI adherence pattern mimics hormone use in post-menopausal women generally, study power will be preserved. We expect that our adherence rates are somewhat better than those of women prescribed hormones

by their personal physician. Berman, et al (1996)[1] reports a stopping ERT rate of 20% at 6 months (with or without progesterone), 38% at 1 year, 51% at 18 months and 59% at 2 years in a study population of 2106 women, aged 46-63, enrolled in a prescription reimbursement plan in Minnesota. Adherence, defined as taking 80% or more pills during the interval since initial prescription was estimated to be 68% at 2 months, 37% at 6 months, 24% at one year and 10% at 2 years. In a 1995 review of 42 studies, Udoff et al[2] displayed ranges for stopping combined continuous HRT of 11%-33% at 6 months, 8%-40% at 1 year and 12-24% at 2 years. This suggests that our experience meets or exceeds the adherence rates in the general population.

The effects on power of somewhat greater drop-out rates and reduced CHD event rates are shown in *Table 3.3*. These calculations assume 7% drop-outs in years 1 and 2 and 4% per year through the remaining follow-up (independent of the 3% loss to follow-up rates) and 2.5% drop-ins per year throughout follow-up. CHD incidence rates were adjusted to reflect the rates observed thus far. In addition to the 33% reduction for healthy volunteer effect throughout, incidence rates in years 1, 2, and 3 were reduced by 75%, 50% and 25% respectively. These changes produced a power for the ERT vs. Placebo comparison on CHD rates of 69% compared to the design value of 81%. For the PERT comparison the power drops from 88% to 78%.

Subsequent tables examine HRT adherence in relation to study subject and program characteristics. The summary adherence measure mentioned above was used in these analyses. Specifically, a binary variable was defined for each HRT participant that described whether (binary variable equal one) or not (binary variable equal zero) she reported taking 80% or more of her HRT pills in the preceding time interval (randomization to SAV-1, SAV-1 to AV-1, or AV-1 to AV-2). The odds ratio for this binary event was then associated jointly with selected study subject and program characteristics, using logistic regression techniques. Similar analyses were also carried out for the binary variable that specifies whether or not a stopped medication (Form 7) was filed. For brevity, and since the criteria for filing Form 7 apparently vary considerably among CCs, these latter analyses are not included.

Table 3.4 shows numbers of HRT women, summary adherence odds ratios (OR), separately by baseline uterine status for the time period up to SAV-1 as a function of various factors. Among women with a uterus, note the lesser adherence among women reporting bleeding at 6 weeks from randomization, and the much improved adherence (OR=2.43) among women receiving the six week phone call. Adherence among these women is somewhat better among women having greater education or higher family income, is slightly poorer if randomized in the DM component of the Clinical Trial, and is noticeably poorer if the woman is of racial/ethnic minority status. Among hysterectomized women, the 6 week phone call is associated with better adherence and minority status with poorer adherence.

Table 3.5 examines adherence in the time period SAV-1 to AV-1 in relation to these and other factors, among women who reported taking 80% or more of their pills up to SAV-1. Given that a

[1] Berman RS et al. Compliance of Women in Taking Estrogen Replacement Therapy. Journal of Women's Health 1996;5(3):213-220.

[2] Udoff L, Langerberg P and Adash EY. Combined Continuous Hormone Replacement Therapy: A Critical Review. Obstetrics & Gynecology 1995;86(2):306-316.

woman was adherent to medication during the first six-month period, her bleeding pattern (among women with a uterus) within that first six months was not strongly related to adherence in the subsequent six months, as was also the case for the six-week phone call. Hence these factors seem important primarily in the first few months from randomization. Note that the relatively small fraction of women who underwent HRT washout prior to randomization have better adherence between SAV-1 and AV-1, perhaps because of a longer history of HRT pill taking, and that minority women become newly non-adherent between SAV-1 and AV-1 at a comparatively higher rate.

Tables 3.6 and *3.7* consider medication adherence between AV-1 and AV-2, and between AV-2 and AV-3, among women who reported taking 80% or more of their HRT pills at the beginning of each interval, respectively. The data are now considerably more sparse. However, women who report bleeding at AV-1 are at increased risk for non-adherence between AV-1 and AV-2. Among hysterectomized women, one can note that younger women (ages 50-54) are at elevated risk for new non-adherence between AV-1 and AV-2 and between AV-2 and AV-3.

Baseline psychosocial variables (Form 37) were also examined in relation to medication adherence up to SAV-1 and between SAV-1 and AV-1 and psychosocial variables at AV-1 (Form 38) were examined in relation to adherence between AV-1 and AV-2. For brevity only selected odds ratios from these analyses are given in *Table 3.8*. These analyses also include the factors listed in *Table 3.4* as control variables. The left side of *Table 3.8* lists psychosocial variable constructs, along with a small number of individual questionnaire items and identifies the Form 37/38 questions from which these variables are constructed. (For descriptions of the psychosocial behavioral constructs, see Appendix A.) The odds ratios shown correspond to a 0.5 standard deviation upward shift in the listed variable. All variables were defined so that larger values represent a more favorable state than smaller values, by reversing the sign of the variable (as indicated on table) if necessary.

Even though the odds ratios in *Table 3.8* tend to be close to unity (in part because they reflect shift of only 0.5 standard deviation) it is impressive that virtually all odds ratios are in the anticipated direction (i.e. greater than unity) and that many are significantly greater than unity. This also tended to be true for the responses to other individual Form 37/38 questions (not shown). The general interpretation of these analyses seems clear: women with few health or emotional limitations or symptoms, and women who are satisfied with their lives and have a supportive environment tend to adhere a little better to their HRT medications. The same patterns tend to hold for adherence up to SAV-1 and between SAV-1 and AV-1 in relation to baseline psychosocial measures and for adherence between AV-1 and AV-2 in relation to psychosocial measures at AV-1. As in previous tables, adherence analyses for SAV-1 to AV-1 were based on women consuming 80% or more of their pills at SAV-1 and adherence analysis for SAV-1 to AV-2 were based on women consuming 80% or more of their pills at AV-1.

A number of additional factors were also examined in relation to HRT adherence. These include From 2/3 (Eligible Screen) variables related to the form of first WHI contact (mailed letter, friend/relative,...), and the woman's initial expression of interest in HRT; Form 20 (Personal Information) variables related to use of medical care and previous medical procedures; From 30 (Medical History) variables related to hospitalization and health conditions; Form 31 (Reproductive

History) variables related to age at menopause, menopausal symptoms, and breast biopsies; Form 32 (Family History) variables related to selected vascular diseases, cancers and fractures; Form 34 (Personal Habits) variables related to smoking and diet; Form 80 (Physical Measurement) variables; Form 85 (Mammogram); and Form 100 (Blood Counts). In general there was little relationship between these factors and HRT adherence, so that detailed analyses are not listed here. It can be commented that women with a uterus who had a breast biopsy were somewhat less likely to be adherent (odds ratio 0.8 between baseline and SAV-1, and 0.7 between SAV-1 and AV-1; both significant) as was also the case among women who reported breast cancer in a female relative (odds ratio 0.8 between baseline and SAV-1, and 0.8 between SAV-1 and AV-1, the latter significant). These associations were, however, not apparent among hysterectomized women.

Table 3.9 - Reasons for Stopping HRT summarizes the frequency of reported reasons for stopping interventions by hysterectomy status.

3.2 Symptoms

Women may report symptoms potentially related to HRT at routine follow-up contacts or through non-routine contacts with the CC. The primary symptoms being monitored are bleeding and breast changes. Reports of bleeding and breast changes by contact type are shown in *Tables 3.10* and *3.11*, respectively. Note that 5% or more of women with a uterus report bleeding at each annual visit through AV-4.

3.3 Safety Monitoring

Table 3.12 - Results of Endometrial Monitoring presents results of endometrial aspirations by time since randomization and study arm. 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 to address bleeding problems. Among 1793 biopsies, 52 (2.9%) yielded an abnormal result: 31 cystic, 6 adenomatous, 12 atypia and 3 cancer.

3.4 Issues

While HRT adherence rates in the WHI appear to be impressive relative to adherence rates in routine clinical practice, they fall somewhat short of CT design assumptions, particularly between AV-1 and AV-2. WHI adherence data can help identify program activities that may help to enhance adherence, and can help identify subsets of women who may need additional support and assistance to remain adherent.

Improving adherence to the HRT regimen is a high priority of the WHI program. To address adherence problems associated with bleeding, we have modified the protocol to allow additional flexibility for the local gynecologists to use additional, open-label medroxyprogesterone (MPA 2.5 or 5 mg) or open-label conjugated equine estrogen (CEE 0.3 mg) as an option for short-term treatment for bleeding after the first 6 months.

Other sources of adherence problems appear to be related to external pressure from primary care providers to be on active hormones and the need for more support and reassurance from clinics to stay on blinded medications in the face of conflicting information and non-specific symptoms.

An HRT Adherence Summit was convened in May 1997 to review analysis of factors associated with adherence, to identify strategies to improve adherence and to develop a plan to implement these. Multivariate analyses similar to those shown above examined the relationship between psychosocial factors assessed at baseline and subsequent adherence. These analysis confirmed our general intuition that better mental health and social support were associated with better adherence. The effect of the 6-week phone call in improving adherence also suggests that more attention from clinic staff can help. The challenge, of course, is to accomplish this within the existing resources. Those in attendance generated ideas for participant and clinic level tasks that should be considered for their potential to increase adherence without substantial increases in costs. These suggestions were incorporated into a section of the WHI Manuals, *Volume 2 – Procedures, Appendix G.2.* Suggestions were also incorporated into other clinic resource and participant materials.

The PMC is also focusing on adherence. They have conducted site visits specifically for CCs having poorer than average adherence. To become more pro-active, the PMC also visited sites with good adherence to learn about their systems and efforts to track and manage adherence problems. The information gleaned from these fact finding visits was incorporated into training modules presented at the Regional Retention and Adherence Workshops presented to all Clinical Centers in April/May 1998.

Table 3.1
HRT Adherence Summary
Data as of: August 31, 1998

	Due	Conducted		Conducted in Window		Stopped HRT during interval		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	%	%
6 Week	25898	24534	95	20731	80													
Semi-Annual																		
Visit-1	24806	24140	97	20545	83	1273	5	1452	6	22994	94	891	4	1712	7	20391	89	83
Without Uterus	9751	9433	97	7914	81	484	5	663	7	9074	93	364	4	753	8	7957	88	82
With Uterus	15055	14707	98	12631	84	789	5	789	5	13920	95	527	4	959	7	12434	89	85
Annual Visit-1	20924	20072	96	16659	80	1003	5	1202	6	17998	94	742	4	1518	8	15738	87	77
Without Uterus	8243	7855	95	6519	79	438	5	538	7	7151	93	291	4	684	10	6176	86	75
With Uterus	12681	12217	96	10140	80	565	5	664	6	10847	94	451	4	834	8	9562	88	78
Annual Visit-2	11300	10504	93	8566	76	998	9	1074	11	8529	89	298	4	791	9	7440	87	68
Without Uterus	4516	4140	92	3368	75	440	10	489	12	3449	88	116	3	360	10	2973	86	66
With Uterus	6784	6364	94	5198	77	558	9	585	10	5080	90	182	4	431	9	4467	88	70
Annual Visit –3	4807	4415	92	3649	76	273	6	308	9	3192	91	107	3	296	9	2789	87	63
Without Uterus	1965	1778	90	1484	76	132	7	135	9	1348	91	50	4	143	11	1155	86	60
With Uterus	2842	2637	93	2165	76	141	6	173	9	1844	91	57	3	153	8	1634	89	66
Annual Visit –4	1304	1182	91	1003	77	80	7	81	10	742	90	19	3	53	7	670	90	60
Without Uterus	545	485	89	413	76	33	6	35	9	348	91	7	2	29	8	312	90	58
With Uterus	759	697	92	590	78	47	8	46	11	394	90	12	3	24	6	358	91	61

[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.

Table 3.2
HRT Drop-Out and Drop-In Rates by Follow-Up Time
(Design-specified values in parentheses)
Data as of: August 31, 1998

	Without Uterus				With Uterus				Overall Total			
	Interval[1]		Cumulative[2]		Interval		Cumulative		Interval		Cumulative	
Drop-Outs[3]												
AV-1	10.0	(8.8)	10.0	(8.8)	9.8	(8.8)	9.8	(8.8)	9.8	(8.8)	9.8	(8.8)
AV-2	9.8	(5.9)	18.9	(14.2)	8.7	(5.9)	17.6	(14.2)	9.2	(5.9)	18.1	(14.2)
AV-3	6.8	(5.9)	24.4	(19.2)	5.7	(5.9)	22.3	(19.2)	6.2	(5.9)	23.2	(19.2)
AV-4	6.1	(5.9)	29.0	(24.0)	8.0	(5.9)	28.5	(24.0)	7.1	(5.9)	28.7	(24.0)
Drop-Ins[4]												
AV-1	2.8	(1.5)	2.8	(1.5)	2.1	(1.5)	2.1	(1.5)	2.4	(1.5)	2.4	(1.5)
AV-3	5.1	(2.9)	7.8	(4.4)	2.9	(2.9)	4.9	(4.4)	3.8	(2.9)	6.1	(4.4)

[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 3.3
Sensitivity of HRT Study Power to Adherence Assumptions

Outcome	Year	Intervention Effect[1] (%)	Percentage of Cases[1]				Power			
			Intervention		Control		ERT vs. Placebo		PERT vs. Placebo	
			Design	Revised[2]	Design	Revised[2]	Design[3]	Revised Adherence & Incidence Rates[4]	Design[3]	Revised Adherence & Incidence Rates[4]
CHD	2001	17	2.71	2.07	3.26	2.51	46	38	54	45
		21	2.60	1.97	3.26	2.51	62	52	70	61
		24	2.49	1.88	3.25	2.50	76	66	84	75
	2004	17	4.16	3.56	5.03	4.27	64	53	73	61
		21	3.97	3.40	5.02	4.26	81	69	88	78
		24	3.79	3.23	5.01	4.24	92	83	96	90

[1] 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.

[2] Revised incidence rates reflect greater healthy volunteer effects in years 1-3.

[3] Combined Drop-out and loss to follow-up rates of 8.8% in year 1, 5.9% per year thereafter; Drop-in rate of 1.5% per year.

[4] Combined Drop-out and loss to follow-up rates of 10% in years 1 and 2, 6.9% thereafter; Drop-in rate of 2.5% per year.

Table 3.4
Logistic Regression Analysis of HRT Medication Adherence between Baseline and Semi-annual Visit (SAV-1)[1]
Data as of: August 31, 1998

	HRT (N=24446)					
	Without Uterus (N=9737)			With Uterus (N=14709)		
	Non-Adherent Participants (N=1780)	Adherent Participants[2] (N=7957)	OR for adherence (>80%)[3]	Non-Adherent Participants (N=2275)	Adherent Participants[2] (N=12434)	OR for adherence (>80%)[3]
Age:						
50-54[4]	283	1108	1.00	324	1639	1.00
55-59	379	1486	0.95	514	2844	1.03
60-69	711	3510	1.11	911	5420	1.04
70-79	407	1853	0.98	526	2531	.84*
Ethnicity:						
White	1135	6188	1.00	1699	10666	1.00
Black	397	1069	0.54**	228	736	0.55**
Hispanic	182	430	0.51**	246	561	0.52**
Other Minority	63	256	0.78	96	441	0.77*
Education:						
0-8 Yrs	75	220	1.00	116	232	1.00
Some H.S./Diploma	527	2344	0.93	586	2917	1.40*
Post H.S.	1151	5327	0.99	1554	9209	1.59**
Income:						
<20K	600	2323	1.00	670	2661	1.00
20-35K	452	2252	1.11	566	3278	1.23**
35-50K	305	1447	1.03	394	2530	1.32**
>50K	363	1750	1.03	577	3707	1.29**
DM Randomized:						
No	1193	5377	1.00	1575	8929	1.00
Yes	587	2580	1.04	700	3505	0.90*
HRT Washout:						
No	1552	6776	1.00	2127	11464	1.00
Yes	228	1181	1.20*	148	970	1.20
Marital Status:						
Married	900	4433	1.00	1235	7372	1.00
Not Married	862	3487	0.91	1021	5019	0.95
Hormones Ever:						
No	694	3023	1.00	1368	7483	1.00
Yes	1086	4934	0.93	907	4951	0.94

(continues)

[1] Excludes ERT to PERT participants. The following demographic variables were included in the logistic model: Age, ethnicity, education, income, DM randomized, HRT washout, marital status, hormones ever, 6 week phone call, breast changes, bleeding reported.
[2] Adherence defined as participants who took at least 80% of HRT medications. If a participant does not have a pill collection, then her adherence estimate equals 0.
[3] Assuming asymptotic normality for parameter estimates.
[4] Underlined levels are reference categories
*P-value <=.05 from Wald test.
** P-value <=.01 from Wald test.

Table 3.4 (continued)
Logistic Regression Analysis of HRT Medication Adherence between Baseline and Semi-annual Visit (SAV-1)[1]
Data as of: August 31, 1998

	HRT (N=24446)					
	Without Uterus (N=9737)			With Uterus (N=14709)		
	Non-Adherent Participants (N=1780)	Adherent Participants[2] (N=7957)	OR for adherence (>80%)[3]	Non-Adherent Participants (N=2275)	Adherent Participants[2] (N=12434)	OR for adherence (>80%)[3]
6 wk phone call						
No	189	423	1.00	259	569	1.00
Yes	1591	7534	1.80**	2016	11865	2.43**
On-Study Bleeding						
No bleeding at 6 weeks				1691	9675	1.00
Bleeding at 6 weeks				557	2686	0.75**

[1] Excludes ERT to PERT participants. The following demographic variables were included in the logistic model: Age, ethnicity, education, income, DM randomized, HRT washout, marital status, hormones ever, 6 week phone call, breast changes, bleeding reported.
[2] Adherence defined as participants who took at least 80% of HRT medications. If a participant does not have a pill collection, then her adherence estimate equals 0.
[3] Assuming asymptotic normality for parameter estimates.
[4] Underlined levels are reference categories
* P-value <=.05 from Wald test.
** P-value <=.01 from Wald test.

Table 3.5
Logistic Regression Analysis of HRT Medication Adherence between Semi-annual Visit 1 (SAV1) and Annual Visit 1 (AV1) for those Participants with 80% Medication Adherence at Semi-annual Visit 1 (SAV1)[1]
Data as of: August 31, 1998

	HRT (N=17127)					
	Without Uterus (N=6713)			With Uterus (N=10414)		
	Non-Adherent Participants (N=1000)	Adherent Participants[2] (N=5713)	OR for adherence (>80%)[3]	Non-Adherent Participants (N=1393)	Adherent Participants[2] (N=9021)	OR for adherence (>80%)[3]
Age:						
50-54[4]	179	910	1.00	218	1375	1.00
55-59	192	1098	1.10	320	2095	1.02
60-69	421	2428	1.07	577	3832	1.00
70-79	208	1277	1.14	278	1719	0.98
Ethnicity:						
White	689	4542	1.00	1114	7846	1.00
Black	198	702	0.55**	128	489	0.57**
Hispanic	75	294	0.69*	88	375	0.75*
Other Minority	37	166	0.70	59	291	0.72*
Education:						
0-8 Yrs	39	159	1.00	41	142	1.00
Some H.S./Diploma	267	1664	1.13	335	2073	1.42
Post H.S.	688	3837	1.05	1001	6755	1.58*
Income:						
<20K	310	1675	1.00	333	1886	1.00
20-35K	280	1595	0.96	358	2371	1.02
35-50K	164	1041	1.07	263	1861	1.04
>50K	217	1270	0.98	405	2725	0.96
DM Randomized:						
No	691	3795	1.00	996	6419	1.00
Yes	309	1918	1.20*	397	2602	1.03
HRT Washout:						
No	876	4863	1.00	1316	8298	1.00
Yes	124	850	1.28*	77	723	1.57**
Marital Status:						
Married	524	3223	1.00	762	5439	1.00
Not Married	471	2462	0.94	619	3557	0.83**
Hormones Ever:						
No	375	2200	1.00	815	5400	1.00
Yes	625	3513	0.88	578	3621	0.87*

(continues)

[1] Excludes ERT to PERT participants. The following demographic variables were included in the logistic model: Age, ethnicity, education, income, DM randomized, HRT washout, marital status, hormones ever, 6 week phone call, breast changes, bleeding reported.
[2] Adherence defined as participants who took at least 80% of HRT medications. If a participant does not have a pill collection, then her adherence estimate equals 0.
[3] Assuming asymptotic normality for parameter estimates.
[4] Underlined levels are reference categories
* P-value <=.05 from Wald test.
** P-value <=.01 from Wald test.

Table 3.5 (continued)
Logistic Regression Analysis of HRT Medication Adherence between Semi-annual Visit 1 (SAV1) and Annual Visit 1 (AV1) for those Participants with 80% Medication Adherence at Semi-annual Visit 1 (SAV1)[1]
Data as of: August 31, 1998

	HRT (N=17127)					
	Without Uterus (N=6713)			With Uterus (N=10414)		
	Non-Adherent Participants (N=1000)	Adherent Participants[2] (N=5713)	OR for adherence (>80%)[3]	Non-Adherent Participants (N=1393)	Adherent Participants[2] (N=9021)	OR for adherence (>80%)[3]
6 wk phone call						
No	77	319	1.00	75	398	1.00
Yes	923	5394	1.25	1318	8623	1.06
Reported breast changes at 6 mths						
No	938	5453	1.00	1284	8551	1.00
Yes	58	228	0.67**	96	429	0.71**
On-Study Bleeding						
No bleeding at 6 weeks				897	6099	1.00
Bleeding at 6 weeks only				48	278	0.90
Bleeding at 6 months only				146	841	0.86
Bleeding at 6 wks *and* 6 mths				278	1682	0.89

[1] Excludes ERT to PERT participants. The following demographic variables were included in the logistic model: Age, ethnicity, education, income, DM randomized, HRT washout, marital status, hormones ever, 6 week phone call, breast changes, bleeding reported.
[2] Adherence defined as participants who took at least 80% of HRT medications. If a participant does not have a pill collection, then her adherence estimate equals 0.
[3] Assuming asymptotic normality for parameter estimates.
[4] Underlined levels are reference categories
* P-value <=.05 from Wald test.
** P-value <=.01 from Wald test.

Table 3.6
Logistic Regression Analysis of HRT Medication Adherence between Annual Visit 1 (AV1) and Annual Visit 2 (AV2) for those Participants with 80% Medication Adherence at AV1[1]
Data as of: August 31, 1998

	HRT (N=8346)					
	Without Uterus (N=3367)			With Uterus (N=4979)		
	Non-Adherent Participants (N=629)	Adherent Participants[2] (N=2738)	OR for adherence (>80%)[3]	Non-Adherent Participants (N=852)	Adherent Participants[2] (N=4127)	OR for adherence (>80%)[3]
Age:						
50-54[4]	147	500	1.00	180	734	1.00
55-59	135	549	1.20	223	1006	1.02
60-69	235	1129	1.35*	301	1742	1.27*
70-79	112	560	1.43*	148	645	1.03
Ethnicity:						
White	425	2184	1.00	673	3635	1.00
Black	119	355	0.64**	94	209	0.49**
Hispanic	61	115	0.46**	60	154	0.63*
Other Minority	22	78	0.73	25	118	0.93
Education:						
0-8 Yrs	26	69	1.00	24	61	1.00
Some H.S./Diploma	167	775	1.05	172	911	1.30
Post H.S.	429	1869	1.01	650	3136	1.13
Income:						
<20K	200	764	1.00	225	815	1.00
20-35K	185	789	0.98	210	1115	1.35**
35-50K	99	537	1.27	150	874	1.54**
>50K	126	596	1.20	245	1258	1.35*
DM Randomized:						
No	411	1746	1.00	574	2821	1.00
Yes	218	992	1.11	278	1306	0.95
HRT Washout:						
No	538	2342	1.00	788	3766	1.00
Yes	91	396	1.11	64	361	1.42*
Marital Status:						
Married	333	1575	1.00	478	2530	1.00
Not Married	289	1149	0.93	369	1588	0.96
Hormones Ever:						
No	235	1073	1.00	468	2413	1.00
Yes	394	1665	0.88	384	1714	0.82*

(continues)

[1] Excludes ERT to PERT participants. The following demographic variables were included in the logistic model: Age, ethnicity, education, income, DM randomized, HRT washout, marital status, hormones ever, 6 week phone call, breast changes, bleeding reported.
[2] Adherence defined as participants who took at least 80% of HRT medications. If a participant does not have a pill collection, then her adherence estimate equals 0.
[3] Assuming asymptotic normality for parameter estimates.
[4] Underlined levels are reference categories
* P-value <=.05 from Wald test.
** P-value <=.01 from Wald test.

Table 3.6 (continued)
Logistic Regression Analysis of HRT Medication Adherence between Annual Visit 1 (AV1) and Annual Visit 2 (AV2) for those Participants with 80% Medication Adherence at AV1[1]
Data as of: August 31, 1998

	HRT (N=8346)					
	Without Uterus (N=3367)			With Uterus (N=4979)		
	Non-Adherent Participants (N=629)	Adherent Participants[2] (N=2738)	OR for adherence (>80%)[3]	Non-Adherent Participants (N=852)	Adherent Participants[2] (N=4127)	OR for adherence (>80%)[3]
6 wk phone call						
No	58	194	1.00	55	230	1.00
Yes	571	2544	1.06	797	3897	1.05
Reported breast changes						
No breast changes	561	2497	1.00	772	3726	1.00
Breast changes at 6 months only	28	118	0.90	36	204	1.23
Breast changes at 1 year only	27	66	.49**	25	124	1.01
Breast changes at 6 mths and 1 yr	2	17	1.66	9	22	0.45
On-Study Bleeding						
No bleeding reported at 6wks				525	2665	1.00
Bleeding at 6 weeks only				22	105	0.99
Bleeding at 6 months only				44	250	1.18
Bleeding at 6 wks and 6 mths				55	335	1.17
Bleeding at 1 year				39	86	0.42**
Bleeding at 6 wks and 1 yr				8	27	0.66
Bleeding at 6 mths and 1 yr				30	157	1.05
Bleeding at 6 wks, 6 mths, 1 yr				107	401	0.69**

[1] Excludes ERT to PERT participants. The following demographic variables were included in the logistic model: Age, ethnicity, education, income, DM randomized, HRT washout, marital status, hormones ever, 6 week phone call, breast changes, bleeding reported.
[2] Adherence defined as participants who took at least 80% of HRT medications. If a participant does not have a pill collection, then her adherence estimate equals 0.
[3] Assuming asymptotic normality for parameter estimates.
[4] Underlined levels are reference categories
* P-value <=.05 from Wald test.
** P-value <=.01 from Wald test.

Table 3.7
Logistic Regression Analysis of HRT Medication Adherence between Annual Visit 2 (AV2) and Annual Visit 3 (AV3) for those Participants with 80% Medication Adherence at AV2[1]
Data as of: August 31, 1998

	HRT (N=3046)					
	Without Uterus (N=1289)			With Uterus (N=1757)		
	Non-Adherent Participants (N=238)	Adherent Participants[2] (N=1051)	OR for adherence (>80%)[3]	Non-Adherent Participants (N=246)	Adherent Participants[2] (N=1511)	OR for adherence (>80%)[3]
Age:						
50-54[4]	47	171	1.00	42	250	1.00
55-59	42	188	1.26	60	360	1.00
60-69	92	486	1.50	98	696	1.27
70-79	57	206	1.07	46	205	0.88
Ethnicity:						
White	187	871	1.00	216	1370	1.00
Black	39	128	0.82	16	73	0.96
Hispanic	10	28	0.78	9	34	0.70
Other Minority	1	22	6.74	4	33	1.22
Education:						
0-8 Yrs	7	25	1.00	6	22	1.00
Some H.S./Diploma	61	313	0.95	59	354	1.94
Post H.S.	169	707	0.87	179	1131	1.95
Income:						
<20K	66	288	1.00	56	288	1.00
20-35K	67	307	0.91	80	405	0.90
35-50K	43	210	0.89	51	334	1.27
>50K	53	224	0.86	55	464	1.60
DM Randomized:						
No	140	634	1.00	155	943	1.00
Yes	98	417	0.92	91	568	1.02
HRT Washout:						
No	220	938	1.00	230	1416	1.00
Yes	18	113	1.63	16	95	0.94
Marital Status:						
Married	121	626	1.00	137	949	1.00
Not Married	116	419	0.71*	108	557	0.94
Hormones Ever:						
No	93	420	1.00	140	890	1.00
Yes	145	631	0.89	106	621	1.01

(continues)

[1] Excludes ERT to PERT participants. The following demographic variables were included in the logistic model: Age, ethnicity, education, income, DM randomized, HRT washout, marital status, hormones ever, 6 week phone call, breast changes, bleeding reported.
[2] Adherence defined as participants who took at least 80% of HRT medications. If a participant does not have a pill collection, then her adherence estimate equals 0.
[3] Assuming asymptotic normality for parameter estimates.
[4] Underlined levels are reference categories
* P-value <=.05 from Wald test.
** P-value <=.01 from Wald test.

Table 3.7 (continued)
Logistic Regression Analysis of HRT Medication Adherence between Annual Visit 2 (AV2) and Annual Visit 3 (AV3) for those Participants with 80% Medication Adherence at AV2[1]
Data as of: August 31, 1998

	HRT (N=3046)					
	Without Uterus (N=1289)			With Uterus (N=1757)		
	Non-Adherent Participants (N=238)	Adherent Participants[2] (N=1051)	OR for adherence (>80%)[3]	Non-Adherent Participants (N=246)	Adherent Participants[2] (N=1511)	OR for adherence (>80%)[3]
6 wk phone call						
No	28	100	1.00	24	125	1.00
Yes	210	951	0.97	222	1386	0.69
Reported breast changes						
No breast changes	215	954	1.00	211	1328	1.00
Breast changes at 6 months only	12	53	1.11	20	98	0.78
Breast changes at 1 year only	6	20	0.62	10	50	0.90
Breast changes at 6 mths and 1 yr	3	11	0.89	0	14	N.A.
On-Study bleeding						
No bleeding at 6 weeks				158	997	1.00
Bleeding at 6 weeks only				8	34	0.73
Bleeding at 6 months only				16	82	0.83
Bleeding at 6 wks and 6 mnths				8	143	3.34**
Bleeding at 1 year only				5	26	0.88
Bleeding at 6 wks and 1 year				3	11	0.58
Bleeding at 6 months and 1 year				16	48	0.48*
Bleeding at 6 wks, 6 mnths, 1 yr				23	135	0.87

[1] Excludes ERT to PERT participants. The following demographic variables were included in the logistic model:Age, ethnicity, education, income, DM randomized, HRT washout, marital status, hormones ever, 6 week phone call, breast changes, bleeding reported.
[2] Adherence defined as participants who took at least 80% of HRT medications. If a participant does not have a pill collection, then her adherence estimate equals 0.
[3] Assuming asymptotic normality for parameter estimates.
[4] Underlined levels are reference categories
* P-value <=.05 from Wald test.
** P-value <=.01 from Wald test.

Table 3.8
Logistic Regression Analysis[a] of Psychosocial and Behavioral Measures on HRT Adherence
Data as of : August 31, 1998

	Without Uterus			With Uterus		
	HRT Adherence from[c]:					
	Baseline to SAV-1	SAV-1 to AV-1	AV-1 to AV-2	Baseline to SAV-1	SAV-1 to AV-1	AV-1 to AV-2
Psychosocial Behavioral Constructs[b]	Baseline Variables[d]		AV-1 Variables[d]	Baseline Variables[d]		AV-1 Variables[d]
Number of Women	9737	6713	3367	14709	10414	4979
(a higher score indicates...)						
Social Support Construct (greater support)	1.10 *	1.05		1.05 *	1.11 *	
Social Strain Construct[c] (less strain)	1.06 *	1.09 *		1.10 *	1.08 *	
Optimism Construct (more optimism)	1.09 *	1.09 *		1.06 *	1.06	
Negative Emotional Expressiveness[c] (less negative expressiveness)	1.10 *	1.15 *		1.04	1.05	
Ambivalent Emotional Expressiveness[c] (less ambivalence)	1.04	1.03		1.02	1.07 *	
Hostility Construct[c] (less hostility)	1.04	1.08 *		1.07 *	1.07 *	
Overall Quality of Life (higher perceived quality)	1.08 *	1.06	1.13 *	1.07 *	1.09 *	1.10 *
Satisfaction with Quality of Life (more satisfaction)	1.09 *	1.08 *	1.15 *	1.10 *	1.12 *	1.10 *
Physical Functioning Construct (less limitations)	1.07 *	1.09 *	1.09 *	1.10 *	1.07 *	1.19 *
Limitations Due to Physical Health Construct (less limitations)	1.12 *	1.12 *	1.20 *	1.07 *	1.10 *	1.10 *
Limitations Due to Emotional Problems Construct (less limitations)	1.13 *	1.16 *	1.17 *	1.12 *	1.12 *	1.12 *
Health Interference with Social Activities (less interference)	1.09 *	1.16 *	1.14	1.08 *	1.09 *	1.12 *
Downhearted and Blue (less feeling blue)	1.14 *	1.12 *	1.14 *	1.10 *	1.09 *	1.06
Feel Worn Out (less worn out)	1.10 *	1.14 *	1.09 *	1.10 *	1.05	1.05
Pain Construct (less pain)	1.10 *	1.10 *	1.13	1.04 *	1.11 *	1.09 *
General Health Construct (better health)	1.07 *	1.09 *	1.20 *	1.07 *	1.08 *	1.14 *
Daily Living Activities Construct[c] (less disability)	0.97	1.02	1.05 *	1.04 *	1.04	1.03
Overall Symptom Construct[c] (fewer symptoms)	1.15 *	1.15 *	1.17	1.09 *	1.12 *	1.21 *
Life Event Construct[c] (fewer and less upsettinglife events)	1.13 *	1.04	1.11 *	1.10 *	1.15 *	1.04
CES-D/DIS Depression Construct[c] (less depression)	1.07 *	1.10 *	1.14 *	1.09 *	1.12 *	1.03
Worried that sex will affect health[c] (less worried)	1.04	0.98	1.09 *	1.07 *	1.05	1.05

[a] The following demographic variables were included in the regression model: age, ethnicity, education, income, body mass index, hysterectomy status, and DM randomized.
[b] For descriptions of the psychosocial behavioral constructs, see Appendix A
[c] The sign of the parameter was reversed to reflect the description of the scoring.
[d] Indicates the timeframe for the psychosocial behavioral constructs used in the model.
[e] Each entry is the odds ratio for adherence (>80%) associated with an upward shift of one standard deviation in the psychosocial variable. Adherence analyses for SAV-1 to AV-1 are based on women reported taking 80% or more of their pills at SAV-1, and adherence analyses for AV-1 to AV-2 are based on women who reported taking 80% or more of their pills at AV-1
* Denotes statistical significance at the 0.05 level (from regression t-test)

Table 3.9
Reasons for Stopping HRT
Data as of August 31, 1998

Reasons[1]	Without Uterus (N = 1844)		With Uterus (N =2732)	
Personal	129	(7%)	160	(6%)
Travel	66	(4%)	74	(3%)
Study Procedures	29	(2%)	49	(2%)
Health	770	(42%)	976	(36%)
Experiencing health problems or symptoms not due to intervention	304	(16%)	333	(12%)
Worried about health effects of medical tests	7	(<1%)	10	(<1%)
Worried about costs if adverse effects occur	11	(1%)	1	(<1%)
Advised not to participate by health care provider	343	(19%)	489	(18%)
Study conflicts with health care needs	278	(15%)	363	(13%)
Expected more care	5	(<1%)	8	(<1%)
Intervention	509	(28%)	974	(36%)
Reports health problems or symptoms from WHI intervention	410	(22%)	827	(30%)
Problem with Clinic Practitioner or other CC staff	3	(<1%)	9	(<1%)
Doesn't like taking pills	49	(3%)	52	(2%)
Doesn't like DM requirements	1	(<1%)	3	(<1%)
Problems with DM group nutritionist or group members	1	(<1%)	1	(<1%)
Doesn't like DM eating patterns	1	(<1%)	1	(<1%)
Doesn't like randomized nature of intervention	37	(2%)	62	(2%)
Expected some benefit from intervention	24	(1%)	27	(1%)
Won't participate in safety procedures.	18	(1%)	23	(1%)
Other	541	(29%)	839	(31%)
Not Given	192	(10%)	292	(11%)

[1] Multiple reasons may be reported for a woman

Table 3.10
Reports of Bleeding
Data as of: August 31, 1998

	With Uterus
6 Week HRT Phone Call	
Number with an HRT Safety Interview Number with Bleeding	15496 3552 (22.9%)
Semi-Annual Visit 1	
Number Having Visit Number with Bleeding	14707 4238 (28.8%)
Annual Visit 1	
Number Having Visit Number with Bleeding	12217 2253 (18.4%)
Semi-Annual Visit 2	
Number Having Visit Number with Bleeding	9048 1154 (12.8%)
Annual Visit 2	
Number Having Visit Number with Bleeding	6364 682 (10.7%)
Semi-Annual Visit 3	
Number Having Visit Number with Bleeding	4203 347 (8.3%)
Annual Visit 3	
Number Having Visit Number with Bleeding	2637 194 (7.4%)
Semi-Annual Visit 4	
Number Having Visit Number with Bleeding	1499 88 (5.9%)
Annual Visit 4	
Number Having Visit Number with Bleeding	697 35 (5.0%)
Semi-Annual Visit 5	
Number Having Visit Number with Bleeding	69 2 (2.9%)
Non Routine Visit	
Number Randomized Number with Bleeding	16597 1295 (7.8%)

Table 3.11
Other HRT Symptoms
Data as of: August 31, 1998

	Without Uterus	With Uterus
6 Week HRT Phone Call		
Number with an HRT Safety Interview	9970	15496
Number with Breast Changes	598 (6.0%)	1062 (6.9%)
Semi-Annual Visit 1		
Number Having Visit	9098	14254
Number with Breast Changes	430 (4.7%)	822 (5.8%)
Annual Visit 1		
Number Having Visit	7636	11907
Number with Breast Changes	292 (3.8%)	483 (4.1%)
Semi-Annual Visit 2		
Number Having Visit	5378	8436
Number with Breast Changes	144 (2.7%)	265 (3.1%)
Annual Visit 2		
Number Having Visit	3863	5919
Number with Breast Changes	123 (3.2%)	192 (3.2%)
Semi-Annual Visit 3		
Number Having Visit	2349	3618
Number with Breast Changes	64 (2.7%)	93 (2.6%)
Annual Visit 3		
Number Having Visit	1538	2330
Number with Breast Changes	55 (3.6%)	83 (3.6%)
Semi-Annual Visit 4		
Number Having Visit	855	1210
Number with Breast Changes	21 (2.5%)	28 (2.3%)
Annual Visit 4		
Number Having Visit	393	574
Number with Breast Changes	14 (3.6%)	22 (3.8%)
Semi-Annual Visit 5		
Number Having Visit	33	43
Number with Breast Changes	4 (12.1%)	2 (4.7%)
Non Routine Visit		
Number Randomized	10725	16597
Number with Breast Changes	57 (0.5%)	190 (1.1%)

Table 3.12
Endometrial Aspiration Results

Days since randomized	N of aspirations[1,2]	Number with Abnormal Results[3]				
		Cystic	Adenomatous	Atypia	Cancer	Total[4]
0-90	16	1	0	0	0	0
91-180	62	2	1	0	0	1
181-270	296	7	1	0	0	1
271-360	223	2	1	2	0	3
361-450	473	7	1	2	1	4
451-540	107	1	1	2	1	4
541-630	158	6	1	2	0	3
631-720	68	2	0	1	0	1
721-810	135	1	0	0	0	0
811-900	22	0	0	0	0	0
901-990	48	0	0	0	0	0
991-1080	16	0	0	0	1	1
1081-1170	122	1	0	3	0	3
1171-1260	9	0	0	0	0	0
1261-1350	16	1	0	0	0	0
1351-1440	7	0	0	0	0	0
1441-1520	12	0	0	0	0	0
1521-1610	3	0	0	0	0	0
Total	1793	31	6	12	3	21

[1] 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.

[2] ERT-TO-PERT removed

[3] 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

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

4. DM Intervention Status

4.1 Adherence

Nutrient intake data for adherence monitoring are presented in *Tables 4.1-4.4*. Studywide, the mean difference between Intervention and Comparison women is 11.1% energy from fat at AV-1, 10.0% at AV-2, 9.9% at AV-3, and 7.9% at AV-4. We note some improvement in these values since the last report: 11.2% at AV-1, 9.8% at AV-2, and 8.9% at AV-3. Although the AV-4 figure is somewhat concerning, this estimate is likely a function of the early cohort effect. That is, women randomized early in WHI received higher fat gram goals than the majority of WHI participants, who were randomized after implementation of reduced fat gram goals.

While these Comparison - Intervention (C-I) differences represent a substantial achievement, they fall short of the assumptions of 13% C-I at AV-1 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 new power calculations shown in *Table 4.5* were calculated under a modified assumption of an AV-1 C-I of 11.2% diminishing to 8% at year 10, with adjustment for the actual age distribution of WHI DM participants. These calculations indicate that the study has about 69% power for breast cancer and 84% power for colorectal cancer under the revised adherence assumptions. We note that the intervention effect modeling for design considerations was based on fat intake adjusted for total energy. 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.

Among participants with the reduced fat gram goals, the C-I difference seems to be maintained from AV-1 to AV-3 (*Table 4.2*). By the end of recruitment, approximately 80% of DM Intervention participants will have the reduced fat gram goals. Presently, over 75% of DM Intervention participants have reduced fat gram goals at AV-1, while only about 60% with an AV-2 FFQ have the reduced fat gram goals (*Table 4.2*). The C-I value in minority women is smaller (9.0%) at AV-1 than the overall results, and appears to be diminishing more rapidly in this group than overall (*Table 4.3*). Women over age 70 have a somewhat smaller C-I difference (*Table 4.4*).

Multivariate analyses were conducted to identify factors associated with C-I differences in percentage energy from fat (*Table 4.6-4.7*). Participant characteristics associated with a poorer C-I difference include being older, a minority, or having a higher BMI (*Table 4.6*). Several DM participation variables, including smaller group size, attending sessions, and self-monitoring, have statistically significant positive impacts on the C-I difference at AV-1 and AV-2 (*Table 4.7*).

The effects of psychosocial, dietary, and physical activity factors are presented in *Table 4.8, 4.9,* and *4.10,* respectively. (For descriptions of the psychosocial behavioral constructs, see Appendix A.) Positive responses to psychosocial questions are associated with larger C-I differences. Having personal health-related conditions, such as diabetes or diverticulitis, impacts negatively on C-I percent energy from fat. Having personal dietary regimens (any special diet including diabetic or low calorie) has a negative effect on C-I percent energy from fat (*Table 4.9*). Higher physical activity responses are associated with a slightly lower C-I energy from fat (*Table 4.10*). For both

health-related conditions and physical activity, one potential reason for the negative impact on adherence is that percent energy from fat might be lower upon entry to the WHI. Further data analysis on body weight change and DM adherence is warranted.

Study performance on adherence to program activities are given in *Table 4.11 - Intervention Group Formation* and *Table 4.12-4.14 - Intervention Program Adherence Summary*. Clinic specific data of this type are used to monitor Clinical Center performance. Overall these results are consistent with similar data collected in the Women's Health Trial: Feasibility Study in Minority Populations.

Body weight data (C-I) are presented in *Table 4.15*. Body weight loss can be viewed as an indirect measure of adherence as it is difficult in a free-living setting to maintain the same energy intake while consuming a low-fat dietary pattern instead of a higher fat dietary pattern. However, weight loss is not a goal of the DM Intervention, thus an expected amount of weight loss is difficult to quantify. At AV-1, the Intervention group lost slightly more weight than the control group (2.0 kilograms), though this difference diminishes over time. Minority Intervention participants experienced a non-significant weight gain at AV-3, with some suggestion of increasing weight over time. Women with the revised fat gram goals have a slightly larger weight loss than overall, consistent with the dietary intake results.

The primary concern for DM is to achieve an adequate reduction in fat intake in the Intervention group at AV-1 and to maintain that reduction throughout the duration of follow-up. Specialized efforts directed to participant groups with lower C-I differences, including minority populations and older women, and to Clinical Centers having smaller C-I differences, are underway through the PMC conference calls and adherence visits with Clinical Centers.

Over the past year there has been considerable scientific activity with regard to DM adherence. In January, 1998 a DM advisory Group (composed of behavioral scientists external and internal to WHI), released a review of the DM maintenance protocol with suggestions for improvements. In July, 1998, the DM adherence Summit Progress Report was released and contained many recommendations related to three topic areas: triaging additional assistance, enhancing the maintenance program, and changing the frequency of DM follow-up visits to the Clinical Centers. Many of these suggestions have been implemented and others are currently under study.

One feature of the DM Intervention program to help adherence is Additional Assistance. The Additional Assistance procedure calls for nutritionists to meet with participants who are exceeding their fat gram goals or are not self-monitoring. Additional Assistance is being conducted sporadically among Clinical Centers due in part to high staff demands as recruitment, Intervention, and maintenance activities are in progress simultaneously. This fall, the CCC will begin triage activities to assist clinical centers in concentrating additional assistance resources on those women who are most likely to benefit (i.e., women attending some sessions and/or self-monitoring, but not yet meeting goals).

Over the next several months, The CCC will be releasing a series of reports on ancillary studies related to peer groups, motivational interviewing, and participant reported strategies for overcoming barriers to adherence. These studies will provide an empirical basis for DM adherence and retention

activities, and thereby help us orient future efforts to achieve and maintain an adequate C-I difference.

4.2 Adherence to Follow-up

Table 4.16 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 adherence rates are above these rates for Years 1 through 4. However, there is some suggestion of a reduction in follow-up adherence at the semi-annual Contact 5, which will be carefully monitored.

Table 4.17 gives the number of active participants who have missed their last three consecutive contacts. Of the 30,547 DM participants who should have had at least 3 follow-up contacts, 403 (1.3%) have missed their last 3 consecutive contacts. Control women are at somewhat lower risk of missing their last 3 required contacts, but the numbers are within an acceptable range (0.4 - 1.9%).

Overall, 3.8% percent (n=740) of women randomized to DM Intervention have stopped Intervention. Reasons for stopping DM Intervention are listed in *Table 4.18* and include personal, not liking the DM Intervention or eating pattern and health problem(s) not related to the Intervention. Women are contacted periodically by Clinic staff to talk about the reasons why the women stopped the intervention and if they are able or willing to consider re-starting the DM Intervention. Women who have stopped the Intervention continue to participate in follow-up clinic visits, unless they request not to be followed up. In the intervention arm, 1.3% of participants have stopped active follow-up. In the control arm, 1.4% of participants have stopped active follow-up.

4.3 Safety

We define WHI DM safety as not compromising the nutritional status of participants because of participation in the WHI DM. We assess nutritional status using estimated nutrient intake and weight loss, comparing the Intervention group to the Control (Comparison) group. Dietary fat is the sole reductive goal of the WHI DM Intervention (Dietary Change). Thus, for the safety of women randomized to the WHI DM Intervention we monitor fat intake primarily, and weight loss secondarily as a marker of decreased fat intake.

By examining the lower tail of the fat intake distribution, e.g., 5th and 10th percentiles, we can estimate adequacy of fat intake (*Tables 4.19-4.20*). We can measure the adequacy of fat intake in the WHI DM Intervention relative to the FAO/WHO guidelines for fat intake for adults. The FAO/WHO guidelines suggest that most adults should consume at least 15% energy from fat in order to meet essential fatty acid and fat-soluble vitamin requirements. WHI Food Frequency data show that the 5th percentile for percentage energy from fat is 14.5% for Intervention participants and 24.6% for Control participants one year post-randomization. In fact, the actual 5th percentile will be higher than 14.5% for DM Intervention participants upon acknowledging the major random (and systematic) measurement error in the FFQ self-report of percent energy from fat.

Procedures exist for WHI nutritionists to assess the overall nutritional balance of DM Intervention participants. Nutritionists and DM Intervention participants meet once individually during the first

year of Intervention to discuss adherence and safety (WHI Manuals: *Volume 2 - Procedures, Section 6 - Dietary Modification*). During this individual session, the nutritionists and participants review self-monitored food intake records and identify areas to change. Nutritionists meet with participants individually as needed to discuss any concerns expressed by participants regarding the DM Intervention, ranging from nutrient intake to quality of life issues. To date, most participant-generated requests for individual visits with a nutritionist have included concerns about consuming too little fat, hair loss, dry nails, dry skin, and compatibility of the low-fat dietary pattern with other special needs (e.g., weight loss, diabetes).

Table 4.1
Nutrient Intake Monitoring
Data as of: August 31, 1998

	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]	14243	24.8	7.5	20981	35.9	6.9	11.1	0.1	0.00
FFQ Year 2[4]	2857	25.4	7.3	4162	35.4	7.1	10.0	0.2	0.00
FFQ Year 3[5]	459	25.7	7.1	577	35.6	7.1	9.9	0.4	0.00
FFQ Year 4[6]	112	27.5	8.0	155	35.4	6.3	7.9	0.9	0.00
4DFR Baseline	871	32.8	6.4	1302	33.0	6.7	0.2	0.3	0.40
4DFR Year 1	542	21.9	7.4	804	32.8	6.8	10.9	0.4	0.00
24 Hr Recall, post-Baseline	208	22.9	9.3	246	32.0	7.7	9.1	0.8	0.00
24 Hr Recall, Year 1	119	22.0	7.7	169	32.3	8.0	10.3	0.9	0.00
24 Hr Recall, Year 2	52	24.2	10.4	88	32.6	9.1	8.4	1.7	0.00
24 Hr Recall, Year 3	31	25.8	9.5	47	32.5	9.6	6.7	2.2	0.00
Total Energy (kcal)									
FFQ Baseline	19542	1789	713	29295	1789	707	0.0	6.6	0.92
FFQ Year 1	14243	1477	530	20981	1586	641	109.0	6.5	0.00
FFQ Year 2	2857	1502	518	4162	1576	607	74.0	13.9	0.00
FFQ Year 3	459	1514	534	577	1540	618	26.0	36.4	1.00
FFQ Year 4	112	1483	509	155	1599	597	116.0	69.7	0.20
4DFR Baseline	871	1709	455	1302	1715	456	6.0	19.9	0.76
4DFR Year 1	542	1442	367	804	1625	431	183.0	22.6	0.00
24 Hr Recall, post-Baseline	208	1519	424	246	1654	492	135.0	43.5	0.00
24 Hr Recall, Year 1	119	1530	389	169	1661	520	131.0	56.3	0.05
24 Hr Recall, Year 2	52	1486	422	88	1661	599	175.0	94.5	0.12
24 Hr Recall, Year 3	31	1473	350	47	1721	463	248.0	97.6	0.01
Total Fat (g)									
FFQ Baseline	19542	77.9	35.3	29295	77.8	34.7	0.1	0.3	0.86
FFQ Year 1	14243	40.9	21.2	20981	64.3	31.6	23.4	0.3	0.00
FFQ Year 2	2857	42.5	20.2	4162	63.1	30.2	20.6	0.6	0.00
FFQ Year 3	459	43.7	21.8	577	61.9	30.1	18.2	1.7	0.00
FFQ Year 4	112	45.6	21.7	155	63.7	29.4	18.1	3.3	0.00
4DFR Baseline	871	63.1	23.7	1302	63.9	24.4	0.8	1.1	0.58
4DFR Year 1	542	34.9	15.0	804	59.9	22.5	25.0	1.1	0.00
24 Hr Recall, post-Baseline	208	39.7	22.2	246	60.4	26.4	20.7	2.3	0.00
24 Hr Recall, Year 1	119	37.7	17.9	169	61.2	27.3	23.5	2.9	0.00
24 Hr Recall, Year 2	52	40.3	22.4	88	62.7	32.8	22.4	5.1	0.00
24 Hr Recall, Year 3	31	43.4	21.8	47	63.6	28.7	20.2	6.1	0.00

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat
[3] 4125 (29%) Intervention women had <=20% energy from fat at year 1.
[4] 703 (25%) Intervention women had <=20% energy from fat at year 2.
[5] 94 (20%) Intervention women had <=20% energy from fat at year 3.
[6] 18 (16%) Intervention women had <=20% energy from fat at year 4.

Table 4.1 (continued)
Nutrient Intake Monitoring
Data as of: August 31, 1998

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	19542	27.4	13.4	29295	27.3	13.2	0.1	0.1	0.86
FFQ Year 1[3]	14243	14.0	7.9	20981	22.5	11.9	8.5	0.1	0.00
FFQ Year 2[4]	2857	14.6	7.6	4162	22.1	11.3	7.5	0.2	0.00
FFQ Year 3[5]	459	14.9	8.1	577	22.0	11.6	7.1	0.6	0.00
FFQ Year 4[6]	112	15.8	7.9	155	22.1	11.0	6.3	1.2	0.00
4DFR Baseline	871	20.7	9.0	1302	21.0	9.2	0.3	0.4	0.69
4DFR Year 1	542	10.9	5.4	804	19.4	8.1	8.5	0.4	0.00
24 Hr Recall, post-Baseline	208	12.9	7.9	246	20.0	9.4	7.1	0.8	0.00
24 Hr Recall, Year 1	119	12.2	6.6	169	20.2	11.0	8.0	1.1	0.00
24 Hr Recall, Year 2	52	12.9	7.3	88	20.3	11.6	7.4	1.8	0.00
24 Hr Recall, Year 3	31	14.5	8.0	47	21.3	10.2	6.8	2.2	0.00
Polyunsaturated Fat (g)									
FFQ Baseline	19542	15.3	7.6	29295	15.3	7.6	0.0	0.1	0.77
FFQ Year 1	14243	7.7	4.2	20981	12.4	6.7	4.7	0.1	0.00
FFQ Year 2	2857	7.9	4.1	4162	12.0	6.3	4.1	0.1	0.00
FFQ Year 3	459	8.3	4.3	577	11.6	5.9	3.3	0.3	0.00
FFQ Year 4	112	8.9	5.1	155	12.5	6.1	3.6	0.7	0.00
4DFR Baseline	871	13.2	5.8	1302	13.5	6.1	0.3	0.3	0.25
4DFR Year 1	542	7.5	3.4	804	12.7	6.0	5.2	0.3	0.00
24 Hr Recall, post-Baseline	208	8.3	5.1	246	12.4	7.2	4.1	0.6	0.00
24 Hr Recall, Year 1	119	7.8	4.6	169	12.8	6.7	5.0	0.7	0.00
24 Hr Recall, Year 2	52	8.4	6.4	88	13.5	9.4	5.1	1.5	0.00
24 Hr Recall, Year 3	31	8.1	4.8	47	13.9	7.8	5.8	1.6	0.00
Fruits and Vegetables (servings)									
FFQ Baseline	19471	3.6	1.8	29217	3.6	1.8	0.0	0.0	0.52
FFQ Year 1	14351	5.1	2.3	21184	3.8	2.0	1.3	0.0	0.00
FFQ Year 2	2926	5.2	2.4	4280	3.9	2.0	1.3	0.1	0.00
FFQ Year 3	498	5.3	2.4	626	3.9	2.0	1.4	0.1	0.00
FFQ Year 4	118	5.3	2.4	173	4.1	2.0	1.2	0.3	0.00

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat
[3] 4125 (29%) Intervention women had <=20% energy from fat at year 1.
[4] 703 (25%) Intervention women had <=20% energy from fat at year 2.
[5] 94 (20%) Intervention women had <=20% energy from fat at year 3.
[6] 18 (16%) Intervention women had <=20% energy from fat at year 4.

Table 4.2
Nutrient Intake Monitoring For Women With Revised Fat Gram Goals
Data as of: August 31, 1998

	Intervention[1]			Control[2]			Difference		
	N	Mean	SD	N	Mean	SD	Mean[3]	SE	p-value[4]
% Energy from Fat									
FFQ Baseline	15854	38.8	5.0	23754	38.8	4.9	0.0	0.1	0.49
FFQ Year 1	10822	24.9	7.6	15987	36.1	6.9	11.2	0.1	0.00
FFQ Year 2	1814	25.3	7.4	2501	35.8	7.1	10.5	0.2	0.00
FFQ Year 3	80	25.6	8.0	72	37.7	7.1	12.1	1.2	0.00
4DFR Baseline	670	32.4	6.5	989	33.1	6.9	0.7	0.3	0.03
4DFR Year 1	359	21.9	7.7	525	32.9	7.0	11.0	0.5	0.00
24 Hr Recall, post-Baseline	168	23.4	9.5	188	32.0	7.8	8.6	0.9	0.00
24 Hr Recall, Year 1	70	21.0	7.5	101	32.3	8.0	11.3	1.2	0.00
24 Hr Recall, Year 2	14	22.6	8.2	27	33.0	11.1	10.4	3.4	0.00
Total Energy (kcal)									
FFQ Baseline	15854	1780	701	23754	1786	706	6	7	0.47
FFQ Year 1	10822	1471	528	15987	1591	644	120	7	0.00
FFQ Year 2	1814	1491	515	2501	1580	603	89	18	0.00
FFQ Year 3	80	1530	540	72	1522	589	8	92	0.88
4DFR Baseline	670	1690	456	989	1716	464	26	23	0.28
4DFR Year 1	359	1421	385	525	1613	421	192	28	0.00
24 Hr Recall, post-Baseline	168	1496	425	188	1643	493	147	49	0.00
24 Hr Recall, Year 1	70	1554	384	101	1715	558	161	77	0.09
24 Hr Recall, Year 2	14	1506	358	27	1664	616	158	179	0.64
Total Fat (g)									
FFQ Baseline	15854	77.4	34.6	23754	77.6	34.6	0.2	0.4	0.62
FFQ Year 1	10822	41.0	21.4	15987	64.8	31.8	23.8	0.3	0.00
FFQ Year 2	1814	42.0	20.4	2501	63.8	30.1	21.8	0.8	0.00
FFQ Year 3	80	43.6	20.7	72	64.9	32.0	21.3	4.3	0.00
4DFR Baseline	670	61.6	23.5	989	64.0	24.8	2.4	1.2	0.07
4DFR Year 1	359	34.4	15.9	525	59.8	22.5	25.4	1.4	0.00
24 Hr Recall, post-Baseline	168	39.8	22.4	188	60.1	27.1	20.3	2.7	0.00
24 Hr Recall, Year 1	70	36.4	16.9	101	63.4	28.8	27.0	3.8	0.00
24 Hr Recall, Year 2	14	38.1	17.2	27	65.1	38.3	27.0	10.8	0.03
Saturated Fat (g)									
FFQ Baseline	15854	27.2	13.2	23754	27.2	13.1	0.0	0.1	0.81
FFQ Year 1	10822	14.0	8.0	15987	22.6	12.0	8.6	0.1	0.00
FFQ Year 2	1814	14.4	7.8	2501	22.3	11.3	7.9	0.3	0.00
FFQ Year 3	80	14.9	7.8	72	23.4	13.0	8.5	1.7	0.00
4DFR Baseline	670	20.1	8.9	989	20.9	9.5	0.8	0.5	0.15
4DFR Year 1	359	10.7	5.7	525	19.0	7.9	8.3	0.5	0.00
24 Hr Recall, post-Baseline	168	12.9	8.0	188	20.0	9.4	7.1	0.9	0.00
24 Hr Recall, Year 1	70	11.7	6.2	101	20.8	11.7	9.1	1.5	0.00
24 Hr Recall, Year 2	14	11.5	5.0	27	19.7	11.4	8.2	3.2	0.03

(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 4.2 (continued)
Nutrient Intake Monitoring For Women With Revised Fat Gram Goals
Data as of: August 31, 1998

	Intervention[1]			Control[2]			Difference		
	N	Mean	SD	N	Mean	SD	Mean[3]	SE	p-value[4]
Polyunsaturated Fat (g)									
FFQ Baseline	15854	15.1	7.4	23754	15.1	7.4	0.0	0.1	0.53
FFQ Year 1	10822	7.7	4.2	15987	12.4	6.7	4.7	0.1	0.00
FFQ Year 2	1814	7.9	4.0	2501	12.2	6.3	4.3	0.2	0.00
FFQ Year 3	80	8.2	4.0	72	11.8	5.4	3.6	0.8	0.00
4DFR Baseline	670	12.9	5.8	989	13.6	6.3	0.7	0.3	0.02
4DFR Year 1	359	7.4	3.5	525	12.9	6.5	5.5	0.4	0.00
24 Hr Recall, post-Baseline	168	8.3	5.2	188	12.3	7.3	4.0	0.7	0.00
24 Hr Recall, Year 1	70	7.5	4.4	101	13.3	6.6	5.8	0.9	0.00
24 Hr Recall, Year 2	14	8.6	4.9	27	14.7	11.5	6.1	3.2	0.10
Fruits and Vegetables (servings)									
FFQ Baseline	15813	3.6	1.8	23708	3.6	1.8	0.0	0.0	0.40
FFQ Year 1	10962	5.0	2.3	16216	3.9	2.0	1.1	0.0	0.00
FFQ Year 2	1891	5.2	2.3	2632	4.0	2.1	1.2	0.1	0.00
FFQ Year 3	119	5.5	2.6	128	4.0	2.2	1.5	0.3	0.00
FFQ Year 4	3	6.4	4.0	1	2.7	0.0	3.7	4.6	0.18

[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 4.3
Nutrient Intake Monitoring in Minority Women
Data as of: August 31, 1998

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	3628	39.4	5.2	5348	39.4	5.2	0.0	0.1	0.49
FFQ Year 1[3]	2385	27.3	8.1	3450	36.3	7.3	9.0	0.2	0.00
FFQ Year 2[4]	423	27.5	7.9	621	35.9	7.5	8.4	0.5	0.00
FFQ Year 3[5]	49	29.6	7.9	80	35.5	7.1	5.9	1.3	0.00
FFQ Year 4[6]	9	35.2	8.3	16	36.8	8.5	1.6	3.5	0.61
4DFR Baseline	437	33.0	6.4	647	33.5	6.7	0.5	0.4	0.24
4DFR Year 1	240	23.4	7.9	335	33.3	7.0	9.9	0.6	0.00
24 Hr Recall, post-Baseline	38	24.6	11.0	40	30.5	7.6	5.9	2.1	0.01
24 Hr Recall, Year 1	13	22.2	6.8	26	29.2	7.7	7.0	2.5	0.01
24 Hr Recall, Year 2	10	28.0	13.4	16	30.0	10.2	2.0	4.6	0.27
24 Hr Recall, Year 3	4	37.6	3.9	4	37.6	4.3	0.0	2.9	0.77
Total Energy (kcal)									
FFQ Baseline	3628	1762	811	5348	1757	825	5	18	0.49
FFQ Year 1	2385	1412	618	3450	1507	768	95	19	0.00
FFQ Year 2	423	1441	618	621	1506	738	65	44	0.42
FFQ Year 3	49	1512	668	80	1547	683	35	123	0.88
FFQ Year 4	9	1467	695	16	1491	655	24	279	0.91
4DFR Baseline	437	1676	483	647	1688	472	12	30	0.53
4DFR Year 1	240	1390	393	335	1572	435	182	35	0.00
24 Hr Recall, post-Baseline	38	1484	498	40	1649	417	165	104	0.06
24 Hr Recall, Year 1	13	1571	429	26	1482	411	89	142	0.54
24 Hr Recall, Year 2	10	1450	565	16	1518	460	68	202	0.53
24 Hr Recall, Year 3	4	1424	434	4	1609	429	185	305	0.77
Total Fat (g)									
FFQ Baseline	3628	77.8	39.8	5348	77.7	40.2	0.1	0.9	0.65
FFQ Year 1	2385	43.1	25.4	3450	62.0	36.9	18.9	0.9	0.00
FFQ Year 2	423	44.0	23.3	621	61.4	36.3	17.4	2.0	0.00
FFQ Year 3	49	51.1	29.4	80	62.5	34.0	11.4	5.9	0.04
FFQ Year 4	9	54.2	23.2	16	61.2	30.1	7.0	11.6	0.82
4DFR Baseline	437	62.0	23.4	647	63.9	25.5	1.9	1.5	0.34
4DFR Year 1	240	36.3	17.0	335	59.1	22.5	22.8	1.7	0.00
24 Hr Recall, post-Baseline	38	40.4	23.3	40	56.7	22.2	16.3	5.2	0.00
24 Hr Recall, Year 1	13	38.7	16.1	26	49.8	21.9	11.1	6.9	0.15
24 Hr Recall, Year 2	10	48.5	35.7	16	53.5	28.7	5.0	12.7	0.43
24 Hr Recall, Year 3	4	61.0	23.0	4	69.3	22.1	8.3	15.9	0.77

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 461 (19%) Intervention women had <=20% energy from fat at year 1.
[4] 78 (18%) Intervention women had <=20% energy from fat at year 2.
[5] 5 (10%) Intervention women had <=20% energy from fat at year 3
[6] 0 (0%) Intervention women had <=20% energy from fat at year 4

Table 4.3 (continued)
Nutrient Intake Monitoring in Minority Women
Data as of August 31, 1998

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	3628	25.9	14.2	5348	25.9	14.5	0.0	0.3	0.67
FFQ Year 1[3]	2385	14.2	9.0	3450	20.5	13.0	6.3	0.3	0.00
FFQ Year 2[4]	423	14.4	8.3	621	20.5	13.0	6.1	0.7	0.00
FFQ Year 3[5]	49	16.6	9.7	80	21.6	13.0	5.0	2.2	0.02
FFQ Year 4[6]	9	19.4	10.2	16	20.7	10.4	1.3	4.3	0.73
4DFR Baseline	437	19.6	8.5	647	20.4	9.5	0.8	0.6	0.30
4DFR Year 1	240	11.2	6.0	335	18.1	7.4	6.9	0.6	0.00
24 Hr Recall, post-Baseline	38	12.4	7.7	40	18.4	8.8	6.0	1.9	0.00
24 Hr Recall, Year 1	13	12.8	7.5	26	14.5	6.9	1.7	2.4	0.36
24 Hr Recall, Year 2	10	15.0	11.1	16	14.6	7.6	0.4	3.7	0.64
24 Hr Recall, Year 3	4	21.0	11.3	4	21.5	9.2	0.5	7.3	0.77
Polyunsaturated Fat (g)									
FFQ Baseline	3628	15.9	8.6	5348	15.8	8.6	0.1	0.2	0.53
FFQ Year 1	2385	8.5	5.2	3450	12.6	7.8	4.1	0.2	0.00
FFQ Year 2	423	8.7	5.0	621	12.2	7.3	3.5	0.4	0.00
FFQ Year 3	49	10.3	6.3	80	11.7	6.2	1.4	1.1	0.13
FFQ Year 4	9	9.9	3.8	16	12.3	7.1	2.4	2.6	0.43
4DFR Baseline	437	13.4	6.1	647	13.8	6.5	0.4	0.4	0.39
4DFR Year 1	240	7.9	3.7	335	13.1	6.5	5.2	0.5	0.00
24 Hr Recall, post-Baseline	38	9.0	5.4	40	11.9	6.4	2.9	1.3	0.01
24 Hr Recall, Year 1	13	8.4	3.6	26	12.3	6.4	3.9	1.9	0.01
24 Hr Recall, Year 2	10	10.3	9.7	16	14.6	11.7	4.3	4.4	0.14
24 Hr Recall, Year 3	4	9.9	2.4	4	17.2	5.0	7.3	2.8	0.08
Fruits and Vegetables (servings)									
FFQ Baseline	3619	3.3	1.9	5344	3.2	1.9	0.1	0.0	0.08
FFQ Year 1	2416	4.5	2.5	3494	3.4	2.0	1.1	0.1	0.00
FFQ Year 2	437	4.7	2.6	641	3.5	2.2	1.2	0.1	0.00
FFQ Year 3	59	4.5	2.5	90	3.9	2.3	0.6	0.4	0.10
FFQ Year 4	10	5.2	2.8	17	3.2	2.2	2.0	1.0	0.04

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat.
[3] 461 (19%) Intervention women had <=20% energy from fat at year 1.
[4] 78 (18%) Intervention women had <=20% energy from fat at year 2.
[5] 5 (10%) Intervention women had <=20% energy from fat at year 3
[6] 0 (0%) Intervention women had <=20% energy from fat at year 4

Table 4.4
Nutrient Intake Monitoring in Women Aged 70-79
Data as of: August 31, 1998

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
% Energy from Fat									
FFQ Baseline	3249	38.5	4.7	4871	38.4	4.8	0.1	0.1	0.57
FFQ Year 1[3]	2200	25.8	7.5	3310	35.8	6.4	10.0	0.2	0.00
FFQ Year 2[4]	395	26.8	7.7	572	35.3	6.4	8.5	0.5	0.00
FFQ Year 3[5]	74	27.9	7.5	85	35.4	7.1	7.5	1.2	0.00
FFQ Year 4[6]	20	29.6	6.8	12	35.3	5.0	5.7	2.3	0.02
4DFR Baseline	126	31.4	6.0	188	32.8	6.5	1.4	0.7	0.05
4DFR Year 1	75	21.1	6.4	103	33.6	6.3	12.5	1.0	0.00
24 Hr Recall, post-Baseline	30	23.5	8.6	33	31.0	6.6	7.5	1.9	0.00
24 Hr Recall, Year 1	15	21.5	8.3	20	31.7	8.0	10.2	2.8	0.00
24 Hr Recall, Year 2	4	27.9	12.6	11	32.2	9.3	4.3	5.9	0.51
Total Energy (kcal)									
FFQ Baseline	3249	1691	654	4871	1695	666	4	15	0.99
FFQ Year 1	2200	1431	530	3310	1551	638	120	16	0.00
FFQ Year 2	395	1490	546	572	1479	579	11	37	0.37
FFQ Year 3	74	1522	622	85	1422	553	100	93	0.30
FFQ Year 4	20	1513	447	12	1771	737	258	208	0.40
4DFR Baseline	126	1582	418	188	1646	447	64	50	0.19
4DFR Year 1	75	1391	296	103	1584	420	193	57	0.00
24 Hr Recall, post-Baseline	30	1496	400	33	1630	376	134	98	0.13
24 Hr Recall, Year 1	15	1469	375	20	1469	353	0	124	0.96
24 Hr Recall, Year 2	4	1552	215	11	1447	686	105	356	0.19
Total Fat (g)									
FFQ Baseline	3249	72.8	31.5	4871	72.8	32.1	0.0	0.7	0.83
FFQ Year 1	2200	41.6	22.3	3310	62.7	31.1	21.1	0.8	0.00
FFQ Year 2	395	44.7	22.8	572	58.7	27.3	14.0	1.7	0.00
FFQ Year 3	74	49.0	29.9	85	56.2	24.7	7.2	4.3	0.02
FFQ Year 4	20	50.6	22.3	12	70.4	32.9	19.8	9.7	0.07
4DFR Baseline	126	56.3	21.8	188	61.2	24.0	4.9	2.7	0.07
4DFR Year 1	75	32.5	11.7	103	59.8	22.2	27.3	2.8	0.00
24 Hr Recall, post-Baseline	30	40.0	20.6	33	56.7	19.7	16.7	5.1	0.00
24 Hr Recall, Year 1	15	35.9	19.7	20	52.1	18.7	16.2	6.5	0.01
24 Hr Recall, Year 2	4	49.4	28.5	11	54.2	34.8	4.8	19.5	0.90

(continues)

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat
[3] 522 (24%) Intervention women had <=20% energy from fat at year 1.
[4] 74 (19%) Intervention women had <=20% energy from fat at year 2.
[5] 9 (12%) Intervention women had <=20% energy from fat at year 3.
[6] 2 (10%) Intervention women had <=20% energy from fat at year 4

Table 4.4 (continued)
Nutrient Intake Monitoring in Women Aged 70-79
Data as of August 31, 1998

	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[1]	SE	p-value[2]
Saturated Fat (g)									
FFQ Baseline	3249	25.6	12.0	4871	25.5	12.3	0.1	0.3	0.51
FFQ Year 1[3]	2200	14.4	8.4	3310	22.0	11.6	7.6	0.3	0.00
FFQ Year 2[4]	395	15.7	9.0	572	20.7	10.7	5.0	0.7	0.00
FFQ Year 3[5]	74	17.3	12.3	85	20.1	9.5	2.8	1.7	0.01
FFQ Year 4[6]	20	18.5	8.7	12	23.8	12.0	5.3	3.7	0.24
4DFR Baseline	126	18.8	8.7	188	20.3	9.2	1.5	1.0	0.17
4DFR Year 1	75	10.4	4.6	103	19.9	7.5	9.5	1.0	0.00
24 Hr Recall, post-Baseline	30	12.0	6.1	33	19.9	9.0	7.9	2.0	0.00
24 Hr Recall, Year 1	15	12.3	8.6	20	16.9	6.6	4.6	2.6	0.01
24 Hr Recall, Year 2	4	14.4	5.8	11	18.6	16.5	4.2	8.6	0.90
Polyunsaturated Fat (g)									
FFQ Baseline	3249	14.4	7.0	4871	14.5	7.1	0.1	0.2	0.88
FFQ Year 1	2200	7.9	4.6	3310	12.1	6.5	4.2	0.2	0.00
FFQ Year 2	395	8.3	4.7	572	11.2	5.5	2.9	0.3	0.00
FFQ Year 3	74	8.9	5.1	85	10.3	5.1	1.4	0.8	0.03
FFQ Year 4	20	9.4	4.8	12	13.8	5.9	4.4	1.9	0.02
4DFR Baseline	126	11.3	4.8	188	12.6	6.0	1.3	0.6	0.04
4DFR Year 1	75	6.8	2.3	103	12.8	6.5	6.0	0.8	0.00
24 Hr Recall, post-Baseline	30	8.7	5.1	33	10.7	5.5	2.0	1.3	0.09
24 Hr Recall, Year 1	15	7.6	4.3	20	10.6	3.4	3.0	1.3	0.01
24 Hr Recall, Year 2	4	14.1	13.2	11	10.6	5.9	3.5	4.8	0.70
Fruits and Vegetables (servings)									
FFQ Baseline	3240	3.9	1.9	4862	3.9	1.9	0.0	0.0	0.24
FFQ Year 1	2228	5.0	2.3	3372	4.1	2.0	0.9	0.1	0.00
FFQ Year 2	415	5.3	2.5	591	4.0	1.9	1.3	0.1	0.00
FFQ Year 3	82	5.0	2.2	97	3.9	2.2	1.1	0.3	0.00
FFQ Year 4	22	5.3	2.4	15	5.1	1.7	0.2	0.7	0.79

[1] Absolute difference.
[2] P-values based on testing in the natural log scale except for % Energy from fat
[3] 522 (24%) Intervention women had <=20% energy from fat at year 1.
[4] 74 (19%) Intervention women had <=20% energy from fat at year 2.
[5] 9 (12%) Intervention women had <=20% energy from fat at year 3.
[6] 2 (10%) Intervention women had <=20% energy from fat at year 4

Table 4.5
Sensitivity of DM Study Power to Adherence Assumptions

Outcome	Year	Intervention Effect[1] (%)	Percentage of Cases[1]		Power (%)	
			Control	Intervention	Design[2]	Revised Adherence[3]
Breast Cancer						
	2001	11	1.98	1.86	28	20
		12	1.99	1.85	35	24
		14	1.99	1.83	44	30
	2004	11	2.86	2.61	63	46
		12	2.86	2.57	75	57
		14	2.86	2.54	86[4]	69
Colorectal Cancer						
	2001	18	1.08	0.97	37	26
		20	1.08	0.96	45	32
		22	1.09	0.95	52	37
	2004	18	1.64	1.40	83	66
		20	1.63	1.37	90	76
		22	1.63	1.24	95	84

[1] 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.

[2] C-I % Energy from fat: 13% at AV-1, 11% at year 10

[3] C-I % Energy from fat: 11.2% at AV-1, 8% at year 10

[4] Design values

Table 4.6
Multivariate Analysis of Study Subject Characteristics
on Control - Intervention Difference in % Energy from Fat from FFQ at AV-1:
Data as of: August 31, 1998

Study Subject Characteristics		C - I (%)
Age	50-54 vs. 60-69	0.43
	55-59 vs. 60-69	0.45*
	70-79 vs. 60-69	-1.35**
Ethnicity	Black vs. White	-1.88**
	Hispanic vs. White	-1.83**
	Other Minority vs. White	-1.36**
Education	0-8 Years vs. Post H.S.	0.44
	Some H.S. or Diploma vs. Post H.S.	0.03
Marital Status	Not Married vs. Married	-0.40
Family Income	<20K vs. ≥75K	-0.36
	20-35K vs. ≥75K	-0.03
	35-50K vs. ≥75K	0.15
	50-75K vs. ≥75K	-0.17
HRT Randomized	Yes vs. No	0.35
BMI - Mean(BMI)	BMI - 29.06	-0.02
Hysterectomy	Yes vs. No	-0.09

* Indicates p-value < .05 from two-sided t-test
** Indicates p-value < .01 from two-sided t-test
NOTE: Model adjusted for clinic effects

Table 4.6 (continued)
Multivariate Analysis of Study Subject Characteristics
on Control - Intervention Difference in % Energy from Fat from FFQ at AV-2:
Data as of: August 31, 1998

Study Subject Characteristics		C - I (%)
Age	50-54 vs. 60-69	-0.74
	55-59 vs. 60-69	-0.34
	70-79 vs. 60-69	-1.87**
Ethnicity	Black vs. White	-3.25**
	Hispanic vs. White	0.55
	Other Minority vs. White	-0.45
Education	0-8 Years vs. Post H.S.	0.11
	Some H.S. or Diploma vs. Post H.S.	0.50
Marital Status	Not Married vs. Married	-0.54
Family Income	<20K vs. ≥75K	-0.52
	20-35K vs. ≥75K	-0.51
	35-50K vs. ≥75K	0.27
	50-75K vs. ≥75K	-0.17
HRT Randomized	Yes vs. No	-0.02
BMI - Mean(BMI)	BMI - 29.06	-0.09**
Hysterectomy	Yes vs. No	0.00

* Indicates p-value < .05 from two-sided t-test
** Indicates p-value < .01 from two-sided t-test
NOTE: Model adjusted for clinic effects

Table 4.7
Effects of DM Intervention Participation Variables
on Control - Intervention Difference in % Energy from Fat from FFQ at AV-1:
Data as of: August 31, 1998

DM Implementation/Participation	C-I % Energy from Fat[1]	C-I % Energy from Fat[2]	C-I % Energy from Fat[3]
Intervention Group Size	0.02	0.03	0.02
Days from Randomization to Intervention Group/100	-0.42**	-0.44**	-0.44**
# Sessions (out of 1-18) Attended	0.43**		0.25**
# Sessions (out of 1-18) Completed	0.42**		0.13**
Fat Gram Goal	-0.01	-0.01	-0.01
# Early Sessions Completed (1-6)		0.43**	
# Intermediate Sessions Completed (7-12)		1.06**	
# Late Sessions Completed (13-18)		0.74**	
# Sessions (out of 3-18) Providing Fat Scores			0.47**

[1] Model adjusted for clinic effects, and includes the following terms: Intervention group size, days from randomization to group assignment, # sessions attended, # sessions completed, and fat gram goal.
[2] Model adjusted for clinic effects, and includes the following terms: Intervention group size, days from randomization to group assignment, fat gram goal, # early sessions completed, # intermediate sessions completed, and # late sessions completed.
[3] Model adjusted for clinic effects, and includes the following terms: Intervention group size, days from randomization to group assignment, # sessions attended, # sessions completed, fat gram goal, and #sessions fat score provided.
* Indicates p-value < .05 from two-sided t-test
** Indicates p-value < .01 from two-sided t-test

Table 4.7 (continued)
Effects of DM Intervention Participation Variables
on Control - Intervention Difference in % Energy from Fat from FFQ at AV-2:
Data as of: August 31, 1998

DM Implementation/Participation	C-I % Energy from Fat[1]	C-I % Energy from Fat[2]	C-I % Energy from Fat[3]
Intervention Group Size	-0.02	-0.03	-0.02
Days from Randomization to Intervention Group/100	0.78**	0.45**	0.75**
# Sessions (out of 1-18) Attended	0.23**		0.15*
# Sessions (out of 1-18) Completed	0.52**		0.34**
Fat Gram Goal	-0.10**	-0.01	-0.10**
# Maintenance Sessions (out of 1-4) Attended	0.74**		0.70**
# Maintenance Sessions (out of 1-4) Completed	0.26		0.25
# Early Sessions Completed (1-6)		0.45	
# Intermediate Sessions Completed (7-12)		0.60**	
# Late Sessions Completed (13-18)		1.27**	
# Sessions (out of 3-18) Providing Fat Scores			0.28**

[1] Model adjusted for clinic effects, and includes the following terms: Intervention group size, days from randomization to group assignment, # sessions attended, # sessions completed, and fat gram goal.
[2] Model adjusted for clinic effects, and includes the following terms: Intervention group size, days from randomization to group assignment, fat gram goal, # early sessions completed, # intermediate sessions completed, and # late sessions completed.
[3] Model adjusted for clinic effects, and includes the following terms: Intervention group size, days from randomization to group assignment, # sessions attended, # sessions completed, fat gram goal, and #sessions fat score provided.
* Indicates p-value < .05 from two-sided t-test
** Indicates p-value < .01 from two-sided t-test

Table 4.8
Regression Analysis[a] of Baseline Psychosocial Variables on Control - Intervention Difference in % Energy from Fat (FFQ) at Annual Visit 1 (AV-1) and Annual Visit 2 (AV-2)
Data as of: August 31, 1998

	DM Participants with a % Energy from Fat at:		
	AV-1	AV-2	AV-3
Psychosocial Behavioral Constructs[b]	**Baseline Variables[d]**		**AV-1 Variables[d]**
Number of Women	35681	7249	7249
(a higher score indicates...)			
Social Support Construct (greater support)	0.21*	0.19	
Social Strain Construct[c] (less strain)	0.22*	0.18	
Optimism Construct (more optimism)	0.37*	0.25	
Negative Emotional Expressiveness[c] (less negative expressiveness)	0.22*	0.00	
Ambivalent Emotional Expressiveness[c] (less ambivalence)	0.09	0.00	
Hostility Construct[c] (less hostility)	0.34*	0.44*	
Overall Quality of Life (higher perceived quality)	0.22*	0.29	0.57*
Satisfaction with Quality of Life (more satisfaction)	0.30*	0.39*	0.48*
Physical Functioning Construct (less limitations)	0.37*	0.14	0.41*
Limitations Due to Physical Health Construct (less limitations)	0.40*	0.11	0.42*
Limitations Due to Emotional Problems Construct (less limitations)	0.40*	0.16	0.34
Health Interference with Social Activities (less interference)	0.29*	0.03	0.34
Downhearted and Blue (less feeling blue)	0.42*	0.23	0.27
Feel Worn Out (less worn out)	0.28*	0.01	0.21
Pain Construct (less pain)	0.30*	0.15	0.40*
General Health Construct (better health)	0.49*	0.43*	0.60*
Daily Living Activities Construct[c] (less disability)	-0.17	-0.26	0.22
Overall Symptom Construct[c] (fewer symptoms)	0.49*	0.44*	0.37*
Life Event Construct[c] (fewer and less upsettinglife events)	0.27*	0.35*	-0.08
CES-D/DIS Depression Construct[c] (less depression)	0.22*	0.19	0.11
Worried that sex will affect health[c] (less worried)	0.30*	0.26	0.15

[a] The following demographic variables were included in the regression model: age, ethnicity, education, income, body mass index, hysterectomy status, and HRT randomized.
[b] For descriptions of the psychosocial behavioral constructs, see Appendix A
[c] The sign of the parameter was reversed to reflect the description of the scoring.
[d] Each entry is the estimated change in C-I% energy from fat associated with an upward shift of one standard deviation in the psychosocial variable.
* Denotes statistical significance at the 0.05 level (from regression t-test).

Table 4.9
Regression Analysis[1] of Baseline Dietary Variables on Control-Intervention Difference in % Energy from Fat (FFQ) at Annual Visit 1 (AV-1) and Annual Visit 2 (AV-2)
Data as of: August 31, 1998

NOTE: Underlining denotes reference level.

			DM (n=35681)		DM (n=7249)	
			DM Participants with a %Energy from Fat at AV-1		DM Participants with a %Energy from Fat at AV-2	
Form/ Question #	Question		% Yes	C-I	%Yes	C-I
2/3, 23	Did a doctor ever say that you had sugar diabetes or high blood sugar when you were not pregnant?	Yes vs. No[2]	5.5%	-1.12*	4.6%	-1.22
30, 2	Has a doctor told you that you have any of the following conditions or have you had any of the following procedures? (Please mark all that apply.)					
2.3	High cholesterol requiring pills	Yes vs. No	10.7%	-1.50*	9.7%	-1.53*
2.8	Stomach or duodenal ulcer	Yes vs. No	6.3%	0.03	6.3%	-1.24
2.9	Diverticulitis	Yes vs. No	7.7%	-0.74*	7.4%	0.01
2.10	Ulcerative colitis or Crohn's disease	Yes vs. No	0.9%	-0.04	0.9%	-2.57
2.16	Part of intestines taken out	Yes vs. No	1.4%	0.49	1.2%	0.32
30, 5	Did a doctor ever say that you had gallbladder disease or gallstones:	Yes vs. No	16.2%	-0.17	15.4%	0.04
30, 7	Did a doctor ever say that you had hypertension or high blood pressure? (Do not include high blood pressure that you had only when you were pregnant.)	Yes vs. No	33.1%	-0.07	31.3%	-0.57
30, 10	Have you ever had a colonoscopy or sigmoidoscopy or flex sig (where a doctor inserts a tube in the rectum to check for bowel problems)?	Yes vs. No	48.6%	-0.46*	47.5%	-0.11
2/3, 23.3	Did a doctor ever tell you to keep a special diet for your diabetes?	Yes vs. No	4.2%	-1.03*	3.5%	-1.53

[1] The following demographic variables were included in the regression models: age, ethnicity, education, income, body mass index, hysterectomy status, and HRT randomized.
[2] Underlining denotes reference level.
* Denote statistical significance at the 5% level (from regression t-test).

(continues)

Table 4.9 (continued)
Regression Analysis[1] of Baseline Dietary Variables on Control-Intervention Difference in % Energy from Fat (FFQ) at Annual Visit 1 (AV-1) and Annual Visit 2 (AV-2)
Data as of: August 31, 1998

			DM (n=35681)		DM (n=7249)	
			DM Participants with a %Energy from Fat at AV-1		DM Participants with a %Energy from Fat at AV-2	
Form/ Question #	Question		% Yes	C-I	%Yes	C-I
34, 5	The next set of questions are about special diets or types of foods women may choose or may be told to eat by their doctors. Are you now on any of the following special diets?					
5.1	A low calorie diet?	Yes vs. No	6.4%	-1.65*	6.5%	-2.55*
5.2	A low-fat or low cholesterol diet?	Yes vs. No	24.7%	-1.93*	25.1%	-1.55*
5.3	A low salt (low sodium) diet?	Yes vs. No	17.3%	-1.16*	17.3%	-1.11*
5.4	A high-fiber diet?	Yes vs. No	11.2%	-1.57*	11.6%	-1.12*
5.5	A diabetic or ADA diet?	Yes vs. No	3.5%	-1.64*	2.9%	-1.77
5.6	A lactose-free (no milk or diary foods) diet?	Yes vs. No	3.8%	-0.92*	3.8%	-1.75
5.7	Any other diet?	Yes vs. No	5.8%	-0.41	5.9%	-0.20
45	Current Supplements	Yes vs. No	63.8%	-0.25	62.5%	-0.81*
34, 1.7	Have you ever smoked to keep from gaining weight or to lose weight?	Yes vs. No	8.1%	-0.54	8.9%	-0.27
34, 4	Women's weights change during their adult lives. Mark the one answer that best describes you during your adult life. Please don't include times when you were pregnant or sick. (Mark only one.)					
4.2	Steady gain in weight vs. Weight has stayed about the same (within 10 pounds)		39.3%	0.36	39.8%	-0.59
4.3	Lost weight as an adult and kept it off vs. Weight has stayed about the same (within 10 pounds)		1.3%	-1.57*	1.3%	-1.40
4.4	Weight has gone up and down again by more than 10 pounds vs. Weight has stayed about the same (within 10 pounds)		36.7%	0.13	36.9%	-0.67
	Weight change from Baseline to AV-1 (Kg)		0.91*	0.08*	1.18*	0.12*

[1] Mean difference

Table 4.10
Regression Analysis of Physical Activity Variables on Control-Intervention Difference in % Energy from Fat (FFQ)
at Annual Visit 1 (AV-1) and Annual Visit 2 (AV-2)
Data as of 8/31/98

The following demographic variables were included in the regression model: age, ethnicity, education, income, body mass index, hysterectomy status, and HRT randomized. Each entry is the estimated change in C-I percent energy from fat. An asterisk denotes statistical significance at the 0.05 level (from regression t-test).

	DM (n = 35681)		DM (n = 7249)	
	DM Participants with a %Energy from Fat at AV1		DM Participants with a %Energy from Fat at AV2	
Construct	Mean of Risk Factor[2]	C-I	Mean of Risk Factor[2]	C-I
Expenditure of energy (kcal/week*kg) from walking.	3.6	-0.03	3.6	-0.03
Episodes per week of physical activity (walking, hard, moderate, and mild exercise).	4.0	-0.07*	4.0	-0.08
Minutes per week of physical activity (walking, hard, moderate, and mild exercise).	142.8	-0.001	144.7	-0.001
Episodes per week of moderate and strenuous physical activity (MET >=4.0).	2.3	-0.11*	2.3	-0.11
Minutes per week of moderate and strenuous physical activity (MET >=4.0).	80.1	-0.002*	82.6	-0.002
Episodes per week of strenuous physical activity (MET >=6.0).	0.5	-0.15*	0.5	-0.16
Minutes per week of strenuous physical activity (MET >=6.0).	22	-0.001	22.4	-0.002
Total expenditure (kcal/week*kg) from physical activity.	10.5	-0.01	10.7	-0.01
Episodes per week of physical activity of >=20 minutes duration per session.	3.1	-0.08*	3.1	-0.08
Episodes per week of moderate and strenuous physical activity of >=20 minutes duration per session (MET>=4.0).	1.8	-0.12*	1.8	-0.09*

[1] The following demographic variables were included in the regression models: age, ethnicity, education, income, body mass index, hysterectomy status, and HRT randomized. Each entry is the estimated change in C-I percent energy from fat.
[2] Inactive women included in the mean. Women who do not engage in these activities are given a value of zero.
* Denote statistical significance at the 0.05 level (from regression t-test).

Table 4.11
Intervention Group Formation
Data as of: August 31, 1998

	VCC		NCC		Total	
	N	%	N	%	N	%
Randomized to Intervention	8879	-	10663	-	19542	-
Awaiting Intervention	259	3%	1152	11%	1411	7%
Waiting >= 20 weeks	180	69%	756	66%	936	66%
Number of DM Intervention Participants Who Have Reached AV1 w/o Having Started Intervention[1]	271	3%	527	7%	798	5%
Intervention Started	8620	97%	9511	89%	18131	93%
Waited >=20 weeks	1317	15%	2113	22%	3430	19%
Number of Groups Started	724	-	726	-	1450	-
Number of DM Intervention Participants who Have Stopped Intervention	352	4%	388	4%	740	4%
Number of DM Intervention Participants who Have Missed 3 or More Consecutive Sessions[2]	1102	14%	955	8%	2057	11%

[1] Includes participants who have stopped Intervention.

[2] Of participants who have completed session 1 and have been assigned to 3 or more sessions

Table 4.12
Intervention Program Adherence Summary
Data as of: August 31, 1998

	Intervention Session			
	4	**8**	**12**	**16**
Participants Assigned	18193	17673	16088	14606
Attendance	83%	76%	69%	64%
Completion	96%	94%	89%	84%
Self-Monitoring				
Fat gram				
Score obtained	92%	87%	82%	77%
Average score[1]	28.4	25.1	24.2	24.3
Average goal	26.1	26.2	26.3	26.5
% ≤ Fat Gram goal[1]	50%	64%	70%	70%
Fruit/Vegetable servings				
Score obtained	n. a.	84%	82%	77%
Average score[1]	n. a.	5.6	5.6	5.6
Goal	n. a.	≥ 5	≥ 5	≥ 5
% ≥ Fruit/Vegetable goal[1]	n. a.	66%	66%	68%
Grain servings				
Score obtained	n. a.	84%	82%	77%
Average score[1]	n. a.	4.9	5.1	5.3
Goal	n. a.	≥ 6	≥ 6	≥ 6
% ≥ Grain goal[1]	n. a.	26%	28%	34%

(continues)

[1] Of participants providing a score

Table 4.13
Intervention Program Adherence Summary
Participants with Revised (Lower) Fat Gram Goals[1]
Data as of: February 28, 1998

	Intervention Session			
	4	**8**	**12**	**16**
Participants Assigned	14539	14032	12475	11027
Attendance	82%	75%	68%	63%
Completion	96%	93%	87%	82%
Self-Monitoring				
Fat gram				
Score obtained	91%	86%	81%	75%
Average score[2]	27.6	24.2	23.1	23.1
Average goal	24.5	24.5	24.5	24.5
% ≤ Fat Gram goal[2]	47%	61%	67%	67%
Fruit/Vegetable servings				
Score obtained	n. a.	83%	81%	75%
Average score[2]	n. a.	5.6	5.6	5.6
Goal	n. a.	≥ 5	≥ 5	≥ 5
% ≥ Fruit/Vegetable goal[2]	n. a.	66%	67%	68%
Grain servings				
Score obtained	n. a.	83%	81%	75%
Average score[2]	n. a.	4.9	5.1	5.3
Goal	n. a.	≥ 6	≥ 6	≥ 6
% ≥ Grain goal[2]	n. a.	27%	28%	33%

[1] Implemented in women starting DM Intervention after September 15, 1995

[2] Of participants providing a score

Table 4.14
Maintenance Sessions Adherence Summary
Data as of August 31, 1998

	Maintenance Session - Year 2			
	Spring	**Summer**	**Fall**	**Winter**
Participants Assigned	6090	6762	7896	8813
Attendance	63%	61%	63%	60%
Completion	84%	83%	83%	82%
Self-Monitoring				
Fat gram				
Score obtained	70%	70%	69%	68%
Average score[1]	25.6	25.3	25.1	25.5
Average goal	29.1	28.6	28.1	27.7
% ≤ Fat Gram goal[1]	74%	73%	73%	68%
Fruit/Vegetable servings				
Score obtained	70%	70%	69%	68%
Average score[1]	5.7	5.9	5.9	5.7
Goal	≥ 5	≥ 5	≥ 5	≥ 5
% ≥ Fruit/Vegetable goal[1]	71%	76%	74%	70%
Grain servings				
Score obtained	70%	70%	69%	68%
Average score[1]	5.5	5.5	5.4	5.5
Goal	≥ 6	≥ 6	≥ 6	≥ 6
% ≥ Grain goal[1]	38%	36%	34%	37%

(continues)

[1] Of participants providing a score

Table 4.14 (continued)
Maintenance Sessions Adherence Summary
Data as of: August 31, 1998

	Maintenance Session - Year 3			
	Spring	**Summer**	**Fall**	**Winter**
Participants Assigned	2593	2766	3331	4237
Attendance	55%	55%	56%	55%
Completion	75%	78%	76%	78%
Self-Monitoring				
Fat Gram				
Score obtained	62%	62%	62%	63%
Average score[1]	27.4	27.9	27.5	27.2
Average goal	31.5	32.2	32.2	30.7
% ≤ Fat Gram goal[1]	77%	78%	79%	73%
Fruit/Vegetable servings				
Score obtained	62%	62%	62%	63%
Average score[1]	6.0	6.1	6.1	5.8
Goal	≥ 5	≥ 5	≥ 5	≥ 5
% ≥ Fruit/Vegetable goal[1]	78%	79%	79%	74%
Grain servings				
Score obtained	62%	62%	62%	63%
Average score[1]	5.7	5.6	5.6	5.5
Goal	≥ 6	≥ 6	≥ 6	≥ 6
% ≥ Grain goal[1]	41%	40%	39%	38%

(continues)

[1] Of participants providing a score

Table 4.14 (continued)
Maintenance Sessions Adherence Summary
Data as of: August 31, 1998

	Maintenance Session - Year 4			
	Spring	**Summer**	**Fall**	**Winter**
Participants Assigned	9345	11426	1366	2088
Attendance	55%	41%	56%	51%
Completion	75%	52%	75%	71%
Self-Monitoring				
Fat Gram				
Score obtained	62%	51%	58%	60%
Average score[1]	25.1	24.7	26.4	27.5
Average goal	27.3	26.9	30.3	30.7
% ≤ Fat Gram goal[1]	69%	69%	77%	73%
Fruit/Vegetable servings				
Score obtained	62%	51%	59%	60%
Average score[1]	5.8	5.9	5.9	5.8
Goal	≥ 5	≥ 5	≥ 5	≥ 5
% ≥ Fruit/Vegetable goal[1]	73%	74%	79%	74%
Grain servings				
Score obtained	62%	51%	59%	60%
Average score[1]	5.5	5.4	5.6	5.5
Goal	≥ 6	≥ 6	≥ 6	≥ 6
% ≥ Grain goal[1]	34%	32%	38%	38%

[1] Of participants providing a score

Table 4.15
Body Weight
Data as of: August 31, 1998

Body Weight (kg)[1]	Intervention			Control			Difference		
	N	Mean	SD	N	Mean	SD	Mean[2]	SE	p-value
All Participants									
Baseline	19537	76.8	16.7	29290	76.7	16.6	-0.1	0.2	0.34
Year 1	14406	74.2	16.6	21189	76.2	16.7	2.0	0.2	0.00
Year 2	8242	75.2	17.1	12243	76.2	16.2	1.0	0.2	0.00
Year 3	3687	75.0	16.4	5548	75.9	16.0	0.9	0.3	0.01
Year 4	1058	74.9	16.8	1641	75.3	15.8	0.4	0.6	0.54
Minority Participants									
Baseline	3624	80.0	18.7	5347	79.4	18.9	-0.6	0.4	0.11
Year 1	2472	78.8	19.9	3581	78.9	19.1	0.1	0.5	0.83
Year 2	1285	79.4	19.4	1921	79.5	18.6	0.1	0.7	0.91
Year 3	485	80.4	18.4	719	79.9	18.4	-0.5	1.1	0.69
Year 4	103	79.4	15.5	150	76.5	16.9	-2.9	2.1	0.16
Participants Aged 70-79									
Baseline	3249	73.0	14.7	4871	72.9	14.5	-0.1	0.3	0.79
Year 1	2218	70.1	14.6	3338	72.4	15.2	2.3	0.4	0.00
Year 2	1137	70.2	14.5	1689	71.7	14.3	1.5	0.6	0.01
Year 3	504	69.3	13.8	758	71.3	13.8	2.0	0.8	0.02
Year 4	124	71.9	19.1	191	70.9	16.0	-1.0	2.0	0.62
Participants with Revised Fat Gram Goals[3]									
Baseline	15849	77.0	17.0	23749	77.0	17.0	0.0	0.2	0.74
Year 1	10957	74.4	16.9	16128	76.5	17.1	2.1	0.2	0.00
Year 2	4991	75.5	17.4	7410	76.6	16.6	1.1	0.3	0.00
Year 3	584	75.0	16.4	772	76.6	15.7	1.6	0.9	0.07

[1] Shown for 31.75 <= weight (kg) <= 226.8
[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 4.16
Adherence to Follow-up Contacts
Data as of: August 31, 1998

	Due	Conducted		Conducted in window	
	N	N	%	N	%
Semi-Annual Contact 1	45255	42851	94.7%	32478	71.8%
Intervention	18100	17169	94.9%	13078	72.3%
Control	27155	25682	94.6%	19400	71.4%
Annual Visit 1	39174	37128	94.8%	29738	75.9%
Intervention	15679	15000	95.7%	12152	77.5%
Control	23495	22128	94.2%	17586	74.8%
Semi-Annual Contact 2	31755	28861	90.9%	21743	68.5%
Intervention	12709	11561	91.0%	8684	68.3%
Control	19046	17300	90.8%	13059	68.6%
Annual Visit 2	23845	21954	92.1%	17260	72.4%
Intervention	9530	8792	92.3%	6914	72.5%
Control	14315	13162	91.9%	10346	72.3%
Semi-Annual Contact 3	16610	14661	88.3%	10656	64.2%
Intervention	6659	5854	87.9%	4249	63.8%
Control	9951	8807	88.5%	6407	64.4%
Annual Visit 3	10903	9943	91.2%	8025	73.6%
Intervention	4372	3976	90.9%	3185	72.8%
Control	6531	5967	91.4%	4840	74.1%
Semi-Annual Contact 4	6707	5694	84.9%	4121	61.4%
Intervention	2690	2261	84.1%	1625	60.4%
Control	4017	3433	85.5%	2496	62.1%
Annual Visit 4	3320	2952	88.9%	2498	75.2%
Intervention	1322	1164	88.0%	978	74.0%
Control	1998	1788	89.5%	1520	76.1%
Semi-Annual Contact 5	261	208	79.7%	161	61.7%
Intervention	100	82	82.0%	61	61.0%
Control	161	126	78.3%	100	62.1%

Table 4.17
Active DM Participants Missing Last 3 Consecutive Contacts[1]
Data as of: August 31, 1998

	Intervention			Control			Total		
	Due	Missing last 3 Contacts		Due	Missing last 3 Contacts		Due	Missing last 3 Contacts	
Last Contact Due	N	N	%	N	N	%	N	N	%
SA-2	4642	37	0.8	3049	15	0.5	7691	52	0.7
AV-2	4281	90	2.1	2734	26	1.0	7015	116	1.7
SA-3	3303	51	1.5	2138	30	1.4	5441	81	1.5
AV-3	2468	58	2.4	1603	26	1.6	4071	84	2.1
SA-4	1962	26	1.3	1275	8	0.6	3237	34	1.1
AV-4	1857	25	1.3	1235	11	0.9	3092	36	1.2
Total	18513	287	1.6	12034	116	1.0	30547	403	1.3

[1] A participant is considered due for a visit at the end of the 4 week target window when the visit should be completed.

Table 4.18
Reasons for Stopping DM Intervention
Data as of: August 31, 1998

Reasons[1]	(N=740)[2]	
Personal	245	(33%)
Travel	71	(10%)
Study Procedures	37	(5%)
Health	126	(17%)
Experiencing health problems or symptoms not due to intervention	107	(14%)
Worried about health effects of medical tests	1	(<1%)
Worried about costs if adverse effects occur	0	(0%)
Advised not to participate by health care provider	13	(2%)
Study conflicts with health care needs	16	(2%)
Expected more care	6	(1%)
Intervention	184	(25%)
Reports health problems or symptoms from WHI intervention	21	(3%)
Problem with Clinic Practitioner or other CC staff	2	(<1%)
Doesn't like taking pills	2	(<1%)
Doesn't like DM requirements	135	(18%)
Problems with DM group nutritionist or group members	15	(2%)
Doesn't like DM eating patterns	79	(11%)
Doesn't like randomized nature of intervention	6	(1%)
Expected some benefit from intervention	18	(2%)
Won't participate in safety procedures.	0	(0%)
Other	233	(31%)
Not Given	138	(19%)

[1] Multiple reasons may be reported for a woman

[2] Equals 3% of DM Intervention Participants

Table 4.19
Selected Percentiles for Key Nutrients Based on FFQ Data from AV-1
Data as of: August 31, 1998

	5%	10%	50%	90%	95%
% Energy from Fat					
Intervention	14.5	16.1	23.8	35.0	38.8
Control	24.6	27.3	35.9	44.6	47.3
Total Energy (kcal)					
Intervention	733	873	1419	2120	2369
Control	733	869	1502	2380	2721
Total Fat (g)					
Intervention	16.6	20.0	36.7	66.2	79.0
Control	24.8	30.6	58.8	103.4	121.4
Saturated Fat (g)					
Intervention	5.3	6.4	12.4	23.4	28.1
Control	8.0	10.0	20.4	37.4	44.1
Polyunsaturated Fat (g)					
Intervention	3.1	3.7	6.8	12.8	15.5
Control	4.5	5.6	11.1	20.8	24.6
Total Monosaturated Fat (g)					
Intervention	5.9	7.2	13.8	25.4	30.5
Control	9.2	11.4	22.3	39.5	46.8
Calcium FFQ (mg)					
Intervention	264	340	698	1350	1591
Control	236	301	633	1231	1466
Total Calcium (mg)					
Intervention	316	415	984	1975	2312
Control	286	370	889	1854	2207
Iron (mg)					
Intervention	5.8	7.1	12.8	22.4	26.2
Control	5.1	6.2	11.4	20.3	24.2
Fiber (g)					
Intervention	7.2	8.9	16.7	27.0	30.2
Control	5.9	7.2	13.5	22.4	25.7
Protein (g)					
Intervention	29.5	36.2	62.8	99.0	113.2
Control	28.7	34.9	62.9	102.2	117.1

(continues)

Table 4.19 (continued)
Selected Percentiles for Key Nutrients Based on FFQ Data from AV-1
Data as of: August 31, 1998

	5%	10%	50%	90%	95%
Carbohydrates (g)					
Intervention	98.1	118.7	203.8	310.5	348.5
Control	81.6	99.2	175.4	278.3	319.2
Alcohol (g)					
Intervention	0.0	0.0	0.8	13.3	18.4
Control	0.0	0.0	0.8	13.3	18.8
Vitamin A (mcg)					
Intervention	441.2	560.7	1106.6	1985.8	2308.3
Control	411.6	518.9	1011.3	1841.2	2159.5
Beta-carotene (mcg RE)					
Intervention	1349.3	1718.8	3864.0	8071.5	9691.4
Control	1141.8	1489.0	3241.4	6890.8	8454.9
Retinol (mcg RE)					
Intervention	106.8	149.8	398.4	850.0	1030.9
Control	120.8	164.7	414.2	863.9	1053.3
Vitamin C (mg)					
Intervention	43.3	56.3	122.3	208.2	238.6
Control	32.9	42.5	96.1	172.2	200.9
Soluble Fiber (g)					
Intervention	2.4	3.0	5.6	9.0	10.1
Control	2.0	2.5	4.6	7.6	8.6
Alpha Toc (mg)					
Intervention	2.8	3.3	5.6	10.6	13.6
Control	3.1	3.8	6.9	12.4	15.1
Vitamin D (mcg)					
Intervention	1.1	1.5	3.8	8.5	10.1
Control	1.2	1.6	4.0	8.5	10.3
Cholesterol (mg)					
Intervention	59.3	74.6	148.0	279.0	334.8
Control	79.7	100.0	202.7	380.7	455.6
Selenium (mcg)					
Intervention	41.8	50.8	90.6	144.8	164.8
Control	40.1	49.1	88.8	144.4	166.1
Insoluble Fiber (g)					
Intervention	4.6	5.7	11.0	18.0	20.1
Control	3.8	4.6	8.9	15.0	17.1

Table 4.20
Selected Percentiles for Key Nutrients Based on FFQ Data from AV-1
For Women with Revised Fat Gram Goals
Data as of: August 31, 1998

	5%	10%	50%	90%	95%
% Energy from Fat					
Intervention[1]	14.5	16.1	23.9	35.3	39.0
Control[2]	25.0	27.6	36.0	44.7	47.3
Total Energy (kcal)					
Intervention	730	870	1412	2111	2360
Control	737	876	1506	2388	2733
Total Fat (g)					
Intervention	16.7	20.0	36.7	66.4	79.8
Control	25.3	31.1	59.3	103.9	122.5
Saturated Fat (g)					
Intervention	5.3	6.4	12.3	23.4	28.3
Control	8.1	10.2	20.4	37.5	44.5
Polyunsaturated Fat (g)					
Intervention	3.1	3.7	6.7	12.7	15.5
Control	4.5	5.6	11.1	20.6	24.6
Total Monosaturated Fat (g)					
Intervention	6.1	7.4	13.9	25.6	30.9
Control	9.4	11.7	22.6	40.2	47.7
Calcium FFQ (mg)					
Intervention	262	339	699	1348	1593
Control	238	302	637	1242	1481
Total Calcium (mg)					
Intervention	319	419	991	1984	2326
Control	290	377	915	1884	2234
Iron (mg)					
Intervention	5.8	7.1	13.0	23.2	27.0
Control	5.2	6.2	11.7	21.1	25.1
Fiber (g)					
Intervention	7.3	9.0	16.8	27.3	30.4
Control	6.0	7.4	13.8	22.8	26.0
Protein (g)					
Intervention	29.4	36.0	62.4	98.7	112.7
Control	28.7	35.0	63.0	102.3	117.3

(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.

Table 4.20 (continued)
Selected Percentiles for Key Nutrients Based on FFQ Data from AV-1
For Women with Revised Fat Gram Goals
Data as of: August 31, 1998

	5%	10%	50%	90%	95%
Carbohydrates (g)					
Intervention[1]	97.3	118.0	202.5	308.4	345.8
Control[2]	81.7	99.2	175.3	278.4	320.0
Alcohol (g)					
Intervention	0.0	0.0	0.9	13.3	18.7
Control	0.0	0.0	0.9	13.6	19.2
Vitamin A (mcg)					
Intervention	439.6	555.7	1103.1	1973.7	2299.2
Control	413.8	521.3	1016.9	1848.7	2172.9
Beta-carotene (mcg RE)					
Intervention	1344.9	1717.9	3882.9	8143.3	9745.3
Control	1152.1	1501.9	3280.7	6959.9	8524.4
Retinol (mcg RE)					
Intervention	104.5	147.4	389.4	831.8	1017.8
Control	121.0	164.6	411.7	865.4	1057.7
Vitamin C (mg)					
Intervention	43.1	56.0	122.2	208.3	239.0
Control	33.1	43.0	96.3	172.6	200.9
Soluble Fiber (g)					
Intervention	2.4	3.0	5.6	9.0	10.1
Control	2.1	2.5	4.6	7.6	8.7
Alpha Toc (mg)					
Intervention	2.8	3.3	5.6	10.7	13.8
Control	3.2	3.9	7.0	12.6	15.2
Vitamin D (mcg)					
Intervention	1.1	1.6	3.9	8.5	10.1
Control	1.3	1.7	4.1	8.6	10.4
Cholesterol (mg)					
Intervention	59.7	74.6	147.7	279.4	335.0
Control	80.4	100.8	204.3	383.9	457.0
Selenium (mcg)					
Intervention	41.3	50.2	88.8	140.5	160.1
Control	39.9	48.7	88.3	143.8	164.6
Insoluble Fiber (g)					
Intervention	4.7	5.8	11.1	18.3	20.4
Control	3.8	4.7	9.1	15.2	17.4

[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.

5. CaD Intervention Status

5.1. Adherence to Supplements

The protocol calls for CT women to be offered CaD randomization at AV-1. A few exceptions are allowed to offer randomization at other times because of logistical constraints. To simplify the displays, women randomized at other times have been excluded from the adherence summaries. Originally, a clinic visit was required 6 months post-CaD randomization and adherence was assessed. Lower than anticipated adherence rates motivated a change in the follow-up procedures for CaD. A phone contact at four weeks post-CaD randomization was instituted to assist women in working through any potential problems they might be experiencing on CaD. To absorb this additional activity without increasing the cost of the study, the visit required at 6 months post-CaD randomization has been relaxed to be in the form of a visit or a telephone contact at clinic discretion. With this change, estimates of the six-month adherence rate become less reliable.

Table 5.1 presents rates of follow-up, stopping intervention and pill collection, and adherence to pill taking by visit schedule. The adherence pattern among women with pill collections is constant over time. The adherence summary, defined as those women known to be consuming 80% or more of the prescribed dose, is about 52%-57%. This low adherence is a function of a significant proportion of women stopping the intervention entirely and lower than expected pill-taking rates among women staying on the intervention.

Table 5.2 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 loss 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 roughly 40%-50% above the assumed level.

Since significant proportions of still active women are taking less than the prescribed dose, it is anticipated that this would have an additional effect on study power beyond drop-out rates. To examine these effects, 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). Total calcium consumption (in mg) of 920, 950, 1000 at baseline, year 1 and year 9, respectively in controls and similarly 1920 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, thus providing FFQ data.

Table 5.3 describes the range of adherence patterns we examined. Using the adherence pattern suggested in *Table 5.1*, and anticipating that the new formulation will alleviate the poor adherence related to the size and taste of the tablets, we assume that a "moderate" adherence pattern may be

achievable. Current adherence data are more suggestive of the "poor" scenario. *Table 5.4* shows the power for Hip Fractures, Other Fractures and colorectal cancer under three possible sample sizes (45,000, 40,000, and 35,000) and all other parameters held constant. NB: Power is low for hip fracture and colo-rectal cancer in scenarios based on poor adherence or sample size <45,000. Power for all clinical fractures is adequate under most scenarios, especially if moderate adherence is achieved.

To understand factors related to adherence, we performed multivariate analyses of study subject characteristics using two measures of adherence calculated at SAV-2 and again at AV-2: the adherence summary value (1=known to be taking ≥ 80% of pills; 0 otherwise); and stopping CaD (1=stopping, 0=continuing). *Tables 5.5* through *5.7* present the fitted models. These analyses are consistent in indicating that increasing age is associated with better adherence while DM only participants and racial/ethnic minorities have lower adherence. The introduction of the 4-week call is associated with a modest, but statistically significant, higher level of adherence.

Table 5.8 summarizes the frequency of reported reasons for stopping CaD. The majority of women stopping study supplements do so of their own accord. Only 7% have indicated that they were advised by their physician to discontinue these supplements. Forty-four percent of the women who have stopped taking their study pills report a reason related to the intervention itself, 22% report health reasons and 6% report personal reasons. Symptoms or health problems associated with the intervention was the most frequently reported intervention-related reason followed by dislike of the pills.

5.2. Issues

Previous efforts indicated that the chewable tablet formulation was a significant barrier to adherence. The tablet manufacturer has recently provided us with a swallowable tablet (OSCal), to offer as an alternative. The active version will contain 500 mg calcium carbonate and 125 IU vitamin D. This represents a small reduction in vitamin D dose, from 400 IU to 250 IU daily, but we consider this a reasonable substitute because this formulation and its placebo already exist and have Investigational New Drug (IND) approval with FDA. The manufacturer has agreed to develop a swallowable formulation with the original vitamin D levels, which we will use as soon as it becomes available.

With the two forms now available (in October 1997), women are given the choice of the chewable or swallowable forms, at randomization and at each follow-up dispensing. The database will track each woman's choice at each time point to support secondary analyses of dose and formulation, as appropriate. Effects on randomization rates have been positive. Though small, global increases in CaD adherence suggest a benefit of the swallowable pill as well.

Table 5.1
CaD Adherence Summary

	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	20543	19807	96	16010	78	1544	8	3303	16	17228	84	2801	16	3715	22	10712	62	52
Annual Visit-2	14878	14331	96	11664	78	782	5	1269	10	12071	91	1432	12	2246	19	8393	70	57
Annual Visit -3	7295	6930	95	5726	79	631	9	854	14	5452	87	617	11	1092	20	3743	69	52
Annual Visit- 4	1966	1846	94	1590	81	102	5	176	11	1410	89	146	10	235	17	1029	73	53

[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 5.2
CaD Drop-Out Rates (%) by Follow-Up Time
(Design-specified values in parentheses)

	Total	
	Interval[1]	Cumulative[2]
Drop-Outs[3]		
AV-2	12.4 (8.8)	12.4 (8.8)
AV-3	8.7 (5.9)	20.0 (14.2)

[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.

Table 5.3
Adherence Patterns used for Sensitivity Analyses

Adherence Pattern	Total Calcium Intake (mg)		
	Intervention	Control	Δ
Design[1]			
Baseline	1920	920	1000
Year 1	1850	950	900
Year 9	1800	1000	800
Moderate Adherence[2]			
Baseline	1920	920	1000
Year 1	1710	930	780
Year 9	1650	950	700
Poor Adherence[3]			
Baseline	1920	920	1000
Year 1	1475	930	545
Year 9	1400	950	450

[1] Original power calculations had the same adherence assumptions as in HRT (i.e., 6% drop-out in Year 1, 3% per year thereafter, 1.5% per year drop-in plus 3% per year lost to follow-up in both arms). These total calcium intake assumptions produce approximately the same power for all designated endpoints in the total intake model.

[2] Moderate adherence is estimated from the median total calcium intake among CaD participants (with FFQs, current supplements and CaD study medications) at AV-1 (time of CaD randomization.) CaD participants without pill collections at AV-1 are excluded. Year 9 values are simple projections.

[3] Poor adherence is estimated from the median total calcium intake among CaD participants (with FFQs, current supplements and CaD study medications) at AV-1 (time of CaD randomization.) CaD participants without pill collections at AV-1 are considered not to be taking any pills. Year 9 values are simple projections.

Table 5.4
Sensitivity of CaD Study Power to Adherence Assumptions
Design Sample Size of 45,000

	Year	Intervention Effect[1] (%)	Percentage of Cases[1]		Power under Various Calcium Intake Assumptions[2]		
			Control	Intervention	Design	Moderate	Poor
Hip Fractures							
	2001	18	1.52	1.27	68	60	29
		22	1.51	1.20	85	77	39
		25	1.49	1.13	95	89	51
	2004	18	2.68	2.19	92	87	47
		22	2.65	2.05	99	97	63
		25	2.62	1.92	>99	99	77
Combined Fractures							
	2001	18	6.13	5.18	>99	99	76
		22	6.07	4.92	>99	>99	90
		25	6.01	4.66	>99	>99	97
	2004	18	9.69	8.07	>99	>99	92
		22	9.59	7.63	>99	>99	98
		25	9.50	7.18	>99	>99	>99
Colorectal Cancer							
	2001	18	0.80	0.69	30	27	14
		20	0.79	0.68	36	32	16
		22	0.78	0.66	42	37	19
	2004	18	1.32	1.06	84	76	39
		20	1.30	1.02	91	85	47
		22	1.29	0.98	96	91	54

[1] 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.

[2] See Table 5.3 for corresponding adherence assumptions.

Table 5.4 (continued)
Sensitivity of CaD Study Power to Adherence Assumptions
Revised Sample Size of 40,000

	Year	Intervention Effect[1] (%)	Percentage of Cases[1]		Power under Various Calcium Intake Assumptions[2]		
			Control	Intervention	Design	Moderate	Poor
Hip Fractures							
	2001	18	1.52	1.27	63	55	26
		22	1.51	1.20	80	72	36
		25	1.49	1.13	92	86	47
	2004	18	2.68	2.19	89	83	43
		22	2.65	2.05	97	95	58
		25	2.62	1.92	>99	99	72
Combined Fractures							
	2001	18	6.13	5.18	99	98	71
		22	6.07	4.92	>99	>99	86
		25	6.01	4.66	>99	>99	95
	2004	18	9.69	8.07	>99	>99	89
		22	9.59	7.63	>99	>99	97
		25	9.50	7.18	>99	>99	>99
Colorectal Cancer							
	2001	18	0.80	0.69	27	24	13
		20	0.79	0.68	33	29	15
		22	0.78	0.66	39	34	17
	2004	18	1.32	1.06	80	71	36
		20	1.30	1.02	88	80	42
		22	1.29	0.98	93	88	50

[1] 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.

[2] See Table 5.3 for corresponding adherence assumptions.

Table 5.4 (continued)
Sensitivity of CaD Study Power to Adherence Assumptions
Revised Sample Size of 35,000

	Year	Intervention Effect[1] (%)	Percentage of Cases[1]		Power under Various Calcium Intake Assumptions[2]		
			Control	Intervention	Design	Moderate	Poor
Hip Fractures							
	2001	18	1.52	1.27	57	50	23
		22	1.51	1.20	75	67	32
		25	1.49	1.13	88	81	42
	2004	18	2.68	2.19	84	78	38
		22	2.65	2.05	95	91	52
		25	2.62	1.92	99	98	66
Combined Fractures							
	2001	18	6.13	5.18	98	96	65
		22	6.07	4.92	>99	99	81
		25	6.01	4.66	>99	>99	92
	2004	18	9.69	8.07	>99	>99	86
		22	9.59	7.63	>99	>99	95
		25	9.50	7.18	>99	>99	99
Colorectal Cancer							
	2001	18	0.80	0.69	25	22	12
		20	0.79	0.68	29	26	14
		22	0.78	0.66	34	30	16
	2004	18	1.32	1.06	74	66	32
		20	1.30	1.02	83	75	38
		22	1.29	0.98	90	83	45

[1] 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.

[2] See Table 5.3 for corresponding adherence assumptions.

Table 5.5
Logistic Regression Analyses of CaD Adherence at Semi-Annual Vist-2 (SAV-2)
Data as of: August 31, 1998

	CaD (N=20531)		
	Non-Adherent Participants (N=9819)	Adherent[1] Participants (N=10712)	OR
Age:			
50-54[2]	2252	1795	1.00
55-59	2601	2562	1.22**
60-69	3576	4599	1.53**
70-79	1390	1756	1.46**
Ethnicity:			
White	7899	9240	1.00
Black	1110	756	0.67**
Hispanic	472	382	0.72**
Other Minority	317	315	0.89
Education:			
Post H.S.	7623	8091	1.00
Some H.S. / Diploma	1981	2419	1.05
0-8 Years	148	140	0.93
Income:			
<20 K	1534	1709	1.00
20-35K	2314	2692	1.02
35K-50K	1943	2222	1.05
>50K	3532	3567	1.02
Marital Status:			
Married	6049	6805	1.00
Not Married	3722	3874	0.92*
Four Week Phone Call[3]:			
No	1560	1273	1.00
Yes	5269	6540	1.40**
Primary CT Randomization:			
DM and HRT	1219	1775	1.00
HRT only	2252	3468	1.02
DM only	6348	5469	0.58**

[1] Defined as taking 80% or more of their study pills. Participants with missing pill collections are considered non-adherent (adherence=0).

[2] Underlined levels are reference categories.

[3] Includes participants randomized to CaD after 8/15/96.

*P-values <=.05 from Wald Test.

**P-values <=.01 from Wald Test.

Table 5.6
Logistic Regression Analyses of CaD Adherence at Annual Visit-2 (AV-2)
for Participants with >80% CaD Adherence at SAV-2
Data as of: August 31, 1998

	CaD (N=7378)		
	Non-Adherent Participants (N=1605)	Adherent[1] Participants (N=5773)	OR
Age:			
50-54[2]	331	1001	1.00
55-59	408	1387	1.13
60-69	629	2512	1.26**
70-79	237	873	1.15
Ethnicity:			
White	1308	5115	1.00
Black	171	351	0.53**
Hispanic	72	170	0.61**
Other Minority	49	131	0.69*
Education:			
Post H.S.	1252	4331	1.00
Some H.S. / Diploma	319	1338	1.14
0-8 Years	26	71	0.97
Income:			
<20 K	260	911	1.00
20-35K	380	1507	1.06
35K-50K	319	1227	1.05
>50K	565	1877	0.94
Marital Status:			
Married	974	3768	1.00
Not Married	625	1989	0.83**
Primary CT Randomization:			
DM and HRT	229	1007	1.00
HRT only	394	1936	1.10
DM only	982	2830	0.64**

[1] Defined as taking 80% or more of their study pills. Participants with missing pill collections are considered non-adherent (adherence=0).

[2] Underlined levels are reference categories.

*P-values <=.05 from Wald Test.

**P-values <=.01 from Wald Test.

Table 5.7
Logistic Regression Analyses of CaD Adherence at Annual Visit-3 (AV-3)
for Participants with >80% CaD Adherence at AV-2
Data as of: August 31, 1998

	CaD (N=3180)		
	Non-Adherent Participants (N=741)	Adherent[1] Participants (N=2439)	OR
Age:			
50-54[2]	155	413	1.00
55-59	187	581	1.13
60-69	298	1068	1.23
70-79	101	377	1.39*
Ethnicity:			
White	627	2215	1.00
Black	82	125	0.53**
Hispanic	16	56	1.15
Other Minority	14	42	0.94
Education:			
Post H.S.	565	1811	1.00
Some H.S. / Diploma	158	588	1.06
0-8 Years	12	30	0.73
Income:			
<20 K	114	387	1.00
20-35K	206	659	0.95
35K-50K	153	514	0.99
>50K	242	775	1.04
Marital Status:			
Married	453	1632	1.00
Not Married	284	799	0.82*
Primary CT Randomization:			
DM and HRT	106	455	1.00
HRT only	159	715	1.04
DM only	476	1269	0.61**

[1] Defined as taking 80% or more of their study pills. Participants with missing pill collections are considered non-adherent (adherence=0).

[2] Underlined levels are reference categories.

*P-values <=.05 from Wald Test.

**P-values <=.01 from Wald Test.

Table 5.8
Reasons for Stopping CaD
Data as of: August 31, 1998

Reasons[1]	(N=3206)	
Personal	185	(6%)
Travel	47	(1%)
Study Procedures	37	(1%)
Health	695	(22%)
Experiencing health problems or symptoms not due to intervention	389	(12%)
Worried about health effects of medical tests	15	(<1%)
Worried about costs if adverse effects occur	9	(<1%)
Advised not to participate by health care provider	228	(7%)
Study conflicts with health care needs	158	(5%)
Expected more care	9	(<1%)
Intervention	1408	(44%)
Reports health problems or symptoms from WHI Intervention	932	(29%)
Problem with Clinic Practitioner or other CC staff	2	(<1%)
Doesn't like taking pills	415	(13%)
Doesn't like DM requirements	7	(<1%)
Problems with DM group nutritionist or group members	2	(<1%)
Doesn't like DM eating patterns	3	(<1%)
Doesn't like randomized nature of intervention	128	(4%)
Expected some benefit from intervention	24	(1%)
Won't participate in safety procedures.	12	(<1%)
Other	1016	(32%)
Not Given	424	(13%)

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

6. OS Activities

6.1. 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. To date, Year 3 visits have been completed for 89.4% of those participants due for the visit overall (range across CCs: 82%-100% complete).

6.2. Completeness of Follow-up

Table 6.1 shows completeness of OS mail follow-up by follow-up year, type of contact and clinic group. These rates reflect our experience with those participants for whom the sequence of mailings are complete and there has been at least two months for CC follow-up.

The overall response of 94.5% for Year 1 data collection, which includes mailings plus CC follow-up of non-responders, is close to meeting the 95% goal. For Year 2, however, the rates fall short of the 94% goal, due in part to the lack of required CC follow-up of non-responders. Response rates to Year 4 data collection mailings, which began in July 1998, are not yet available.

Table 6.1
Response rates to OS Follow-up Procedures

		Mailings Initiated[1]		Response to Mailings		Response to CC follow-up		Total Responses	
	# Due	N	%	N	%[2]	N	%[3]	N	%[4]
Year 1	42899	42854	99.9	39724	92.7	798	25.5	40522	94.5
VCC	20728	20711	99.9	19444	93.9	359	28.3	19803	95.5
NCC	22171	22143	99.9	20280	91.6	439	23.6	20719	93.5
Year 2	13755	13715	99.7	12351	90.1	N/A		12351	90.0
VCC	8596	8594	99.9	7831	91.1	N/A		7831	91.1
NCC	5159	5121	99.3	4520	88.3	N/A		4520	87.6

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

7. Intermediate Outcomes

7.1 Blood Specimen Analysis

WHI assesses intermediate effects of interventions through analyses of stored blood samples on a small subsample of CT participants at baseline and years 1, 3, 6 and 9. This subsample is stratified by study component (HRT vs. DM), Clinical Center and by race with oversampling of minorities. To reduce the variability that could arise from laboratory drift, baseline and year one samples are paired and sent to the laboratory in the same batch. The laboratory is blinded to all participant information.

Table 7.1 shows the mean values of all routine blood analytes at baseline and AV-1, the changes over time and the differences between HRT participants with and without a uterus. To make these results more representative of the accrued population, weighted averages and standard errors of the ethnic-specific results are presented with the weights defined as the proportion currently enrolled in each racial/ethnic category (Whites, Blacks, Hispanics, and Other) in each respective CT component.

For reference, the table below compares the published results of the PEPI[1] and HERS[2] studies to WHI for selected outcomes. The results are for three years (PEPI) or one year (HERS and WHI) following baseline. PEPI did not stratify by hysterectomy status so they report a single placebo arm. The results missing for HERS were not recorded in the published manuscript. Note that the WHI analyses, here and subsequently, pool intervention and control groups.

	PEPI 3 Year Results			Current WHI 1 Year Results		HERS 1 Year Results	
	ERT	PERT	Placebo	Without Uterus	With Uterus	PERT	Placebo
Fibrinogen (mg/dl)	-20†	1†	10†	-6.9	-3.1	NA	NA
HDL-C (mg/dl)	5.6	1.2	-1.2	4.5	2.2	4	-1
LDL-C (mg/dl)	-14.5	-16.5	-4.1	-15.6	-12.7	-20	-5
Total cholesterol (mg/dl)	-7.6	-14.0	-4.2	-10.8	-10.3	NA	NA
Triglycerides (mg/dl)	13.7†	11.4†	-3.2†	1.5	1.1	13	5
Glucose (mg/dl)	-2.8	-2.1	-0.5	-2.8	-2.6	NA	NA
Insulin (uIU/ml)	-.24†	-.53†	.53†	-0.5	-0.2	NA	NA

† Calculated on log-transformed values.

Table 7.2 displays the same analytes measured in DM women. For comparison purposes, the Women's Health Trial: Feasibility Study in Minority Populations have reported dietary intake and

[1] The Writing Group for the PEPI Trial. Effects of Estrogen or Estrogen/Progestin Regimens on Heart Disease Risk Factors in Postmenopausal Women. JAMA 1995;273(3):199-208.

[2] Hully S, Grady D, Bush T, et al. Randomized trial of estrogen plus progestin for secondary prevention of coronary heart disease in postmenopausal women. JAMA 1998;280:605-613.

changes in total cholesterol.[1] The results at baseline and approximately 12 months post-randomization are summarized below to indicate the magnitude of effect we might expect to see.

	WHT:FSMP Results		
	Intervention	Control	C-I
FFQ % cal from fat			
Baseline	39.7	39.1	-0.6
12 months	25.7	36.0	10.3
Total cholesterol (mg/dl)			
Baseline	219	219	0
Change at 12 months	-8.4	-4.9	-3.5

Prospective analyses of OS bloods for these routine measures will be conducted for participants in the OS Measurement Precision Study. These data are not yet available.

7.2 Bone Mineral Density

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

Tables 7.3 - 7.5 show CT component specific BMD means and standard deviations for baseline, AV-1 and AV-3 along with % change from baseline for the three types of scans available: whole body, spine, and hip. *Table 7.6* presents the same descriptive statistics for bone mineral density in OS women at baseline and year 3. For women who have completed AV-3, their average baseline results and the average % change from baseline is also provided. The current data suggest overall a very small increase in bone density over three years in this group of women.

7.3 ECG Data

Electrocardiograms (ECGs) are given to all CT participants at baseline, and years 3, 6 and 9. The ECGs are sent for analysis to EPICARE (Pentti Rautaharju, 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, defined as MIs detected by this ECG analysis but not reported by the participant. Analysis of individual ECGs may also be of interest, since abnormalities in ECGs are known to be predictors of future cardiovascular problems.

[1] Coates RJ, Bowen DJ, Kristal AR, et al. The Women's Health Trial Feasibility Study in Minority Populations: changes in dietary intakes. Unpublished manuscript

As of August 31, 1998 the CCC had received serial analysis on 8,973 CT participants, whose year 3 ECGs had been analyzed by EPICARE. Currently the CCC, the Morbidity & Mortality Advisory Committee and the investigators at EPICARE are analyzing this data for use in future monitoring. In this report we present some preliminary analysis of the serial ECG data.

Table 7.7 - Cross-tabulation of ECG Codes Suggesting an Incident MI and Locally Confirmed and Self-Reported MI for all CT participants shows the relation between MIs that have been identified before the year 3 ECG and incident MIs as identified by the ECG analysis. We note that only a small number of the MIs identified by the WHI outcomes process were found by the ECG analysis (3 of 49 confirmed MIs). At our request, Dr. Rautaharju examined the ECGs of those participants for whom WHI identified an MI, but EPICARE did not find one based on the serial ECG analysis. Some signs of ECG abnormalities were evident in about 40% of these cases, at either baseline or follow-up, but these abnormalities had not evolved sufficiently to identify an incident MI. For the other cases, the ECGs showed no abnormalities. Based on these data, the 24 participants who had an incident MI found based on their ECGs, but who did not have a locally confirmed MI would be considered to have had silent MIs.

Table 7.1
Blood Specimen Analysis: HRT Participants
Data as of: August 31, 1998

	Without Uterus			With Uterus		
	n	mean*	std.*	n	mean*	std.*
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	321	0.08	0.08	358	0.10	0.07
AV-1	318	0.07	0.04	357	0.09	0.07
AV-1 - Baseline	318	-0.01	0.07	357	-0.01	0.04
Alpha-tocopherol (µg/ml)						
Baseline	321	15.4	5.5	358	15.1	5.4
AV-1	318	16.7	6.0	358	15.3	5.4
AV-1 - Baseline	318	1.2	5.1	358	0.2	4.3
Beta-Carotene (µg/ml)						
Baseline	320	0.27	0.14	358	0.32	0.23
AV-1	317	0.24	0.26	358	0.29	0.26
AV-1 - Baseline	317	-0.02	0.27	358	-0.03	0.14
Beta-Cryptoxanthine (µg/ml)						
Baseline	321	0.07	0.04	358	0.09	0.07
AV-1	318	0.07	0.04	358	0.08	0.06
AV-1 - Baseline	318	0.00	0.04	358	0.00	0.05
Gamma-tocopherol (µg/ml)						
Baseline	321	2.44	1.20	358	2.34	1.10
AV-1	318	2.24	1.20	358	1.94	0.95
AV-1 - Baseline	318	-0.22	0.95	358	-0.40	0.82
Lycopene (µg/ml)						
Baseline	321	0.37	0.15	358	0.39	0.16
AV-1	318	0.35	0.11	358	0.38	0.15
AV-1 - Baseline	318	-0.02	0.11	358	0.00	0.15
Lutein and Zeaxanthin (µg/ml)						
Baseline	321	0.20	0.07	358	0.21	0.08
AV-1	318	0.20	0.07	358	0.21	0.08
AV-1 - Baseline	318	0.00	0.05	358	0.00	0.05
Retinol (µg/ml)						
Baseline	321	0.60	0.11	358	0.58	0.11
AV-1	318	0.62	0.14	358	0.59	0.11
AV-1 - Baseline	318	0.02	0.09	358	0.01	0.08

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

Table 7.1 (Continued)

	Without Uterus			With Uterus		
	n	mean*	std.*	n	mean*	std.*
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	315	122.6	20.6	352	113.5	22.9
AV-1	312	126.3	25.9	354	118.7	25.0
AV-1 – Baseline	307	4.9	16.4	349	5.2	16.9
Factor VII C (%)						
Baseline	307	135.1	20.6	345	123.8	24.5
AV-1	305	140.1	29.7	349	122.4	23.3
AV-1 – Baseline	295	5.7	25.0	338	-1.3	18.0
Fibrinogen (mg/dl)						
Baseline	315	321.7	53.8	352	308.2	47.1
AV-1	311	316.0	53.2	353	304.9	49.9
AV-1 – Baseline	306	-6.9	47.3	348	-3.1	48.4
Hormones / Other						
Glucose (mg/dl)						
Baseline	320	106.2	29.3	357	101.1	25.6
AV-1	317	103.6	24.2	358	98.5	19.2
AV-1 – Baseline	317	-2.8	16.8	357	-2.6	13.8
Insulin (μIU/ml)						
Baseline	317	12.6	5.9	356	10.9	4.4
AV-1	317	12.2	5.9	357	10.6	4.1
AV-1 – Baseline	314	-0.5	3.5	355	-0.2	2.8

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

Table 7.1 (Continued)

	Without Uterus			With Uterus		
	n	mean*	std.*	n	mean*	std.*
Lipoproteins						
HDL-2 (mg/dl)						
Baseline	315	15.4	6.8	346	16.4	6.6
AV-1	312	17.8	8.0	350	18.2	7.5
AV-1 – Baseline	307	2.5	3.9	340	1.3	3.8
HDL-3 (mg/dl)						
Baseline	316	39.7	6.1	346	40.0	6.1
AV-1	314	42.3	7.0	351	40.9	5.8
AV-1 – Baseline	309	2.0	4.7	341	0.8	4.2
HDL-C (mg/dl)						
Baseline	319	55.3	11.5	357	56.7	11.4
AV-1	317	60.0	12.6	356	59.1	11.5
AV-1 – Baseline	316	4.5	7.4	355	2.2	5.9
LDL-C (mg/dl)						
Baseline	316	144.0	31.0	351	140.3	30.3
AV-1	313	129.5	27.0	351	127.9	26.6
AV-1 – Baseline	311	-15.6	24.1	347	-12.7	23.4
Total Cholesterol (mg/dl)						
Baseline	320	232.7	32.2	357	227.1	34.8
AV-1	317	222.8	27.4	356	217.0	29.9
AV-1 – Baseline	316	-10.8	25.8	355	-10.3	25.2
Triglyceride (mg/dl)						
Baseline	320	167.9	64.0	357	148.9	67.4
AV-1	317	169.0	70.0	355	149.1	53.6
AV-1 – Baseline	316	1.5	50.7	354	1.1	45.6

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

Table 7.2
Blood Specimen Analysis: DM Participants
Data as of: August 31, 1998

	n	mean*	std.*
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	838	0.08	0.06
AV-1	838	0.09	0.05
AV-1 – Baseline	836	0.00	0.05
Alpha-tocopherol (µg/ml)			
Baseline	838	15.5	5.3
AV-1	838	16.1	5.4
AV-1 – Baseline	836	0.6	3.8
Beta-Carotene (µg/ml)			
Baseline	838	0.28	0.18
AV-1	838	0.28	0.21
AV-1 – Baseline	836	0.01	0.19
Beta-Cryptoxanthine (µg/ml)			
Baseline	838	0.08	0.04
AV-1	838	0.08	0.05
AV-1 – Baseline	836	0.00	0.04
Gamma-tocopherol (µg/ml)			
Baseline	838	2.25	1.14
AV-1	837	1.90	1.00
AV-1 – Baseline	835	-0.36	0.82
Lycopene (µg/ml)			
Baseline	838	0.40	0.15
AV-1	838	0.40	0.15
AV-1 – Baseline	836	0.00	0.13
Lutein and Zeaxanthin (µg/ml)			
Baseline	838	0.22	0.09
AV-1	838	0.22	0.08
AV-1 – Baseline	836	0.00	0.06
Retinol (µg/ml)			
Baseline	838	0.61	0.12
AV-1	838	0.61	0.13
AV-1 – Baseline	836	0.00	0.09

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

Table 7.2 (Continued)

	n	mean*	std.*
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	834	122.8	24.7
AV-1	826	122.7	26.0
AV-1 - Baseline	821	0.0	16.7
Factor VII C (%)			
Baseline	814	132.7	26.9
AV-1	802	129.0	25.3
AV-1 - Baseline	787	-3.7	21.7
Fibrinogen (mg/dl)			
Baseline	834	300.9	47.8
AV-1	826	301.1	49.5
AV-1 - Baseline	821	0.3	40.9
Hormones/Other			
Glucose (mg/dl)			
Baseline	839	98.5	20.0
AV-1	837	97.3	19.2
AV-1 - Baseline	836	-1.2	15.9
Insulin (μIU/ml)			
Baseline	834	11.1	5.2
AV-1	833	11.2	12.9
AV-1 - Baseline	827	0.2	11.6

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

Table 7.2 (Continued)

	n	mean*	std.*
Lipoproteins			
HDL-2 (mg/dl)			
Baseline	820	17.8	7.2
AV-1	824	18.1	7.2
AV-1 - Baseline	809	0.3	4.3
HDL-3 (mg/dl)			
Baseline	822	42.3	7.2
AV-1	825	41.5	6.6
AV-1 - Baseline	812	-0.8	4.5
HDL-C (mg/dl)			
Baseline	836	60.1	12.8
AV-1	836	59.6	11.9
AV-1 - Baseline	833	-0.4	6.7
LDL-C (mg/dl)			
Baseline	828	135.1	29.7
AV-1	824	129.3	28.1
AV-1 - Baseline	819	-6.1	18.8
Total Cholesterol (mg/dl)			
Baseline	837	226.6	33.7
AV-1	836	220.5	30.6
AV-1 - Baseline	834	-6.5	21.8
Triglyceride (mg/dl)			
Baseline	837	153.3	63.8
AV-1	836	156.8	63.9
AV-1 - Baseline	834	2.8	43.6

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

Table 7.3
Bone Mineral Density Analysis: HRT Participants
Data as of: August 31, 1998

	Without Uterus			With Uterus		
	n	mean	std.	n	mean	std.
Whole Body Scan						
Baseline	935	1.01	0.11	1023	0.99	0.10
AV1	729	1.01	0.11	806	1.00	0.10
AV3	320	1.03	0.11	330	1.01	0.10
AV1 % Change from baseline BMD[1]	726	0.39	2.68	804	0.24	2.36
AV3 % Change from baseline BMD[2]	317	1.62	3.22	330	1.86	3.13
Spine Scan						
Baseline	909	0.97	0.16	1000	0.95	0.16
AV1	713	0.99	0.16	788	0.97	0.16
AV3	313	1.01	0.17	325	0.98	0.16
AV1 % Change from baseline BMD	711	1.83	4.62	785	2.06	4.19
AV3 % Change from baseline BMD	311	3.54	6.07	325	4.42	5.95
Hip Scan						
Baseline	932	0.86	0.14	1021	0.84	0.13
AV1	729	0.87	0.14	805	0.85	0.13
AV3	318	0.89	0.15	331	0.87	0.13
AV1 % Change from baseline BMD	726	0.66	3.09	804	0.56	3.01
AV3 % Change from baseline BMD	315	2.29	4.37	331	2.43	4.32

[1] AV1 % Change from baseline BMD is defined as ((AV1-Baseline)/Baseline)x100
[2] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100

Table 7.4
Bone Mineral Density Analysis: DM Participants
Data as of: August 31, 1998

	n	mean	std.
Whole Body Scan			
Baseline	3610	1.03	0.11
AV1	3200	1.03	0.11
AV3	1427	1.04	0.11
AV1 % Change from baseline BMD[1]	3172	0.17	2.50
AV3 % Change from baseline BMD[2]	1409	1.32	3.10
Spine Scan			
Baseline	3543	0.99	0.17
AV1	3145	1.00	0.17
AV3	1396	1.00	0.17
AV1 % Change from baseline BMD	3120	0.71	3.84
AV3 % Change from baseline BMD	1385	2.20	5.20
Hip Scan			
Baseline	3609	0.87	0.14
AV1	3198	0.87	0.14
AV3	1414	0.88	0.14
AV1 % Change from baseline BMD	3181	-0.04	2.77
AV3 % Change from baseline BMD	1404	1.24	4.13

[1] AV1 % Change from baseline BMD is defined as ((AV1-Baseline)/Baseline)x100
[2] AV3 % Change from baseline BMD is defined as ((AV3-Baseline)/Baseline)x100

Table 7.5
Bone Mineral Density Analysis: CaD Participants
Data as of: August 31, 1998

	n	mean	std.
Whole Body Scan			
AV1	2210	1.02	0.11
AV3	1033	1.04	0.11
AV3 % Change from baseline BMD[1]	1009	1.88	2.75
Spine Scan			
AV1	2165	1.00	0.17
AV3	1013	1.01	0.16
AV3 % Change from baseline BMD[1]	990	1.87	4.28
Hip Scan			
AV1	2204	0.87	0.14
AV3	1025	0.88	0.14
AV3 % Change from baseline BMD[1]	1004	1.87	3.21

[1]Percent Change from BMD is defined as ((AV3-AV1)/AV1)x100

Table 7.6
Bone Mineral Density Analysis: OS Participants
Data as of: August 31, 1998

	n	mean	std.
Whole Body Scan			
Baseline	6394	1.01	0.11
Baseline (for ppts. with an AV3 scan)	1487	1.01	0.11
AV3	1496	1.02	0.11
AV3 % Change from baseline BMD[1]	1487	0.62	3.46
Spine Scan			
Baseline	6302	0.98	0.17
AV3 (for ppts. with an AV3 scan)	1470	0.97	0.17
AV3	1472	0.99	0.18
AV3 % Change from baseline BMD	1470	1.82	5.07
Hip Scan			
Baseline	6397	0.84	0.14
AV3 (for ppts. with an AV3 scan)	1497	0.84	0.14
AV3	1499	0.84	0.14
AV3 % Change from baseline BMD	1497	0.25	4.02

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

Table 7.7
Cross-tabulation of ECG Codes Suggesting an Incident MI and Locally Confirmed and Self-Reported MI for all CT participants
Data as of: August 31, 1998

	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]	8255	5	34	8294
Borderline Q-wave change[4]	355	1	2	358
Ischemic ST-T evolution[5]	136	0	6	142
Possible evolving Q-wave MI[6]	148	0	4	152
Evolving Q-wave MI[7]	24[8]	0	3	27
Total	**8918**	**6**	**49**	**8973**
HRT Participants				
No significant Q or ST-T evolution[3]	2835	2	16	2853
Borderline Q-wave change[4]	126	0	1	127
Ischemic ST-T evolution[5]	53	0	3	56
Possible evolving Q-wave MI[6]	64	0	1	65
Evolving Q-wave MI[7]	12	0	1	13
Total	**3090**	**2**	**22**	**3114**
DM Participants				
No significant Q or ST-T evolution[3]	6532	4	25	6561
Borderline Q-wave change[4]	278	1	1	280
Ischemic ST-T evolution[5]	101	0	3	104
Possible evolving Q-wave MI[6]	110	0	4	114
Evolving Q-wave MI[7]	18	0	3	21
Total	**7039**	**5**	**36**	**7080**
CaD Participants				
No significant Q or ST-T evolution[3]	4637	3	18	4640
Borderline Q-wave change[4]	214	0	1	214
Ischemic ST-T evolution[5]	67	0	2	67
Possible evolving Q-wave MI[6]	79	0	2	79
Evolving Q-wave MI[7]	13	0	3	13
Total	**5010**	**3**	**26**	**5013**

[1] Includes only self-reports of events before the year 3 ECG.
[2] Includes only locally confirmed MIs that took place before the year 3 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] Novacode Incident MI code I 5.1 and I.5.2.
[8] The cases in this cell are potentially the silent MIs.

8. Outcomes

8.1 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 execute a database function that identifies adjudication cases based on the *Form 33D* information. CCs then request hospital and related records as specified in *Volume 8 - Outcomes* for each outcome category. Once the cases are documented, clinic staff send the charts to the local physician adjudicator for evaluation and classification. Upon return, clinic staff enter the local determinations into the WHI database. Key cardiovascular outcomes are 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.

We present data both for self-reported and locally adjudicated outcomes. The monitoring analysis is conducted on outcomes as classified by the local adjudicator, however. 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. The central adjudication process should therefore be viewed primarily as a quality assurance effort.

8.2 Terminology

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

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

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

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

4c. Those 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. Reasons for not obtaining documentation are:

- The provider named by the participant does not have or will not release documentation about the WHI participant, and the WHI participant is not able to name another provider

- The provider indicated by the participant does not respond after repeated contacts by the CC over a period of at least one year (common for hospitalizations out of the country).

8.3 Outcomes Data Quality

Tables 8.1-8.2 - Timeliness and Completeness of Local Adjudications displays 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. Thus, some of the more recent data will improve when more adjudications are key entered. Overall 83% of self-reported outcomes in the CT and 75% of the self-reported outcomes in the OS requiring adjudication have been closed, 30% of the outcomes in the CT and 36% of the outcomes in the OS have been closed within 90 days of self-report and 50% (CT) and 59% (OS) within 180 days. (Note: the fact that the percentages for the CT appear better is because most of the outcomes in 1996 and earlier, when outcomes processing was considerably slower, are CT outcomes.)

Since the May 1998 DSMB meeting there has been a coordinated effort from CCs, CCC, Project Office, Performance Monitoring Committee, and Efficiency Task Force to improve the timeliness and completeness of the local adjudication process. Since then considerable progress with both timeliness and completeness of the local adjudication process has been made. For example, the percentage of forms that were adjudicated within 90 days has increased from about 40-50% to about 60% for the month of June 1998. (Note that forms that were received by the clinic at the end of June only have had 60 days between entering and the database consolidation of August 31, 1998, so this percentage for June will likely improve further). 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 6.3% for the CT and 7.2% for the OS.

Figure 8.1 – CT Timeliness per Quarter-Year of Self-Report and *Figure 8.2 - CT Timeliness per Year of Self-Report* display Kaplan-Meier curves for the time period from reporting an outcome on *Form 33D* until the adjudication case is closed. The Kaplan-Meier curves for each of the quarter-years in *Figure 8.1* show the recent increased activity in outcomes processing.

Figure 8.3 - OS Timeliness per Quarter-Year of Self-Report and *Figure 8.4 - OS Timeliness per Year of Self-Report* display the same information as *Figures 8.1-8.2* for the OS. It is very encouraging to note that while most of the activities related to outcomes efficiency have focussed on the CT, the timeliness for the OS has improved as much as the timeliness for the CT.

The outcomes ascertainment, documentation and adjudication effort is by necessity a lengthy process involving interaction between the clinical center, the participant, and her health care providers. Some of the biggest hurdles are related to the interactions with the providers and these will continue to slow the outcomes process, particularly when the event of interest occurred near the time of the participant's self-report. In these instances the chart may not be complete or available, causing CCs to issue multiple requests. The CCC continues to work closely with the Performance Monitoring Committee to develop reports and other tools that will facilitate timely outcomes processing by the CCs. Since the effect of many recent improvements in the outcomes processing will only yield results over time we hope to see further improvements in the future.

Table 8.3 - Agreement of Local Adjudications with Self-Reports shows 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 anyway. 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 *Table 8.3* is defined to be a participant rather than an outcome event. For some of the participants who's self-report is denied related outcomes may be found based on the adjudication case of the denied self-report. 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 *Table 8.2*, which includes TIA, is substantially larger than that in some of the later tables.

Reasons why a self-report of an outcome may be denied include: (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) took place; (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. One reason that the accuracy of cancer and fracture self-reports is higher than the accuracy of cardiovascular self-reports is that many more cardiovascular self-reports result in a related outcome. If those related outcomes are included with the confirmed self-reports, cardiovascular and fracture outcomes have about

an 80% and cancers about an 85% agreement rate between self-reports and locally confirmed outcomes.

The percentage of agreement between self-report and locally confirmed outcomes for fractures is considerably larger than six months ago. The reason for this is that this time we excluded self-reports for non-WHI fractures, such as rib, toe and finger fractures, which in the previous report ended up in the *administrative denials* category. Currently the number of administrative denials is still considerably larger for fractures than for any other category since many more fractures are treated outpatient, and it turns out to be harder to receive satisfactory documentation of some outpatient providers. Note that the accuracy of self-reports for *other fractures* reflects the percentage of people who reported an *other fracture* for whom any of the fractures in the other category was found, even if the participant indicated the wrong broken bone.

Table 8.4 - Agreement of Central Adjudications with Local Adjudications shows 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 quality assurance, data regarding such cross-classification is not shown.

8.4 Outcomes Overview

Tables 8.5-8.9 - Counts (Annualized Percentages) of Participants with Self-Reported Outcomes for the Clinical trial, Dietary Modification Component, Hormone Replacement Therapy Component, Calcium and Vitamin D Component, and Observational Study, contains counts of the number of self-reports for the major WHI outcomes. Note that for many of the outcomes the participants over-report (see *Table 8.3*), so the numbers in these tables should be seen as upper bounds to the number of outcomes that currently have occurred. For most outcomes the number of self-reports that eventually gets confirmed, usually for the self-reported outcome, sometimes for a related outcome, is about 80-85%. Except for the fact that there is still a sizable backlog in the adjudication process, we recommend using the number of locally confirmed outcomes in *Tables 8.10-8.14.*

For the DM, HRT and CaD tables, the counts and rates are based on all the participants in the control arm(s) and the intervention arm(s). Because of the blinding of the study, we cannot provide information about the number of outcomes in separate arms.

It is interesting to notice that the participant in the Observational Study have a lower annualized rate of ever being hospitalized than the Clinical Trial participants (6.97% versus 8.01%). For most cardiovascular outcomes the CT participants seem to have slightly higher rates than the OS participants, while the OS participants have higher rates for the cancer outcomes, but the difference between the CT and OS rate is typically quite small.

Currently we are observing higher rates of breast cancer than of MI in both the CT and the OS. We expect that this will change over time, since there likely is a considerably larger ``healthy volunteer effect" for MI than for breast cancer. This healthy volunteer effect has reduced

slightly over the last year, and it should reduce further in the next few years. Currently, we are observing approximately the population rates of breast and colorectal cancer, while the current WHI rates of MI are only about half of what is observed in the general population. Hip fractures rates are even lower, and run at about 25% of those observed in the population.

Tables 8.10-8.14 - Counts (Annualized Percentages) of Participants with Locally Verified Outcomes for the Clinical trial, Dietary Modification Component, Hormone Replacement Therapy Component, Calcium and Vitamin D Component, and Observational Study, contains the same information as *Tables 8.5* through *8.9,* but for the locally verified outcomes, rather than self-reports. Since a number of the outcomes still need to be adjudicated, the numbers in these tables give a lower bound on the number of outcomes that currently have occurred. When we get further in the study, hopefully the number of not yet adjudicated cases will decrease as a fraction of the total number of cases, at which stage these tables may give more accurate information than *Tables 8.5-8.9.*

Tables 8.15 - Counts (Annualized Percentages) of Locally Verified Outcomes for HRT participants With and Without Uterus compares outcome rates among all participants with a uterus (PERT and placebo arm combined) with those for all participants without a uterus (ERT and placebo arm combined).

Table 8.1
Timeliness and Completeness of Local Adjudications - CT[1]
Data as of: August 31, 1998

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		91 - 180		>180		Not yet adjudicated	
	N	N	%	N	%	N	%	N	%
<= June 30 1996	3771	262	7%	514	14%	2834	75%	161	4%
1996 July - December	1359	314	23%	424	31%	535	39%	86	6%
1997 January	358	119	33%	88	25%	117	33%	34	9%
1997 February	315	109	35%	94	30%	84	27%	28	9%
1997 March	334	115	34%	87	26%	106	32%	26	8%
1997 April	397	157	40%	99	25%	110	28%	31	8%
1997 May	339	126	37%	108	32%	78	23%	27	8%
1997 June	402	148	37%	101	25%	123	31%	30	7%
1997 July	410	160	39%	98	24%	114	28%	38	9%
1997 August	369	157	43%	76	21%	100	27%	36	10%
1997 September	392	173	44%	75	19%	97	25%	47	12%
1997 October	487	169	35%	119	24%	126	26%	73	15%
1997 November	423	172	41%	98	23%	93	22%	60	14%
1997 December	409	160	39%	84	21%	107	26%	58	14%
1998 January	529	210	40%	165	31%	81	15%	73	14%
1998 February	504	232	46%	152	30%	34	7%	86	17%
1998 March	628	266	42%	234	37%			128	20%
1998 April	620	288	46%	172	28%			160	26%
1998 May	549	268	49%	77	14%			204	37%
1998 June	693	422	61%					271	39%
1998 July	637	212	33%					425	67%
1998 August	452	44	10%					408	90%
Total	14377	4283	30%	2865	20%	4739	33%	2490	17%

[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.

Thus, the entries below the horizontal lines in the columns ≤ 90 and 91-180 will still improve when more adjudications are entered in the database.

[2]Conditions are self-reported events that require additional documentation.

Figure 8.1 CT Timeliness per Year of Self-Report

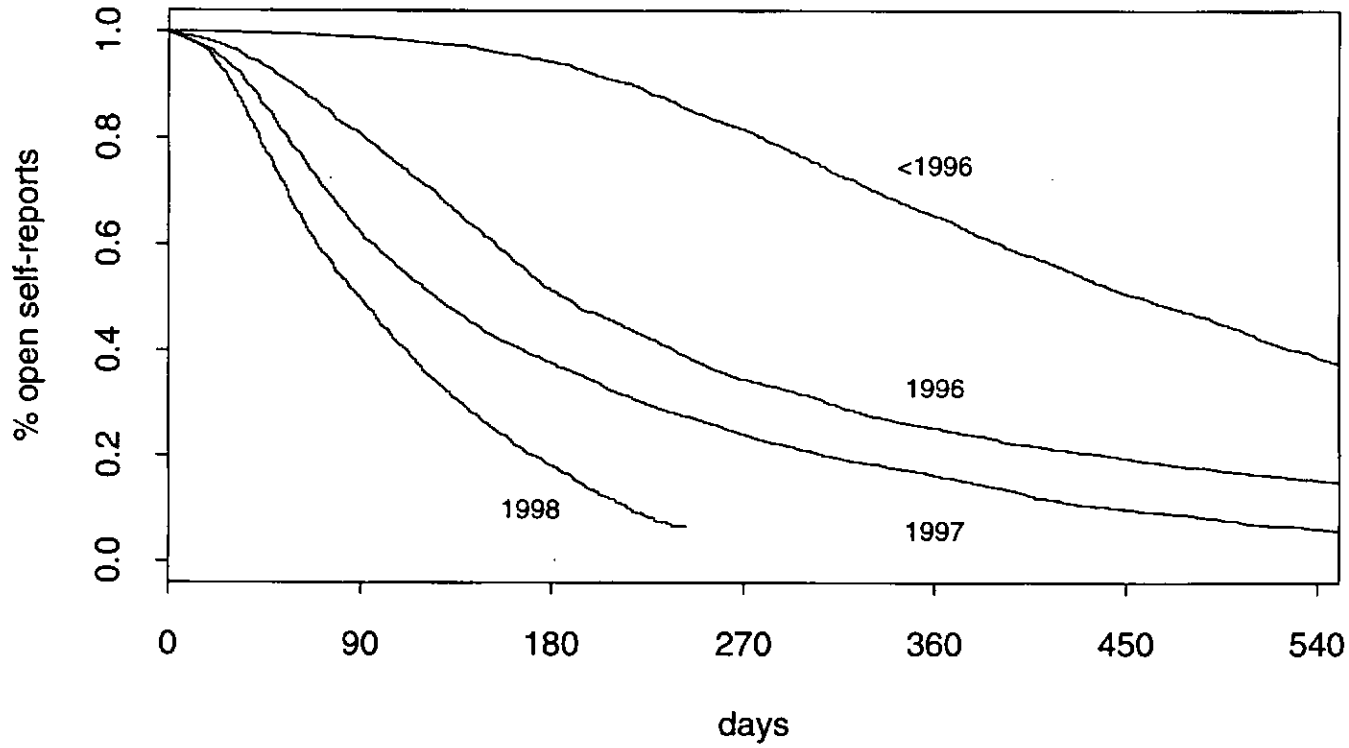


Figure 8.2 CT Timeliness per Quarter-Year of Self-Report

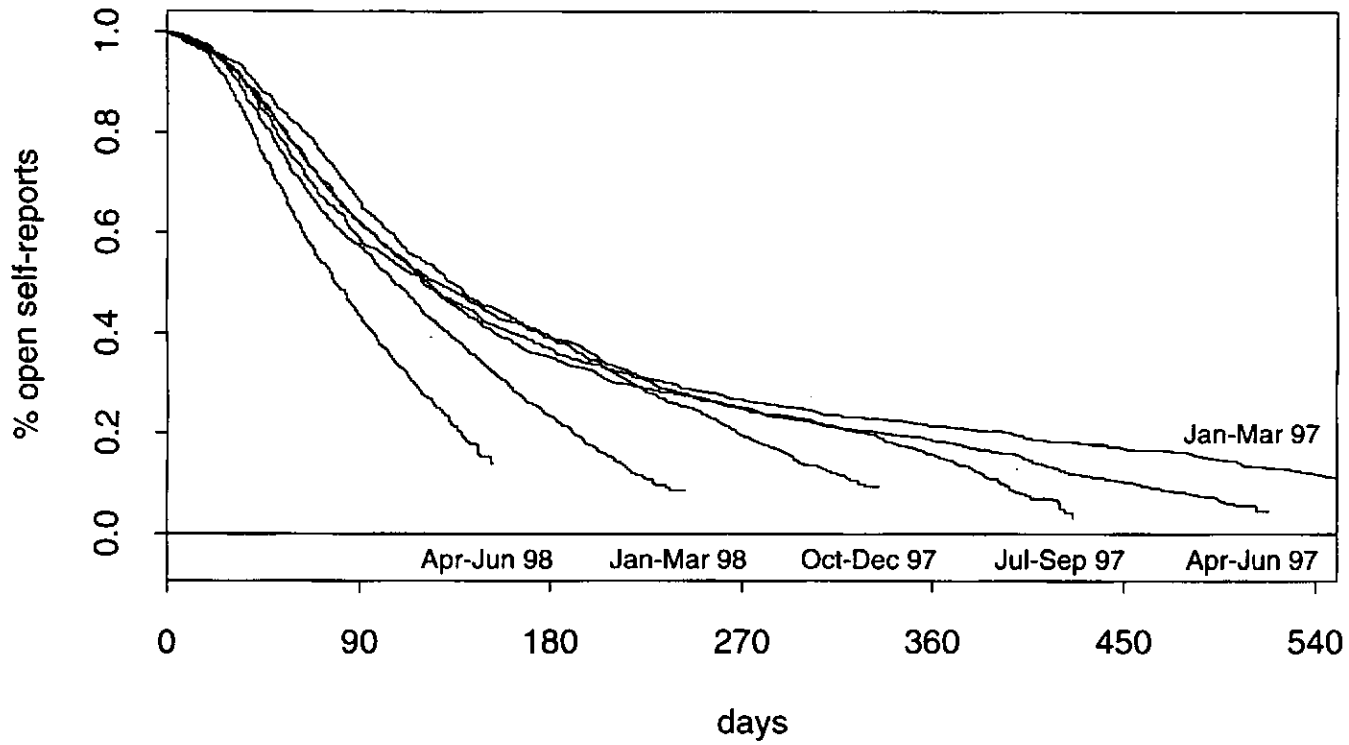


Figure 8.3 OS Timeliness per Year of Self-Report

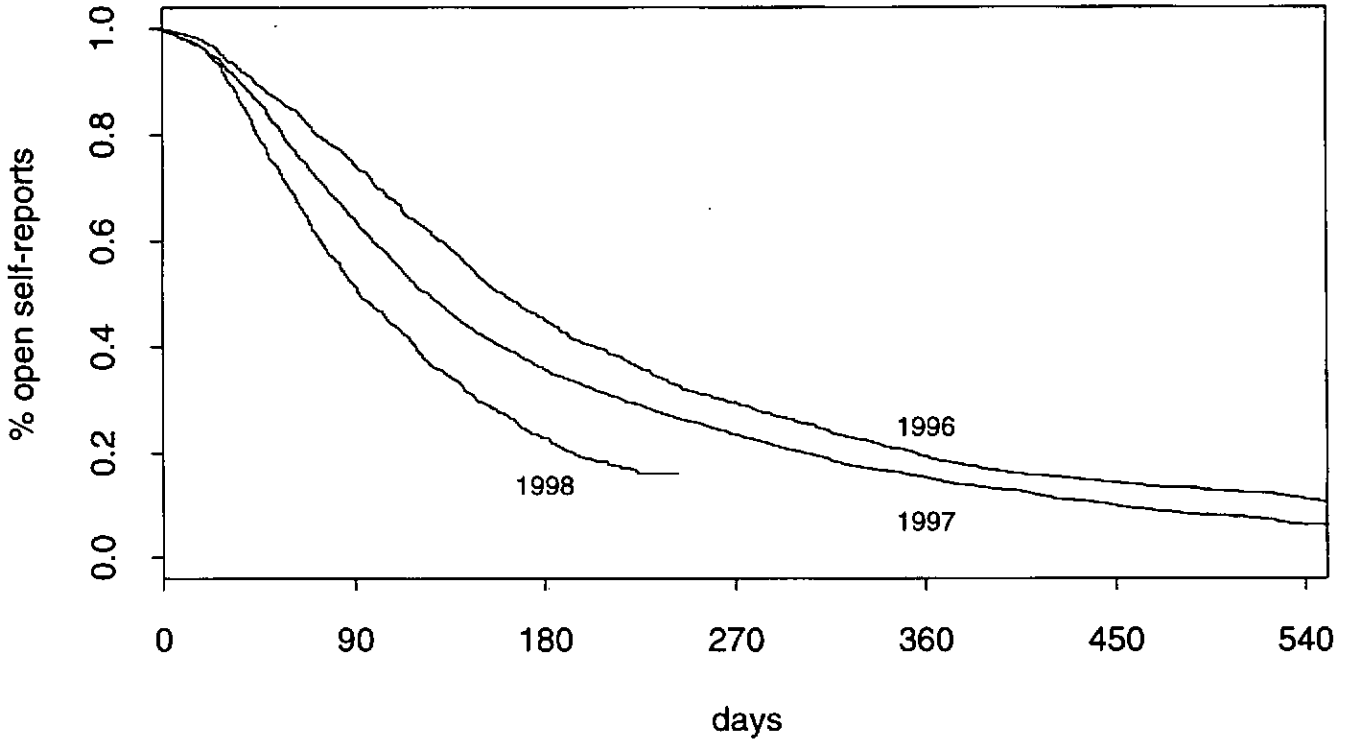


Figure 8.4 OS Timeliness per Quarter-Year of Self-Report

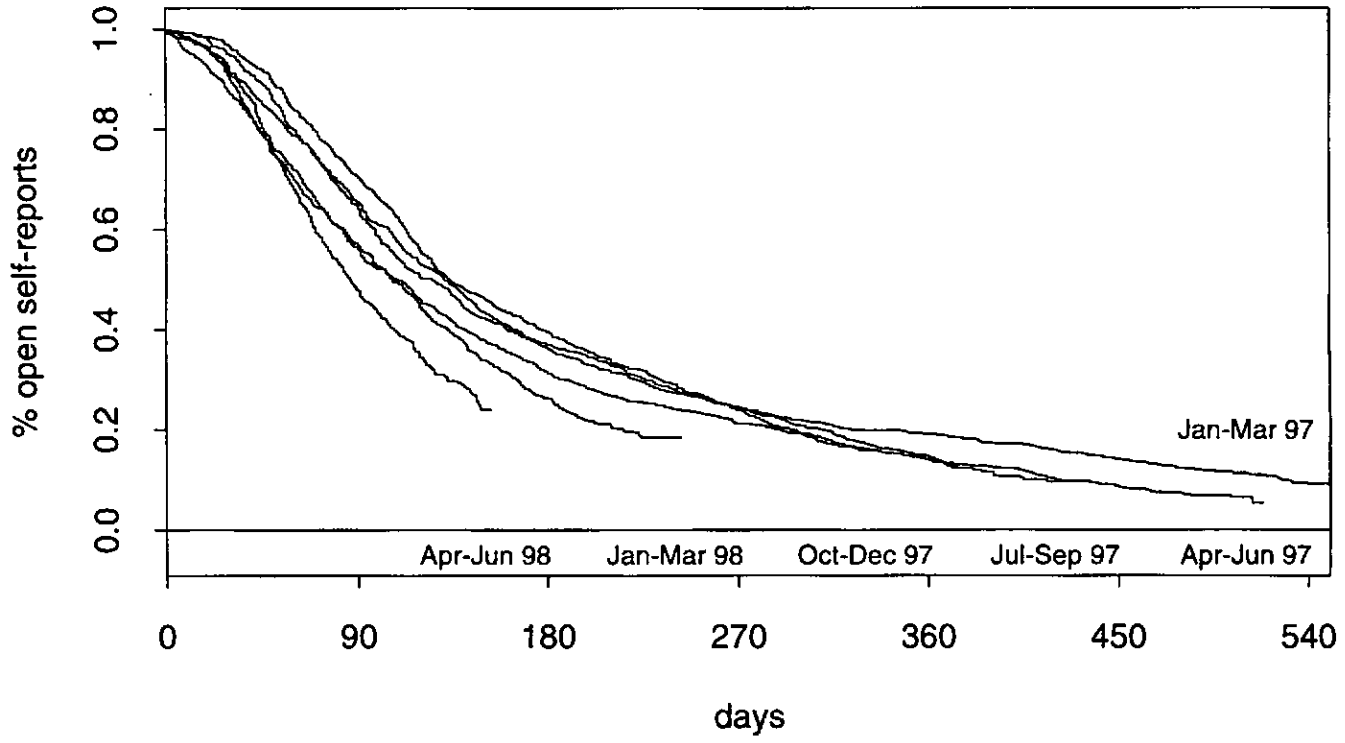


Table 8.2
Timeliness and Completeness of Local Adjudications - OS[1]
Data as of: August 31, 1998

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		91 - 180		>180		Not yet adjudicated	
	N	N	%	N	%	N	%	N	%
<= June 30 1996	233	85	36%	43	18%	93	40%	12	5%
1996 July - December	1298	313	24%	403	31%	507	39%	75	6%
1997 January	282	93	33%	84	30%	83	29%	22	8%
1997 February	236	73	31%	67	28%	69	29%	27	11%
1997 March	317	138	44%	78	25%	78	25%	23	7%
1997 April	489	242	49%	110	22%	107	22%	30	6%
1997 May	351	176	50%	92	26%	58	17%	25	7%
1997 June	464	145	31%	133	29%	141	30%	45	10%
1997 July	360	108	30%	125	35%	80	22%	47	13%
1997 August	362	139	38%	110	30%	82	23%	31	9%
1997 September	376	133	35%	84	22%	98	26%	61	16%
1997 October	463	109	24%	160	35%	114	25%	80	17%
1997 November	334	133	40%	104	31%	45	13%	52	16%
1997 December	367	101	28%	93	25%	56	15%	117	32%
1998 January	407	194	48%	102	25%	34	8%	77	19%
1998 February	365	150	41%	113	31%	16	4%	86	24%
1998 March	440	195	44%	133	30%		0%	112	25%
1998 April	501	242	48%	101	20%		0%	158	32%
1998 May	508	215	42%	56	11%		0%	237	47%
1998 June	550	290	53%		0%		0%	258	47%
1998 July	589	172	29%		0%		0%	417	71%
1998 August	433	25	6%		0%		0%	408	94%
Total	9725	3471	36%	2191	23%	1661	17%	2400	25%

[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.

Thus, the entries below the horizontal lines in the columns ≤ 90 and 91-180 will still improve when more adjudications are entered in the database.

[2]Conditions are self-reported events that require additional documentation.

Table 8.3
Agreement of the Local Adjudications with Self-Reports
Data as of : August 31, 1998

	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	430	311	72%	225	(72%)	54	(17%)	29	(9%)	3	(1%)
Angina[2]	1125	818	73%	369	(45%)	111	(14%)	321	(39%)	17	(2%)
Congestive heart failure	289	191	66%	135	(71%)	21	(11%)	33	(17%)	2	(1%)
CABG/PTCA	839	591	70%	519	(88%)	48	(8%)	19	(3%)	5	(1%)
Carotid artery disease	161	122	76%	94	(77%)	18	(15%)	9	(7%)	1	(1%)
Stroke/TIA[3]	666	463	70%	359	(78%)	23	(5%)	70	(15%)	11	(2%)
PVD	124	90	73%	49	(54%)	16	(18%)	21	(23%)	4	(4%)
DVT[4]	92	72	78%	52	(72%)	7	(10%)	11	(15%)	2	(3%)
PE[4]	37	27	73%	23	(85%)	0	(0%)	4	(15%)	0	(0%)
Cancers											
Breast cancer	1067	722	68%	658	(91%)	0	(0%)	58	(8%)	6	(1%)
Ovary cancer	104	69	66%	46	(67%)	13	(19%)	9	(13%)	1	(1%)
Endometrial cancer	116	88	76%	67	(76%)	14	(16%)	7	(8%)	0	(0%)
Colorectal	251	182	73%	152	(84%)	10	(5%)	16	(9%)	4	(2%)
Other cancer[5]	1148	761	66%	511	(67%)	41	(5%)	180	(24%)	29	(4%)
Fractures											
Hip fracture	189	135	71%	104	(77%)	5	(4%)	22	(16%)	4	(3%)
Vertebral fracture	215	168	78%	88	(52%)	8	(5%)	60	(36%)	12	(7%)
Other fracture	2133	1647	77%	1342	(81%)	11	(1%)	232	(14%)	62	(4%)

[1] Percentages between parentheses are relative to "closed."
[2] Angina that is self-reported after a confirmed MI, is not adjudicated. In particular, 74 self-reports of angina (73 denied related, 1 administrative denial) are associated with participants who have a confirmed MI.
[3] Stroke and TIA have a combined self-report. Only stroke is monitored. There were 132 participants who reported stroke/TIA for whom only TIA was confirmed.
[4] HRT Participants only.
[5] Excludes non-melanoma skin cancer

Table 8.4
Agreement of Central Adjudications with Local Adjudications
Data as of: August 31, 1998

	Locally confirmed N	Centrally adjudicated N	%	In agreement N	%[1]
Cardiovascular					
MI	347	181	52%	164	91%
Angina[2]	749	383	51%	331	86%
Congestive heart failure	303	158	52%	127	80%
CABG/PTCA	581	296	51%	288	97%
DVT[3]	65	38	58%	38	100%
PE[3]	29	18	62%	17	94%
Cancers					
Breast cancer	673	218	32%	213	98%
Invasive	530	162	31%	155	96%
In situ	148	56	38%	43	77%
Ovary cancer	58	22	38%	21	95%
Endometrial cancer	95	34	36%	34	100%
Colorectal	171	64	37%	62	97%
Fractures					
Hip fracture	130	88	68%	83	94%

[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 8.5
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes for Clinical Trial
Data as of: August 31, 1998

	Total	Age								Ethnicity			
		50-54		55-59		60-69		70-79		Minority[1]		White	
No. of participants w/ Form 33	62019	8967		14155		27474		11423		11061		50958	
Mean follow-up (months) [2]	22.3	27.0		23.3		21.2		20.3		21.0		22.6	
Outcomes													
Hospitalizations													
Ever	9237 (8.01%)	1128	(5.59%)	1700	(6.19%)	4181	(8.61%)	2228	(11.52%)	1375	(7.11%)	7862	(8.19%)
Two or more	2941	317		505		1338		781		416		2525	
Cardiovascular	1656 (1.44%)	119	(0.59%)	230	(0.84%)	736	(1.52%)	571	(2.95%)	281	(1.45%)	1375	(1.43%)
Coronary disease[3]	1079 (0.94%)	84	(0.42%)	155	(0.56%)	489	(1.01%)	351	(1.81%)	197	(1.02%)	882	(0.92%)
MI/Stroke/TIA/PE[4]	670 (0.58%)	38	(0.19%)	80	(0.29%)	297	(0.61%)	255	(1.32%)	108	(0.56%)	562	(0.59%)
MI	262 (0.23%)	21	(0.10%)	33	(0.12%)	120	(0.25%)	88	(0.45%)	39	(0.20%)	223	(0.23%)
Angina	623 (0.54%)	55	(0.27%)	89	(0.32%)	277	(0.57%)	202	(1.04%)	125	(0.65%)	498	(0.52%)
Congestive heart failure	148 (0.13%)	9	(0.04%)	19	(0.07%)	64	(0.13%)	56	(0.29%)	30	(0.16%)	118	(0.12%)
CABG/PTCA	453 (0.39%)	25	(0.12%)	63	(0.23%)	211	(0.43%)	154	(0.80%)	60	(0.31%)	393	(0.41%)
Carotid endarterectomy	82 (0.07%)	3	(0.01%)	9	(0.03%)	35	(0.07%)	35	(0.18%)	4	(0.02%)	78	(0.08%)
Stroke/TIA[4]	344 (0.30%)	11	(0.05%)	40	(0.15%)	151	(0.31%)	142	(0.73%)	65	(0.34%)	279	(0.29%)
PVD	55 (0.05%)	6	(0.03%)	15	(0.05%)	23	(0.05%)	11	(0.06%)	8	(0.04%)	47	(0.05%)
DVT	195 (0.17%)	18	(0.09%)	29	(0.11%)	79	(0.16%)	69	(0.36%)	25	(0.13%)	170	(0.18%)
PE	88 (0.08%)	7	(0.03%)	10	(0.04%)	34	(0.07%)	37	(0.19%)	9	(0.05%)	79	(0.08%)
Cancer	1197 (1.04%)	149	(0.74%)	212	(0.77%)	535	(1.10%)	301	(1.56%)	140	(0.72%)	1057	(1.10%)
Breast cancer	433 (0.38%)	55	(0.27%)	96	(0.35%)	191	(0.39%)	91	(0.47%)	50	(0.26%)	383	(0.40%)
Ovary cancer	56 (0.05%)	10	(0.05%)	9	(0.03%)	22	(0.05%)	15	(0.08%)	5	(0.03%)	51	(0.05%)
Endometrial cancer[5]	57 (0.08%)	7	(0.06%)	9	(0.05%)	27	(0.10%)	14	(0.13%)	4	(0.04%)	53	(0.09%)
Colorectal cancer	141 (0.12%)	11	(0.05%)	22	(0.08%)	66	(0.14%)	42	(0.22%)	26	(0.13%)	115	(0.12%)
Other cancer[6,7]	557 (0.48%)	71	(0.35%)	86	(0.31%)	246	(0.51%)	154	(0.80%)	58	(0.30%)	499	(0.52%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, angina, congestive heart failure, and CABG/PTCA.
[4] Stroke and TIA have a combined self-report.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer and hysterectomy.
[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] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

Table 8.5 (continued)
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes for Clinical Trial
Data as of: August 31, 1998

	Total	Age								Ethnicity			
		50-54		55-59		60-69		70-79		Minority[1]		White	
Fractures	2852 (2.47%)	435	(2.16%)	528	(1.92%)	1234	(2.54%)	655	(3.39%)	344	(1.78%)	2508	(2.61%)
Hip fracture	85 (0.07%)	8	(0.04%)	5	(0.02%)	26	(0.05%)	46	(0.24%)	8	(0.04%)	77	(0.08%)
Vertebral fracture	190 (0.16%)	14	(0.07%)	26	(0.09%)	77	(0.16%)	73	(0.38%)	15	(0.08%)	175	(0.18%)
Other fracture [6]	2650 (2.30%)	421	(2.09%)	503	(1.83%)	1159	(2.39%)	567	(2.93%)	327	(1.69%)	2323	(2.42%)
Other													
Diabetes (treated)	2636 (2.29%)	332	(1.65%)	572	(2.08%)	1191	(2.45%)	541	(2.80%)	991	(5.12%)	1645	(1.71%)
Gallbladder disease[8]	1336 (1.16%)	225	(1.12%)	324	(1.18%)	583	(1.20%)	204	(1.05%)	208	(1.08%)	1128	(1.18%)
Hysterectomy [5]	513 (0.76%)	94	(0.81%)	119	(0.70%)	203	(0.73%)	97	(0.90%)	55	(0.57%)	458	(0.80%)
Death	354 (0.31%)	27	(0.13%)	38	(0.14%)	172	(0.35%)	117	(0.60%)	60	(0.31%)	294	(0.31%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, angina, congestive heart failure, and CABG/PTCA.
[4] Stroke and TIA have a combined self-report.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer and hysterectomy.
[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] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

Table 8.6

Counts (Annualized Percentages) of Participants with Self-Reported Outcomes for Hormone Replacement Therapy Component
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
No. of participants w/ Form 33	24649	3324	5213	10720	5392	4662	19987
Mean follow-up (months) [2]	21.2	25.1	21.7	20.8	19.2	20.4	21.4
Outcomes							
Hospitalizations							
Ever	3603 (8.27%)	382 (5.49%)	590 (6.26%)	1652 (8.89%)	979 (11.35%)	579 (7.31%)	3024 (8.48%)
Two or more	1161	108	183	554	316	185	976
Cardiovascular	753 (1.73%)	43 (0.62%)	98 (1.04%)	344 (1.85%)	268 (3.11%)	130 (1.64%)	623 (1.75%)
Coronary disease[3]	490 (1.13%)	29 (0.42%)	67 (0.71%)	227 (1.22%)	167 (1.94%)	93 (1.17%)	397 (1.11%)
MI/Stroke/TIA/PE[4]	334 (0.77%)	15 (0.22%)	33 (0.35%)	148 (0.80%)	138 (1.60%)	48 (0.61%)	286 (0.80%)
MI	141 (0.32%)	8 (0.11%)	14 (0.15%)	68 (0.37%)	51 (0.59%)	18 (0.23%)	123 (0.35%)
Angina	265 (0.61%)	20 (0.29%)	37 (0.39%)	119 (0.64%)	89 (1.03%)	59 (0.74%)	206 (0.58%)
Congestive heart failure	83 (0.19%)	5 (0.07%)	11 (0.12%)	33 (0.18%)	34 (0.39%)	18 (0.23%)	65 (0.18%)
CABG/PTCA	211 (0.48%)	8 (0.11%)	32 (0.34%)	106 (0.57%)	65 (0.75%)	29 (0.37%)	182 (0.51%)
Carotid endarterectomy	36 (0.08%)	1 (0.01%)	5 (0.05%)	15 (0.08%)	15 (0.17%)	2 (0.03%)	34 (0.10%)
Stroke/TIA[4]	165 (0.38%)	5 (0.07%)	16 (0.17%)	70 (0.38%)	74 (0.86%)	28 (0.35%)	137 (0.38%)
PVD	28 (0.06%)	4 (0.06%)	7 (0.07%)	12 (0.06%)	5 (0.06%)	4 (0.05%)	24 (0.07%)
DVT	92 (0.21%)	7 (0.10%)	11 (0.12%)	42 (0.23%)	32 (0.37%)	14 (0.18%)	78 (0.22%)
PE	37 (0.08%)	2 (0.03%)	3 (0.03%)	14 (0.08%)	18 (0.21%)	4 (0.05%)	33 (0.09%)
Cancer	409 (0.94%)	41 (0.59%)	59 (0.63%)	178 (0.96%)	131 (1.52%)	44 (0.56%)	365 (1.02%)
Breast cancer	130 (0.30%)	18 (0.26%)	24 (0.25%)	53 (0.29%)	35 (0.41%)	11 (0.14%)	119 (0.33%)
Ovary cancer	10 (0.02%)	0 (0.00%)	0 (0.00%)	7 (0.04%)	3 (0.03%)	0 (0.00%)	10 (0.03%)
Endometrial cancer[5]	12 (0.05%)	0 (0.00%)	0 (0.00%)	8 (0.07%)	4 (0.08%)	1 (0.03%)	11 (0.05%)
Colorectal cancer	56 (0.13%)	5 (0.07%)	6 (0.06%)	21 (0.11%)	24 (0.28%)	12 (0.15%)	44 (0.12%)
Other cancer[6,7]	218 (0.50%)	19 (0.27%)	32 (0.34%)	98 (0.53%)	69 (0.80%)	22 (0.28%)	196 (0.55%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, angina, congestive heart failure, and CABG/PTCA.
[4] Stroke and TIA have a combined self-report.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer and hysterectomy.
[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] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

Table 8.6 (continued)

Counts (Annualized Percentages) of Participants with Self-Reported Outcomes for Hormone Replacement Therapy Component
Data as of: August 31, 1998

	Total		Age								Ethnicity			
			50-54		55-59		60-69		70-79		Minority[1]		White	
Fractures	1205	(2.77%)	165	(2.37%)	199	(2.11%)	549	(2.95%)	292	(3.38%)	150	(1.89%)	1055	(2.96%)
Hip fracture	35	(0.08%)	2	(0.03%)	1	(0.01%)	10	(0.05%)	22	(0.26%)	3	(0.04%)	32	(0.09%)
Vertebral fracture	81	(0.19%)	4	(0.06%)	14	(0.15%)	33	(0.18%)	30	(0.35%)	7	(0.09%)	74	(0.21%)
Other fracture [6]	1118	(2.57%)	161	(2.31%)	189	(2.00%)	515	(2.77%)	253	(2.93%)	143	(1.80%)	975	(2.74%)
Other														
Diabetes (treated)	1194	(2.74%)	166	(2.39%)	269	(2.85%)	499	(2.69%)	260	(3.01%)	464	(5.85%)	730	(2.05%)
Gallbladder disease[8]	520	(1.19%)	77	(1.11%)	118	(1.25%)	230	(1.24%)	95	(1.10%)	83	(1.05%)	437	(1.23%)
Hysterectomy [5]	126	(0.48%)	16	(0.39%)	16	(0.26%)	58	(0.51%)	36	(0.72%)	13	(0.33%)	113	(0.50%)
Death	162	(0.37%)	10	(0.14%)	15	(0.16%)	77	(0.41%)	60	(0.70%)	27	(0.34%)	135	(0.38%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, angina, congestive heart failure, and CABG/PTCA.
[4] Stroke and TIA have a combined self-report.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer and hysterectomy.
[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] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

Table 8.7
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes for Dietary Modification Component
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
No. of participants w/ Form 33	44817	6814	10671	20043	7289	8003	36814
Mean follow-up (months) [2]	23.0	27.8	24.0	21.5	21.2	21.4	23.4
Outcomes							
Hospitalizations							
Ever	6766 (7.88%)	890 (5.64%)	1316 (6.17%)	3077 (8.57%)	1483 (11.52%)	1003 (7.03%)	5763 (8.03%)
Two or more	2139	250	380	976	533	293	1846
Cardiovascular	1133 (1.32%)	93 (0.59%)	162 (0.76%)	516 (1.44%)	362 (2.81%)	194 (1.36%)	939 (1.31%)
Coronary disease[3]	732 (0.85%)	67 (0.42%)	105 (0.49%)	339 (0.94%)	221 (1.72%)	134 (0.94%)	598 (0.83%)
MI/Stroke/TIA/PE[4]	447 (0.52%)	29 (0.18%)	59 (0.28%)	211 (0.59%)	148 (1.15%)	77 (0.54%)	370 (0.52%)
MI	169 (0.20%)	16 (0.10%)	21 (0.10%)	83 (0.23%)	49 (0.38%)	28 (0.20%)	141 (0.20%)
Angina	438 (0.51%)	43 (0.27%)	63 (0.30%)	198 (0.55%)	134 (1.04%)	84 (0.59%)	354 (0.49%)
Congestive heart failure	84 (0.10%)	7 (0.04%)	10 (0.05%)	39 (0.11%)	28 (0.22%)	20 (0.14%)	64 (0.09%)
CABG/PTCA	295 (0.34%)	20 (0.13%)	37 (0.17%)	139 (0.39%)	99 (0.77%)	37 (0.26%)	258 (0.36%)
Carotid endarterectomy	53 (0.06%)	3 (0.02%)	5 (0.02%)	24 (0.07%)	21 (0.16%)	2 (0.01%)	51 (0.07%)
Stroke/TIA[4]	234 (0.27%)	9 (0.06%)	32 (0.15%)	108 (0.30%)	85 (0.66%)	47 (0.33%)	187 (0.26%)
PVD	35 (0.04%)	3 (0.02%)	10 (0.05%)	16 (0.04%)	6 (0.05%)	5 (0.04%)	30 (0.04%)
DVT	131 (0.15%)	13 (0.08%)	23 (0.11%)	51 (0.14%)	44 (0.34%)	16 (0.11%)	115 (0.16%)
PE	61 (0.07%)	5 (0.03%)	9 (0.04%)	25 (0.07%)	22 (0.17%)	6 (0.04%)	55 (0.08%)
Cancer	926 (1.08%)	123 (0.78%)	179 (0.84%)	420 (1.17%)	204 (1.58%)	112 (0.78%)	814 (1.13%)
Breast cancer	348 (0.41%)	43 (0.27%)	86 (0.40%)	159 (0.44%)	60 (0.47%)	41 (0.29%)	307 (0.43%)
Ovary cancer	48 (0.06%)	10 (0.06%)	9 (0.04%)	16 (0.04%)	13 (0.10%)	5 (0.04%)	43 (0.06%)
Endometrial cancer[5]	48 (0.10%)	7 (0.08%)	9 (0.07%)	20 (0.10%)	12 (0.17%)	3 (0.04%)	45 (0.11%)
Colorectal cancer	106 (0.12%)	8 (0.05%)	18 (0.08%)	54 (0.15%)	26 (0.20%)	20 (0.14%)	86 (0.12%)
Other cancer[6,7]	410 (0.48%)	59 (0.37%)	66 (0.31%)	181 (0.50%)	104 (0.81%)	44 (0.31%)	366 (0.51%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, angina, congestive heart failure, and CABG/PTCA.
[4] Stroke and TIA have a combined self-report.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer and hysterectomy.
[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] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

Table 8.7 (continued)
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes for Dietary Modification Component
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
Fractures	2024 (2.36%)	336 (2.13%)	396 (1.86%)	858 (2.39%)	434 (3.37%)	246 (1.72%)	1778 (2.48%)
Hip fracture	57 (0.07%)	6 (0.04%)	4 (0.02%)	20 (0.06%)	27 (0.21%)	6 (0.04%)	51 (0.07%)
Vertebral fracture	132 (0.15%)	12 (0.08%)	16 (0.07%)	52 (0.14%)	52 (0.40%)	11 (0.08%)	121 (0.17%)
Other fracture [6]	1885 (2.19%)	324 (2.05%)	377 (1.77%)	808 (2.25%)	376 (2.92%)	233 (1.63%)	1652 (2.30%)
Other							
Diabetes (treated)	1840 (2.14%)	218 (1.38%)	403 (1.89%)	867 (2.41%)	352 (2.73%)	694 (4.86%)	1146 (1.60%)
Gallbladder disease[8]	987 (1.15%)	175 (1.11%)	251 (1.18%)	429 (1.19%)	132 (1.03%)	151 (1.06%)	836 (1.16%)
Hysterectomy [5]	422 (0.87%)	83 (0.92%)	106 (0.82%)	160 (0.80%)	73 (1.05%)	43 (0.61%)	379 (0.91%)
Death	239 (0.28%)	21 (0.13%)	27 (0.13%)	118 (0.33%)	73 (0.57%)	37 (0.26%)	202 (0.28%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, angina, congestive heart failure, and CABG/PTCA.
[4] Stroke and TIA have a combined self-report.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer and hysterectomy.
[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] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

Table 8.8
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes for Calcium and Vitamin D Component
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
No. of participants w/ Form 33	16025	3290	4097	6374	2264	2399	13626
Mean follow-up (months) [2]	14.0	13.8	13.7	14.3	13.8	12.7	14.2
Outcomes							
Hospitalizations							
Ever	2442 (13.11%)	349 (9.22%)	493 (10.54%)	1078 (14.19%)	522 (20.05%)	323 (12.72%)	2119 (13.14%)
Two or more	605	79	107	270	149	78	527
Cardiovascular	417 (2.24%)	33 (0.87%)	68 (1.45%)	185 (2.44%)	131 (5.03%)	64 (2.52%)	353 (2.19%)
Coronary disease[3]	288 (1.55%)	26 (0.69%)	45 (0.96%)	126 (1.66%)	91 (3.50%)	45 (1.77%)	243 (1.51%)
MI/Stroke/TIA/PE[4]	164 (0.88%)	10 (0.26%)	23 (0.49%)	76 (1.00%)	55 (2.11%)	21 (0.83%)	143 (0.89%)
MI	67 (0.36%)	6 (0.16%)	6 (0.13%)	30 (0.39%)	25 (0.96%)	5 (0.20%)	62 (0.38%)
Angina	166 (0.89%)	16 (0.42%)	27 (0.58%)	75 (0.99%)	48 (1.84%)	31 (1.22%)	135 (0.84%)
Congestive heart failure	44 (0.24%)	3 (0.08%)	7 (0.15%)	20 (0.26%)	14 (0.54%)	8 (0.32%)	36 (0.22%)
CABG/PTCA	111 (0.60%)	10 (0.26%)	15 (0.32%)	45 (0.59%)	41 (1.57%)	12 (0.47%)	99 (0.61%)
Carotid endarterectomy	13 (0.07%)	1 (0.03%)	0 (0.00%)	4 (0.05%)	8 (0.31%)	1 (0.04%)	12 (0.07%)
Stroke/TIA[4]	88 (0.47%)	2 (0.05%)	15 (0.32%)	45 (0.59%)	26 (1.00%)	15 (0.59%)	73 (0.45%)
PVD	9 (0.05%)	0 (0.00%)	1 (0.02%)	4 (0.05%)	4 (0.15%)	1 (0.04%)	8 (0.05%)
DVT	42 (0.23%)	3 (0.08%)	8 (0.17%)	13 (0.17%)	18 (0.69%)	3 (0.12%)	39 (0.24%)
PE	14 (0.08%)	2 (0.05%)	2 (0.04%)	4 (0.05%)	6 (0.23%)	2 (0.08%)	12 (0.07%)
Cancer	355 (1.91%)	55 (1.45%)	76 (1.62%)	159 (2.09%)	65 (2.50%)	40 (1.58%)	315 (1.95%)
Breast cancer	145 (0.78%)	20 (0.53%)	40 (0.86%)	63 (0.83%)	22 (0.84%)	17 (0.67%)	128 (0.79%)
Ovary cancer	12 (0.06%)	3 (0.08%)	3 (0.06%)	5 (0.07%)	1 (0.04%)	1 (0.04%)	11 (0.07%)
Endometrial cancer[5]	15 (0.14%)	0 (0.00%)	3 (0.11%)	12 (0.27%)	0 (0.00%)	1 (0.08%)	14 (0.14%)
Colorectal cancer	45 (0.24%)	7 (0.19%)	8 (0.17%)	19 (0.25%)	11 (0.42%)	7 (0.28%)	38 (0.24%)
Other cancer[6,7]	151 (0.81%)	25 (0.66%)	28 (0.60%)	65 (0.86%)	33 (1.27%)	14 (0.55%)	137 (0.85%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from CaD enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, angina, congestive heart failure, and CABG/PTCA.
[4] Stroke and TIA have a combined self-report.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer and hysterectomy.
[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] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

Table 8.8 (continued)
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes for Calcium and Vitamin D Component
Data as of: August 31, 1998

	Total		Age								Ethnicity			
			50-54		55-59		60-69		70-79		Minority[1]		White	
Fractures	759	(4.07%)	139	(3.67%)	161	(3.44%)	309	(4.07%)	150	(5.76%)	88	(3.47%)	671	(4.16%)
Hip fracture	20	(0.11%)	3	(0.08%)	1	(0.02%)	7	(0.09%)	9	(0.35%)	2	(0.08%)	18	(0.11%)
Vertebral fracture	46	(0.25%)	4	(0.11%)	8	(0.17%)	17	(0.22%)	17	(0.65%)	4	(0.16%)	42	(0.26%)
Other fracture [6]	712	(3.82%)	135	(3.57%)	153	(3.27%)	294	(3.87%)	130	(4.99%)	84	(3.31%)	628	(3.89%)
Other														
Diabetes (treated)	751	(4.03%)	136	(3.59%)	172	(3.68%)	307	(4.04%)	136	(5.22%)	255	(10.04%)	496	(3.08%)
Gallbladder disease[8]	371	(1.99%)	69	(1.82%)	103	(2.20%)	155	(2.04%)	44	(1.69%)	55	(2.17%)	316	(1.96%)
Hysterectomy [5]	142	(1.30%)	33	(1.51%)	32	(1.12%)	60	(1.34%)	17	(1.18%)	17	(1.41%)	125	(1.28%)
Death	72	(0.39%)	4	(0.11%)	9	(0.19%)	34	(0.45%)	25	(0.96%)	10	(0.39%)	62	(0.38%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from CaD enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, angina, congestive heart failure, and CABG/PTCA.
[4] Stroke and TIA have a combined self-report.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer and hysterectomy.
[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] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

Table 8.9
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes for Observational Study
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
No. of participants w/ Form 33	63810	9853	13098	25992	14867	9021	54789
Mean follow-up (months) [2]	21.3	22.1	21.6	21.3	20.7	20.6	21.4
Outcomes							
Hospitalizations							
Ever	7891 (6.97%)	873 (4.81%)	1174 (4.98%)	3339 (7.24%)	2505 (9.77%)	946 (6.11%)	6945 (7.11%)
Two or more	2049	201	262	867	719	251	1798
Cardiovascular	1408 (1.24%)	94 (0.52%)	153 (0.65%)	587 (1.27%)	574 (2.24%)	185 (1.19%)	1223 (1.25%)
Coronary disease[3]	903 (0.80%)	62 (0.34%)	104 (0.44%)	396 (0.86%)	341 (1.33%)	119 (0.77%)	784 (0.80%)
MI/Stroke/TIA/PE[4]	532 (0.47%)	36 (0.20%)	55 (0.23%)	206 (0.45%)	235 (0.92%)	75 (0.48%)	457 (0.47%)
MI	168 (0.15%)	12 (0.07%)	15 (0.06%)	71 (0.15%)	70 (0.27%)	21 (0.14%)	147 (0.15%)
Angina	502 (0.44%)	42 (0.23%)	72 (0.31%)	215 (0.47%)	173 (0.67%)	66 (0.43%)	436 (0.45%)
Congestive heart failure	141 (0.12%)	8 (0.04%)	13 (0.06%)	58 (0.13%)	62 (0.24%)	20 (0.13%)	121 (0.12%)
CABG/PTCA	386 (0.34%)	19 (0.10%)	36 (0.15%)	181 (0.39%)	150 (0.58%)	41 (0.26%)	345 (0.35%)
Carotid endarterectomy	79 (0.07%)	5 (0.03%)	9 (0.04%)	27 (0.06%)	38 (0.15%)	10 (0.06%)	69 (0.07%)
Stroke/TIA[4]	322 (0.28%)	16 (0.09%)	32 (0.14%)	118 (0.26%)	156 (0.61%)	54 (0.35%)	268 (0.27%)
PVD	65 (0.06%)	5 (0.03%)	6 (0.03%)	24 (0.05%)	30 (0.12%)	7 (0.05%)	58 (0.06%)
DVT	117 (0.10%)	9 (0.05%)	12 (0.05%)	49 (0.11%)	47 (0.18%)	9 (0.06%)	108 (0.11%)
PE	58 (0.05%)	8 (0.04%)	8 (0.03%)	25 (0.05%)	17 (0.07%)	2 (0.01%)	56 (0.06%)
Cancer	1388 (1.23%)	164 (0.90%)	214 (0.91%)	602 (1.30%)	408 (1.59%)	146 (0.94%)	1242 (1.27%)
Breast cancer	636 (0.56%)	84 (0.46%)	111 (0.47%)	281 (0.61%)	160 (0.62%)	79 (0.51%)	557 (0.57%)
Ovary cancer	48 (0.04%)	7 (0.04%)	12 (0.05%)	20 (0.04%)	9 (0.04%)	5 (0.03%)	43 (0.04%)
Endometrial cancer[5]	59 (0.09%)	6 (0.06%)	9 (0.06%)	32 (0.12%)	12 (0.08%)	7 (0.09%)	52 (0.09%)
Colorectal cancer	110 (0.10%)	5 (0.03%)	14 (0.06%)	37 (0.08%)	54 (0.21%)	19 (0.12%)	91 (0.09%)
Other cancer[6,7]	592 (0.52%)	65 (0.36%)	85 (0.36%)	256 (0.55%)	186 (0.73%)	43 (0.28%)	549 (0.56%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, angina, congestive heart failure, and CABG/PTCA.
[4] Stroke and TIA have a combined self-report.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer and hysterectomy.
[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] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

Table 8.9 (continued)
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes for Observational Study
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
Fractures	2600 (2.30%)	340 (1.87%)	472 (2.00%)	1067 (2.31%)	721 (2.81%)	230 (1.49%)	2370 (2.43%)
Hip fracture	104 (0.09%)	2 (0.01%)	13 (0.06%)	37 (0.08%)	52 (0.20%)	7 (0.05%)	97 (0.10%)
Vertebral fracture	193 (0.17%)	16 (0.09%)	19 (0.08%)	75 (0.16%)	83 (0.32%)	8 (0.05%)	185 (0.19%)
Other fracture [6]	2355 (2.08%)	327 (1.80%)	444 (1.88%)	975 (2.11%)	609 (2.37%)	218 (1.41%)	2137 (2.19%)
Other							
Diabetes (treated)	2271 (2.01%)	241 (1.33%)	393 (1.67%)	1016 (2.20%)	621 (2.42%)	723 (4.67%)	1548 (1.58%)
Gallbladder disease[8]	1197 (1.06%)	198 (1.09%)	246 (1.04%)	507 (1.10%)	246 (0.96%)	170 (1.10%)	1027 (1.05%)
Hysterectomy [5]	658 (0.99%)	126 (1.16%)	121 (0.82%)	278 (1.03%)	133 (0.92%)	95 (1.16%)	563 (0.96%)
Death	353 (0.31%)	19 (0.10%)	33 (0.14%)	137 (0.30%)	164 (0.64%)	47 (0.30%)	306 (0.31%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, angina, congestive heart failure, and CABG/PTCA.
[4] Stroke and TIA have a combined self-report.
[5] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer and hysterectomy.
[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] "Gallbladder disease" includes self-reports of both hospitalized and non-hospitalized events.

Table 8.10
Counts (Annualized Percentages) of Participants with Locally Verified Outcomes for Clinical Trial
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
No. of participants w/ Form 33	62019	8967	14155	27474	11423	11061	50958
Mean follow-up (months) [2]	22.3	27.0	23.3	21.2	20.3	21.0	22.6
Outcomes							
Cardiovascular	1048 (0.91%)	59 (0.29%)	132 (0.48%)	485 (1.00%)	372 (1.92%)	134 (0.69%)	914 (0.95%)
Coronary Disease[3]	724 (0.63%)	44 (0.22%)	100 (0.36%)	336 (0.69%)	244 (1.26%)	97 (0.50%)	627 (0.65%)
CHD[4]/Stroke/PE	449 (0.39%)	28 (0.14%)	47 (0.17%)	203 (0.42%)	171 (0.88%)	50 (0.26%)	399 (0.42%)
CHD[4]	257 (0.22%)	20 (0.10%)	32 (0.12%)	115 (0.24%)	90 (0.47%)	26 (0.13%)	231 (0.24%)
MI	228 (0.20%)	19 (0.09%)	30 (0.11%)	105 (0.22%)	74 (0.38%)	23 (0.12%)	205 (0.21%)
Coronary death	42 (0.04%)	1 (0.00%)	3 (0.01%)	17 (0.04%)	21 (0.11%)	6 (0.03%)	36 (0.04%)
Angina	399 (0.35%)	26 (0.13%)	64 (0.23%)	187 (0.39%)	122 (0.63%)	58 (0.30%)	341 (0.36%)
Congestive heart failure	146 (0.13%)	5 (0.02%)	15 (0.05%)	64 (0.13%)	62 (0.32%)	20 (0.10%)	126 (0.13%)
CABG/PTCA	331 (0.29%)	18 (0.09%)	52 (0.19%)	152 (0.31%)	109 (0.56%)	36 (0.19%)	295 (0.31%)
Carotid artery disease	85 (0.07%)	4 (0.02%)	11 (0.04%)	34 (0.07%)	36 (0.19%)	8 (0.04%)	77 (0.08%)
Stroke	168 (0.15%)	7 (0.03%)	14 (0.05%)	79 (0.16%)	68 (0.35%)	20 (0.10%)	148 (0.15%)
PVD	48 (0.04%)	3 (0.01%)	9 (0.03%)	19 (0.04%)	17 (0.09%)	9 (0.05%)	39 (0.04%)
DVT	71 (0.06%)	4 (0.02%)	5 (0.02%)	34 (0.07%)	28 (0.14%)	7 (0.04%)	64 (0.07%)
PE	33 (0.03%)	1 (0.00%)	3 (0.01%)	12 (0.02%)	17 (0.09%)	5 (0.03%)	28 (0.03%)
Cancer	804 (0.70%)	92 (0.46%)	139 (0.51%)	370 (0.76%)	203 (1.05%)	85 (0.44%)	719 (0.75%)
Breast cancer [5]	311 (0.27%)	38 (0.19%)	63 (0.23%)	141 (0.29%)	69 (0.36%)	29 (0.15%)	282 (0.29%)
Invasive breast cancer	242 (0.21%)	28 (0.14%)	48 (0.17%)	112 (0.23%)	54 (0.28%)	24 (0.12%)	218 (0.23%)
In situ breast cancer	73 (0.06%)	11 (0.05%)	15 (0.05%)	30 (0.06%)	17 (0.09%)	5 (0.03%)	68 (0.07%)
Ovary cancer	34 (0.03%)	4 (0.02%)	8 (0.03%)	14 (0.03%)	8 (0.04%)	3 (0.02%)	31 (0.03%)
Endometrial cancer [6]	48 (0.07%)	7 (0.06%)	9 (0.05%)	20 (0.07%)	12 (0.11%)	6 (0.06%)	42 (0.07%)
Colorectal cancer	98 (0.09%)	5 (0.02%)	14 (0.05%)	50 (0.10%)	29 (0.15%)	18 (0.09%)	80 (0.08%)
Other cancer [7,8]	321 (0.28%)	38 (0.19%)	49 (0.18%)	149 (0.31%)	85 (0.44%)	30 (0.16%)	291 (0.30%)

(continues)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, Coronary death, angina,congestive heart failure, and CABG/PTCA.
[4] "CHD" includes MI and coronary death.
[5] Excludes three cases with borderline malignancy.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated.
[8] Excludes non-melanoma skin cancer
[9] "Other fracture" excludes fractures indicated as pathological.

Table 8.10 (continued)
Counts (Annualized Percentages) of Participants with Locally Verified Outcomes for Clinical Trial
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
Fractures	1409 (1.22%)	198 (0.98%)	242 (0.88%)	633 (1.30%)	336 (1.74%)	125 (0.65%)	1284 (1.34%)
Hip fracture	59 (0.05%)	4 (0.02%)	3 (0.01%)	18 (0.04%)	34 (0.18%)	2 (0.01%)	57 (0.06%)
Vertebral fracture	91 (0.08%)	5 (0.02%)	8 (0.03%)	41 (0.08%)	37 (0.19%)	3 (0.02%)	88 (0.09%)
Other fracture [7,9]	1288 (1.12%)	191 (0.95%)	234 (0.85%)	586 (1.21%)	277 (1.43%)	121 (0.63%)	1167 (1.22%)
Other							
Death	354 (0.31%)	27 (0.13%)	38 (0.14%)	172 (0.35%)	117 (0.60%)	60 (0.31%)	294 (0.31%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, Coronary death, angina,congestive heart failure, and CABG/PTCA.
[4] "CHD" includes MI and coronary death.
[5] Excludes three cases with borderline malignancy.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated.
[8] Excludes non-melanoma skin cancer
[9] "Other fracture" excludes fractures indicated as pathological.

Table 8.11
Counts (Annualized Percentages) of Participants with Locally Verified Outcomes for Hormone Replacement Therapy Component
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
No. of participants w/ Form 33	24649	3324	5213	10720	5392	4662	19987
Mean follow-up (months) [2]	21.2	25.1	21.7	20.8	19.2	20.4	21.4
Outcomes							
Cardiovascular	516 (1.18%)	22 (0.32%)	58 (0.62%)	246 (1.32%)	190 (2.20%)	66 (0.83%)	450 (1.26%)
Coronary Disease[3]	326 (0.75%)	14 (0.20%)	41 (0.43%)	157 (0.84%)	114 (1.32%)	43 (0.54%)	283 (0.79%)
CHD[4]/Stroke/PE	225 (0.52%)	13 (0.19%)	22 (0.23%)	102 (0.55%)	88 (1.02%)	29 (0.37%)	196 (0.55%)
CHD[4]	118 (0.27%)	9 (0.13%)	14 (0.15%)	56 (0.30%)	39 (0.45%)	14 (0.18%)	104 (0.29%)
MI	104 (0.24%)	8 (0.11%)	12 (0.13%)	52 (0.28%)	32 (0.37%)	11 (0.14%)	93 (0.26%)
Coronary death	22 (0.05%)	1 (0.01%)	2 (0.02%)	10 (0.05%)	9 (0.10%)	6 (0.08%)	16 (0.04%)
Angina	166 (0.38%)	4 (0.06%)	28 (0.30%)	82 (0.44%)	52 (0.60%)	21 (0.26%)	145 (0.41%)
Congestive heart failure	73 (0.17%)	2 (0.03%)	7 (0.07%)	31 (0.17%)	33 (0.38%)	12 (0.15%)	61 (0.17%)
CABG/PTCA	142 (0.33%)	4 (0.06%)	25 (0.27%)	70 (0.38%)	43 (0.50%)	15 (0.19%)	127 (0.36%)
Carotid artery disease	41 (0.09%)	1 (0.01%)	6 (0.06%)	16 (0.09%)	18 (0.21%)	2 (0.03%)	39 (0.11%)
Stroke	81 (0.19%)	3 (0.04%)	6 (0.06%)	36 (0.19%)	36 (0.42%)	12 (0.15%)	69 (0.19%)
PVD	22 (0.05%)	2 (0.03%)	4 (0.04%)	11 (0.06%)	5 (0.06%)	5 (0.06%)	17 (0.05%)
DVT	65 (0.15%)	3 (0.04%)	5 (0.05%)	32 (0.17%)	25 (0.29%)	6 (0.08%)	59 (0.17%)
PE	29 (0.07%)	1 (0.01%)	3 (0.03%)	11 (0.06%)	14 (0.16%)	4 (0.05%)	25 (0.07%)
Cancer	274 (0.63%)	25 (0.36%)	33 (0.35%)	127 (0.68%)	89 (1.03%)	28 (0.35%)	246 (0.69%)
Breast cancer [5]	91 (0.21%)	11 (0.16%)	15 (0.16%)	40 (0.22%)	25 (0.29%)	7 (0.09%)	84 (0.24%)
Invasive breast cancer	69 (0.16%)	9 (0.13%)	12 (0.13%)	29 (0.16%)	19 (0.22%)	6 (0.08%)	63 (0.18%)
In situ breast cancer	22 (0.05%)	2 (0.03%)	3 (0.03%)	11 (0.06%)	6 (0.07%)	1 (0.01%)	21 (0.06%)
Ovary cancer	8 (0.02%)	0 (0.00%)	0 (0.00%)	7 (0.04%)	1 (0.01%)	0 (0.00%)	8 (0.02%)
Endometrial cancer [6]	8 (0.03%)	0 (0.00%)	0 (0.00%)	4 (0.04%)	4 (0.08%)	1 (0.03%)	7 (0.03%)
Colorectal cancer	39 (0.09%)	1 (0.01%)	3 (0.03%)	18 (0.10%)	17 (0.20%)	8 (0.10%)	31 (0.09%)
Other cancer [7,8]	130 (0.30%)	13 (0.19%)	15 (0.16%)	60 (0.32%)	42 (0.49%)	12 (0.15%)	118 (0.33%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, Coronary death, angina,congestive heart failure, and CABG/PTCA.
[4] "CHD" includes MI and coronary death.
[5] Excludes one case with borderline malignancy.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated.
[8] Excludes non-melanoma skin cancer
[9] "Other fracture" excludes fractures indicated as pathological.
[10] All deaths except those from breast, colorectal, or endometrial cancer, or cardiovascular disease. Includes deaths which are not yet adjudicated.

Table 8.11 (continued)
Counts (Annualized Percentages) of Participants with Locally Verified Outcomes for Hormone Replacement Therapy Component
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
Fractures	608 (1.40%)	78 (1.12%)	89 (0.94%)	297 (1.60%)	144 (1.67%)	53 (0.67%)	555 (1.56%)
Hip fracture	28 (0.06%)	2 (0.03%)	0 (0.00%)	9 (0.05%)	17 (0.20%)	1 (0.01%)	27 (0.08%)
Vertebral fracture	37 (0.08%)	1 (0.01%)	6 (0.06%)	16 (0.09%)	14 (0.16%)	0 (0.00%)	37 (0.10%)
Other fracture [7,9]	554 (1.27%)	76 (1.09%)	85 (0.90%)	273 (1.47%)	120 (1.39%)	52 (0.66%)	502 (1.41%)
Other							
Hysterectomies	129 (0.49%)	17 (0.41%)	17 (0.28%)	58 (0.51%)	37 (0.74%)	15 (0.38%)	114 (0.50%)
Death other causes – HRT[10]	135 (0.31%)	9 (0.13%)	13 (0.14%)	62 (0.33%)	51 (0.59%)	21 (0.26%)	114 (0.32%)
Death	162 (0.37%)	10 (0.14%)	15 (0.16%)	77 (0.41%)	60 (0.70%)	27 (0.34%)	135 (0.38%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, Coronary death, angina,congestive heart failure, and CABG/PTCA.
[4] "CHD" includes MI and coronary death.
[5] Excludes one case with borderline malignancy.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated.
[8] Excludes non-melanoma skin cancer
[9] "Other fracture" excludes fractures indicated as pathological.
[10] All deaths except those from breast, colorectal, or endometrial cancer, or cardiovascular disease. Includes deaths which are not yet adjudicated.

Table 8.12
Counts (Annualized Percentages) of Participants with Locally Verified Outcomes for Dietary Modification Component
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
No. of participants w/ Form 33	44817	6814	10671	20043	7289	8003	36814
Mean follow-up (months) [2]	23.0	27.8	24.0	21.5	21.2	21.4	23.4
Outcomes							
Cardiovascular	683 (0.80%)	44 (0.28%)	85 (0.40%)	330 (0.92%)	224 (1.74%)	89 (0.62%)	594 (0.83%)
Coronary Disease[3]	490 (0.57%)	35 (0.22%)	65 (0.30%)	234 (0.65%)	156 (1.21%)	69 (0.48%)	421 (0.59%)
CHD[4]/Stroke/PE	295 (0.34%)	18 (0.11%)	32 (0.15%)	144 (0.40%)	101 (0.78%)	28 (0.20%)	267 (0.37%)
CHD[4]	176 (0.20%)	12 (0.08%)	22 (0.10%)	81 (0.23%)	61 (0.47%)	15 (0.11%)	161 (0.22%)
MI	156 (0.18%)	12 (0.08%)	21 (0.10%)	74 (0.21%)	49 (0.38%)	15 (0.11%)	141 (0.20%)
Coronary death	27 (0.03%)	0 (0.00%)	2 (0.01%)	10 (0.03%)	15 (0.12%)	1 (0.01%)	26 (0.04%)
Angina	278 (0.32%)	23 (0.15%)	38 (0.18%)	135 (0.38%)	82 (0.64%)	45 (0.32%)	233 (0.32%)
Congestive heart failure	95 (0.11%)	5 (0.03%)	9 (0.04%)	44 (0.12%)	37 (0.29%)	15 (0.11%)	80 (0.11%)
CABG/PTCA	222 (0.26%)	16 (0.10%)	31 (0.15%)	102 (0.28%)	73 (0.57%)	25 (0.18%)	197 (0.27%)
Carotid artery disease	53 (0.06%)	4 (0.03%)	5 (0.02%)	24 (0.07%)	20 (0.16%)	6 (0.04%)	47 (0.07%)
Stroke	113 (0.13%)	6 (0.04%)	11 (0.05%)	60 (0.17%)	36 (0.28%)	11 (0.08%)	102 (0.14%)
PVD	34 (0.04%)	1 (0.01%)	7 (0.03%)	12 (0.03%)	14 (0.11%)	5 (0.04%)	29 (0.04%)
Cancer	622 (0.72%)	75 (0.48%)	121 (0.57%)	288 (0.80%)	138 (1.07%)	67 (0.47%)	555 (0.77%)
Breast cancer [5]	251 (0.29%)	29 (0.18%)	56 (0.26%)	118 (0.33%)	48 (0.37%)	24 (0.17%)	227 (0.32%)
Invasive breast cancer	197 (0.23%)	20 (0.13%)	42 (0.20%)	97 (0.27%)	38 (0.30%)	20 (0.14%)	177 (0.25%)
In situ breast cancer	58 (0.07%)	10 (0.06%)	14 (0.07%)	22 (0.06%)	12 (0.09%)	4 (0.03%)	54 (0.08%)
Ovary cancer	26 (0.03%)	4 (0.03%)	8 (0.04%)	7 (0.02%)	7 (0.05%)	3 (0.02%)	23 (0.03%)
Endometrial cancer [6]	43 (0.09%)	7 (0.08%)	9 (0.07%)	16 (0.08%)	11 (0.16%)	5 (0.07%)	38 (0.09%)
Colorectal cancer	73 (0.08%)	4 (0.03%)	13 (0.06%)	38 (0.11%)	18 (0.14%)	13 (0.09%)	60 (0.08%)
Other cancer [7,8]	236 (0.27%)	31 (0.20%)	39 (0.18%)	112 (0.31%)	54 (0.42%)	23 (0.16%)	213 (0.30%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, Coronary death, angina,congestive heart failure, and CABG/PTCA.
[4] "CHD" includes MI and coronary death.
[5] Excludes two cases with borderline malignancy.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated.
[8] Excludes non-melanoma skin cancer
[9] "Other fracture" excludes fractures indicated as pathological.
[10] All deaths except those from breast or colorectal cancer, or cardiovascular disease. Includes deaths which are not yet adjudicated.

Table 8.12 (continued)
Counts (Annualized Percentages) of Participants with Locally Verified Outcomes for Dietary Modification Component
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
Fractures	972 (1.13%)	148 (0.94%)	182 (0.85%)	427 (1.19%)	215 (1.67%)	85 (0.60%)	887 (1.24%)
Hip fracture	37 (0.04%)	2 (0.01%)	3 (0.01%)	11 (0.03%)	21 (0.16%)	1 (0.01%)	36 (0.05%)
Vertebral fracture	63 (0.07%)	5 (0.03%)	5 (0.02%)	28 (0.08%)	25 (0.19%)	3 (0.02%)	60 (0.08%)
Other fracture [7,9]	892 (1.04%)	142 (0.90%)	175 (0.82%)	399 (1.11%)	176 (1.37%)	82 (0.57%)	810 (1.13%)
Other							
Death other causes – DM[10]	205 (0.24%)	20 (0.13%)	23 (0.11%)	104 (0.29%)	58 (0.45%)	35 (0.25%)	170 (0.24%)
Death	239 (0.28%)	21 (0.13%)	27 (0.13%)	118 (0.33%)	73 (0.57%)	37 (0.26%)	202 (0.28%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, Coronary death, angina,congestive heart failure, and CABG/PTCA.
[4] "CHD" includes MI and coronary death.
[5] Excludes two cases with borderline malignancy.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated. Excludes non-melanoma skin cancer.
[8] Excludes non-melanoma skin cancer
[9] "Other fracture" excludes fractures indicated as pathological.
[10] All deaths except those from breast or colorectal cancer, or cardiovascular disease. Includes deaths which are not yet adjudicated.

Table 8.13
Counts (Annualized Percentages) of Participants with Locally Verified Outcomes for Calcium and Vitamin D Component
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
No. of participants w/ Form 33	16025	3290	4097	6374	2264	2399	13626
Mean follow-up (months) [2]	14.0	13.8	13.7	14.3	13.8	12.7	14.2
Outcomes							
Cardiovascular	233 (1.25%)	15 (0.40%)	30 (0.64%)	108 (1.42%)	80 (3.07%)	16 (0.63%)	217 (1.35%)
Coronary Disease[3]	169 (0.91%)	12 (0.32%)	22 (0.47%)	74 (0.97%)	61 (2.34%)	10 (0.39%)	159 (0.99%)
CHD[4]/Stroke/PE	97 (0.52%)	7 (0.19%)	12 (0.26%)	48 (0.63%)	30 (1.15%)	6 (0.24%)	91 (0.56%)
CHD[4]	58 (0.31%)	5 (0.13%)	7 (0.15%)	27 (0.36%)	19 (0.73%)	2 (0.08%)	56 (0.35%)
MI	52 (0.28%)	5 (0.13%)	7 (0.15%)	25 (0.33%)	15 (0.58%)	1 (0.04%)	51 (0.32%)
Coronary death	8 (0.04%)	0 (0.00%)	0 (0.00%)	3 (0.04%)	5 (0.19%)	1 (0.04%)	7 (0.04%)
Angina	97 (0.52%)	9 (0.24%)	13 (0.28%)	41 (0.54%)	34 (1.31%)	5 (0.20%)	92 (0.57%)
Congestive heart failure	33 (0.18%)	1 (0.03%)	5 (0.11%)	14 (0.18%)	13 (0.50%)	3 (0.12%)	30 (0.19%)
CABG/PTCA	71 (0.38%)	6 (0.16%)	9 (0.19%)	30 (0.39%)	26 (1.00%)	3 (0.12%)	68 (0.42%)
Carotid artery disease	19 (0.10%)	1 (0.03%)	2 (0.04%)	7 (0.09%)	9 (0.35%)	2 (0.08%)	17 (0.11%)
Stroke	38 (0.20%)	2 (0.05%)	6 (0.13%)	18 (0.24%)	12 (0.46%)	3 (0.12%)	35 (0.22%)
PVD	9 (0.05%)	0 (0.00%)	0 (0.00%)	2 (0.03%)	7 (0.27%)	2 (0.08%)	7 (0.04%)
Cancer	225 (1.21%)	31 (0.82%)	48 (1.03%)	109 (1.44%)	37 (1.42%)	20 (0.79%)	205 (1.27%)
Breast cancer [5]	102 (0.55%)	15 (0.40%)	26 (0.56%)	46 (0.61%)	15 (0.58%)	9 (0.35%)	93 (0.58%)
Invasive breast cancer	78 (0.42%)	13 (0.34%)	20 (0.43%)	35 (0.46%)	10 (0.38%)	9 (0.35%)	69 (0.43%)
In situ breast cancer	24 (0.13%)	2 (0.05%)	6 (0.13%)	11 (0.14%)	5 (0.19%)	0 (0.00%)	24 (0.15%)
Ovary cancer	11 (0.06%)	1 (0.03%)	2 (0.04%)	6 (0.08%)	2 (0.08%)	1 (0.04%)	10 (0.06%)
Endometrial cancer [6]	13 (0.12%)	1 (0.05%)	3 (0.11%)	8 (0.18%)	1 (0.07%)	1 (0.08%)	12 (0.12%)
Colorectal cancer	26 (0.14%)	2 (0.05%)	5 (0.11%)	13 (0.17%)	6 (0.23%)	3 (0.12%)	23 (0.14%)
Other cancer [7,8]	76 (0.41%)	12 (0.32%)	13 (0.28%)	38 (0.50%)	13 (0.50%)	6 (0.24%)	70 (0.43%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from CaD enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, Coronary death, angina,congestive heart failure, and CABG/PTCA.
[4] "CHD" includes MI and coronary death.
[5] Excludes two cases with borderline malignancy.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated.
[8] Excludes non-melanoma skin cancer
[9] "Other fracture" excludes fractures indicated as pathological.
[10] All deaths except those from breast or colorectal cancer. Includes deaths which are not yet adjudicated.

Table 8.13 (continued)
Counts (Annualized Percentages) of Participants with Locally Verified Outcomes for Calcium and Vitamin D Component
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
Fractures	337 (1.81%)	54 (1.43%)	65 (1.39%)	144 (1.90%)	74 (2.84%)	27 (1.06%)	310 (1.92%)
Hip fracture	14 (0.08%)	2 (0.05%)	1 (0.02%)	5 (0.07%)	6 (0.23%)	0 (0.00%)	14 (0.09%)
Vertebral fracture	19 (0.10%)	1 (0.03%)	1 (0.02%)	8 (0.11%)	9 (0.35%)	1 (0.04%)	18 (0.11%)
Other fracture [7,9]	313 (1.68%)	52 (1.37%)	63 (1.35%)	136 (1.79%)	62 (2.38%)	26 (1.02%)	287 (1.78%)
Other							
Death other causes – CaD[10]	77 (0.41%)	6 (0.16%)	10 (0.21%)	33 (0.43%)	28 (1.08%)	12 (0.47%)	65 (0.40%)
Death	81 (0.43%)	6 (0.16%)	12 (0.26%)	35 (0.46%)	28 (1.08%)	13 (0.51%)	68 (0.42%)

[1] Participants with unmarked ethnicity are classified as Minority.
[2] Mean follow-up is the number of months from CaD enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*
[3] "Coronary disease" includes MI, Coronary death, angina,congestive heart failure, and CABG/PTCA.
[4] "CHD" includes MI and coronary death.
[5] Excludes two cases with borderline malignancy.
[6] Only women without a baseline hysterectomy are used to compute the annual rates of endometrial cancer.
[7] Only one report of "other cancer" or "other fracture" is counted per woman; however, the first other cancer or other fracture of each type is adjudicated.
[8] Excludes non-melanoma skin cancer
[9] "Other fracture" excludes fractures indicated as pathological.
[10] All deaths except those from breast or colorectal cancer. Includes deaths which are not yet adjudicated.

Table 8.14
Counts (Annualized Percentages) of Participants with Locally Verified Outcomes for Observational Study
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
No. of participants w/ Form 33	63810	9853	13098	25992	14867	9021	54789
Mean follow-up (months) [2]	21.3	22.1	21.6	21.3	20.7	20.6	21.4
Outcomes							
Cardiovascular	800 (0.71%)	33 (0.18%)	73 (0.31%)	311 (0.67%)	383 (1.49%)	93 (0.60%)	707 (0.72%)
Coronary Disease[3]	620 (0.55%)	25 (0.14%)	60 (0.25%)	250 (0.54%)	285 (1.11%)	73 (0.47%)	547 (0.56%)
CHD[4]/Stroke/PE	257 (0.23%)	8 (0.04%)	21 (0.09%)	83 (0.18%)	145 (0.57%)	32 (0.21%)	225 (0.23%)
CHD[4]	139 (0.12%)	5 (0.03%)	11 (0.05%)	43 (0.09%)	80 (0.31%)	12 (0.08%)	127 (0.13%)
MI	119 (0.11%)	5 (0.03%)	10 (0.04%)	40 (0.09%)	64 (0.25%)	9 (0.06%)	110 (0.11%)
Coronary death	26 (0.02%)	0 (0.00%)	1 (0.00%)	4 (0.01%)	21 (0.08%)	3 (0.02%)	23 (0.02%)
Angina	372 (0.33%)	18 (0.10%)	42 (0.18%)	161 (0.35%)	151 (0.59%)	44 (0.28%)	328 (0.34%)
Congestive heart failure	157 (0.14%)	4 (0.02%)	13 (0.06%)	59 (0.13%)	81 (0.32%)	24 (0.15%)	133 (0.14%)
CABG/PTCA	250 (0.22%)	9 (0.05%)	24 (0.10%)	108 (0.23%)	109 (0.43%)	23 (0.15%)	227 (0.23%)
Carotid artery disease	63 (0.06%)	5 (0.03%)	4 (0.02%)	22 (0.05%)	32 (0.12%)	7 (0.05%)	56 (0.06%)
Stroke	115 (0.10%)	3 (0.02%)	10 (0.04%)	40 (0.09%)	62 (0.24%)	20 (0.13%)	95 (0.10%)
PVD	47 (0.04%)	2 (0.01%)	2 (0.01%)	15 (0.03%)	28 (0.11%)	3 (0.02%)	44 (0.05%)
DVT	2 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.00%)	1 (0.00%)	0 (0.00%)	2 (0.00%)
PE	3 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (0.01%)	0 (0.00%)	3 (0.00%)
Cancer	803 (0.71%)	86 (0.47%)	116 (0.49%)	357 (0.77%)	244 (0.95%)	79 (0.51%)	724 (0.74%)
Breast cancer [5]	377 (0.33%)	50 (0.28%)	59 (0.25%)	173 (0.37%)	95 (0.37%)	40 (0.26%)	337 (0.34%)
Invasive breast cancer	303 (0.27%)	41 (0.23%)	47 (0.20%)	139 (0.30%)	76 (0.30%)	30 (0.19%)	273 (0.28%)
In situ breast cancer	74 (0.07%)	10 (0.06%)	12 (0.05%)	35 (0.08%)	17 (0.07%)	10 (0.06%)	64 (0.07%)
Ovary cancer	26 (0.02%)	1 (0.01%)	6 (0.03%)	14 (0.03%)	5 (0.02%)	2 (0.01%)	24 (0.02%)
Endometrial cancer [6]	47 (0.07%)	5 (0.05%)	6 (0.04%)	24 (0.09%)	12 (0.08%)	6 (0.07%)	41 (0.07%)
Colorectal cancer	76 (0.07%)	5 (0.03%)	7 (0.03%)	25 (0.05%)	39 (0.15%)	11 (0.07%)	65 (0.07%)
Other cancer [7,8]	284 (0.25%)	26 (0.14%)	39 (0.17%)	122 (0.26%)	97 (0.38%)	21 (0.14%)	263 (0.27%)

[1] Participants with unmarked ethnicity are classified as Minority.

[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*

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

[4] "CHD" includes MI and coronary death.

[5] Excludes two cases with borderline malignancy.

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

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

[8] Excludes non-melanoma skin cancer

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

Table 8.14 (continued)
Counts (Annualized Percentages) of Participants with Locally Verified Outcomes for Observational Study
Data as of: August 31, 1998

	Total	Age				Ethnicity	
		50-54	55-59	60-69	70-79	Minority[1]	White
Fractures	555 (0.49%)	51 (0.28%)	99 (0.42%)	234 (0.51%)	171 (0.67%)	34 (0.22%)	521 (0.53%)
Hip fracture	71 (0.06%)	2 (0.01%)	8 (0.03%)	27 (0.06%)	34 (0.13%)	2 (0.01%)	69 (0.07%)
Vertebral fracture	42 (0.06%)	2 (0.01%)	5 (0.02%)	18 (0.04%)	17 (0.07%)	0 (0.00%)	42 (0.04%)
Other fracture [7,9]	452 (0.04%)	48 (0.26%)	87 (0.37%)	192 (0.42%)	125 (0.49%)	33 (0.21%)	419 (0.43%)
Other							
Death	352 (0.00%)	19 (0.10%)	33 (0.14%)	137 (0.30%)	163 (0.64%)	47 (0.30%)	305 (0.31%)

[1] Participants with unmarked ethnicity are classified as Minority.

[2] Mean follow-up is the number of months from enrollment to the date the last *Form 33* was completed, or date of death from *Form 120 - Initial Notification of Death.*

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

[4] "CHD" includes MI and coronary death.

[5] Excludes two cases with borderline malignancy.

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

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

[8] Excludes non-melanoma skin cancer

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

Table 8.15
Counts (Annualized Percentages) of Participants with Locally Verified Outcomes for HRT Participants Without and With Uterus
Data as of: August 31, 1998

	Without Uterus		With Uterus	
No. of Participants w/ Form 33	9670		14979	
Mean follow-up (months) [1]	21.4		21.1	
Outcomes				
Cardiovascular	235	(1.36%)	281	(1.07%)
Coronary disease [2]	154	(0.89%)	172	(0.65%)
CHD[3]/Stroke[5]/PE	94	(0.55%)	131	(0.50%)
CHD[3]	44	(0.26%)	74	(0.28%)
MI	34	(0.20%)	70	(0.27%)
Coronary death	15	(0.09%)	7	(0.03%)
Angina	87	(0.50%)	79	(0.30%)
Congestive heart failure	36	(0.21%)	37	(0.14%)
CABG/PTCA	61	(0.35%)	81	(0.31%)
Carotid artery disease	21	(0.12%)	20	(0.08%)
Stroke	45	(0.26%)	36	(0.14%)
PVD	14	(0.08%)	8	(0.03%)
DVT	18	(0.10%)	47	(0.18%)
PE	8	(0.05%)	21	(0.08%)
Cancer	102	(0.59%)	172	(0.65%)
Breast cancer	28	(0.16%)	63	(0.24%)
Invasive breast cancer	17	(0.10%)	52	(0.20%)
In situ breast cancer	11	(0.06%)	11	(0.04%)
Ovary cancer	2	(0.01%)	6	(0.02%)
Endometrial cancer			8	(0.03%)
Colorectal cancer	20	(0.12%)	19	(0.07%)
Other cancer[4]	52	(0.30%)	78	(0.30%)
Fractures	222	(1.29%)	386	(1.47%)
Hip fracture	13	(0.08%)	15	(0.06%)
Vertebral fracture	11	(0.06%)	26	(0.10%)
Other fracture	200	(1.16%)	354	(1.34%)
Other				
Death	85	(0.49%)	77	(0.29%)

[1] Mean follow-up is the number of months from enrollment to the last *Form 33* or date of death from *Form 120 - Initial Notification of Death.*
[2] "Coronary disease" includes MI, coronary death, angina, congestive heart failure, and CABG/PTCA.
[3] "CHD" includes MI and coronary death.
[4] Excludes non-melanoma skin cancer

9. Clinical Center Performance Monitoring

9.1 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. The Performance Monitoring Committee (PMC) Report, updated quarterly, summaries clinic-specific performance (see *Table 9.1 - Clinical Center Profile* and *Table 9.2 - Clinical Center Performance Summary* for cumulative data through August 31, 1998).

9.2 PMC Committee Activity

For the first half of the last year, the PMC continued to monitor Clinical Center progress in recruitment. During the year, however, the PMC increased its focus on adherence, retention and outcomes issues. From November 1997 through January 1998, the PMC conducted a series of meetings at four clinics to gather and discuss strategies for maximizing adherence and retention. PIs and lead staff from other clinics also attended these meetings. Information gathered at these meetings guided the development of topics and strategies to discuss with clinical centers.

In April and May, four workshops were held addressing adherence and retention issues. Each clinical center sent two staff representatives who attended background presentations on adherence and retention models and application of those models to WHI, and practice sessions on listening skills and communication strategies. Each clinical center received an extensive resource notebook containing handouts, such as a summary of current resources available and training modules on topics such as effective communications. Based on feedback from these workshops and requests from the clinical centers, the PMC recommended a workshop addressing minority adherence and retention issues.

In July the PMC agreed to separate its monitoring activities into two separate groups, with one group addressing outcomes and one group addressing adherence/retention and other issues. Membership of each PMC group would continue to be representatives from the CCC, the CFC, and the Project Office. It was also agreed that two PI representatives be added to each group to add a peer review component to the monitoring process and to assure that the PMC had adequate representation of Clinical Center issues and to broaden the expertise of the PMC. Anne McTiernan, CCC, was named chair of the Outcomes PMC, and David Curb, Honolulu Clinical Center, and Marian Limacher, Gainesville Clinical Center, were named as PI representations. Sally Shumaker, CFC, was named chair of the Adherence/Retention PMC, and Shirley Beresford, Seattle, and Cheryl Ritenbaugh, Portland, were named as PI representatives. Each group held its first conference call in August to discuss its charge and orient the new PI members.

Over the past year, the PMC continued to hold one to two conference calls per month, reviewing 4-5 clinical centers on each call. It conducted one Level 4 visit to a clinic and held 3 follow-up conference calls with CCs to follow the CCs progress on recommendations made at a previous PMC visit. The PMC also conducted 5 outcomes-specific conference calls.

Specific plans for the next year include conducting the minority adherence and retention workshop and distributing a step-by-step adherence and retention template which clinical centers can use to optimize and enhance their adherence and retention efforts.

Table 9.1
Clinical Center Profile
Data as of: August 31, 1998

CC Profile - VCC

						Lead Staff Turnover within past 12 months						Ancillary Studies			
												Active		Proposed	
	Enhanced Recruitment	Minority	Satellite	Multiple Studies	Bone Density	PI	Clinic Manager	Lead Practitioner	Lead Nutritionist	Outcomes Spec.	Data Coordinator	Coordinating	Participating in	Coordinating	Participating in
Atlanta	125	Y		Y		1							1		
Birmingham	125	Y		Y	Y							5	1		
Bowman			Y			1			1		1	2	1		
Brigham	150												1	1	
Buffalo												1	1	2	
Chicago			Y	Y				1		1		2	1		
Iowa	200[1]		Y	Y									1		
LaJolla	150	Y	Y	Y								3	1	1	
Memphis	125		Y	Y									1		
Minneapolis	125			Y									1		
Newark	150		Y	Y						1	1	1	1		
Pawtucket	175		Y						2	1			1		
Pittsburgh				Y	Y							1	1		
Seattle				Y		1				1		1			
Tucson	125	Y	Y	Y	Y	1	1	1				1	1	2	
UCDavis				Y					1	1			1	1	

[1] Iowa - 200% enhanced recruitment for HRT and 150% for OS.

Table 9.1 (continued)

CC Profile - NCC

						Lead Staff Turnover within past 12 months						Ancillary Studies			
												Active		Proposed	
	Enhanced Recruitment	Minority	Satellite	Multiple Studies	Bone Density	PI	Clinic Manager	Lead Practitioner	Lead Nutritionist	Outcomes Spec.	Data Coordinator	Coordinating	Participating in	Coordinating	Participating in
Chapel Hill						1		1		1		1	1	2	
Chi-Rush	50	Y		Y									1		
Cincinnati	125								1		1		1		
Columbus				Y									1		
Detroit		Y							2			1	1		
Gainesville	125		Y	Y/N						1	1		1	1	
GWU-DC				Y				1				1	1		
Honolulu		Y		Y								1	1	1	
Houston								1		1	1		1		
Irvine								1	1				1		
LA				Y									1		
Madison									1	1	1		1		
Medlantic		Y		Y						1	1		1		
Miami		Y		Y		1	1	1	1	2		1	1	1	
Milwaukee										1			1		
Nevada				Y									1	1	
NY City	125										1	2	1	2	
Oakland				Y		1							1		
Portland				Y		1				1			1		
San Antonio		Y		Y									1		
Stanford	125												1		
Stony Brook													1		
Torrance	75			Y					1	1			1	1	
Worcester				Y									1	1	

Table 9.2
Clinical Center Performance Summary
Data as of: August 31, 1998

Summary - VCC

	Recruitment		HRT Follow-up		DM Follow-up		Retention		HRT Intervention		DM Intervention		CaD Intervention		Outcomes		Central Lab		Data	
	June-Aug	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98
Atlanta	94	78	92	86	89	81	7.6	8.2	75	75	9.7	9.8	66	65	30	27	94	95	93	91
Birmingham	110	82	95	90	95	89	6.8	7.0	81	80	7.8	7.6	67	63	13	20	96	96	73	72
Bowman	492	84	92	86	89	80	9.0	10.0	78	77	9.7	9.9	69	69	38	39	97	98	92	93
Brigham	61	87	96	95	94	87	6.6	6.7	83	83	10.4	10.3	68	69	24	22	96	96	74	76
Buffalo	186	100	91	83	90	82	8.1	8.3	76	76	9.9	9.6	71	71	62	75	95	94	97	97
Chicago	182	94	90	80	91	74	7.6	8.0	82	81	10.5	10.6	58	62	30	26	96	97	81	82
Iowa	107	102	98	94	98	94	2.6	3.0	90	90	12.4	12.4	78	79	48	55	96	95	94	94
LaJolla	75	87	90	85	90	83	8.4	8.7	75	75	8.4	8.6	71	69	55	55	96	97	92	93
Memphis	77	89	93	85	90	79	8.2	8.8	82	82	10.7	10.7	62	61	24	24	93	94	70	70
Minneapolis	91	92	86	84	81	77	4.9	4.9	83	84	11.7	11.7	76	77	39	44	99	99	90	88
Newark	83	94	87	77	78	67	5.0	5.8	77	78	10.8	10.6	57	56	36	44	97	96	83	84
Pawtucket	69	88	92	86	91	84	7.3	7.7	82	82	9.7	9.5	66	67	55	59	94	94	80	80
Pittsburgh	109	92	95	75	94	69	5.3	5.5	85	85	11.8	11.8	73	74	40	44	98	97	85	86
Seattle	38	101	93	81	95	82	7.4	7.9	79	79	11.9	11.9	67	68	49	57	95	94	79	79
Tucson	77	101	88	73	91	75	8.1	8.6	71	71	9.3	9.3	60	59	47	47	93	90	91	91
UCDavis	58	112	91	88	91	86	6.9	7.5	83	83	10.0	10.1	64	66	58	63	96	96	76	77

Note: Summary data is taken from the summary columns of the PMC Reports corresponding to the column headings, except DM Intervention cum. numbers from the previous month. These data are taken directly from that quarter's PMC report.

DM Intervention cum. Nov. 97 numbers are based on a weighted average of the AV1 FFQ and 4DFR, whereas the cum. Feb. 98 numbers are based on the average of the AV1 and AV2 FFQs.

Table 9.2 (continued)

Summary - NCC

	Recruitment		HRT Followup		DM Followup		Retention		HRT Intervention		DM Intervention		CaD Intervention		Outcomes		Central Labs		Data	
	June-Aug	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98
Chapel Hill	86	89	97	92	93	82	2.8	3.5	90	87	9.8	9.3	68	67	46	42	94	95	79	80
Chi-Rush	95	141	95	91	96	92	4.1	4.8	78	80	11.9	10.8	71	74	50	48	95	95	80	82
Cincinnati	103	76	93	83	88	78	5.3	5.9	87	82	10.0	10.2	64	64	37	36	92	90	77	78
Columbus	84	93	96	91	92	81	5.3	6.2	81	80	13.1	12.6	71	74	34	40	94	95	86	86
Detroit	112	78	72	55	66	55	4.1	4.9	80	70	7.8	9.8	61	61	35	36	90	93	78	78
Gainesville	43	89	96	91	95	89	6.1	6.8	85	85	11.6	11.5	67	72	64	60	94	94	96	97
GWU-DC	89	86	95	89	93	86	6.9	6.0	82	78	11.5	11.6	67	68	50	54	94	95	96	97
Honolulu	59	74	89	85	86	83	2.5	2.8	84	88	10.4	10.1	65	73	58	58	97	96	89	89
Houston	79	69	83	75	71	59	4.4	4.9	82	79	10.8	10.8	71	70	13	30	92	90	86	87
Irvine	75	93	79	74	82	68	5.1	5.8	77	75	13.0	11.7	51	62	62	28	95	96	65	66
LA	83	101	92	84	81	68	4.0	4.4	85	82	13.1	12.6	56	62	63	65	97	98	81	82
Madison	77	95	98	95	98	93	5.4	6.3	88	85	11.6	11.6	70	70	76	82	97	99	98	98
Medlantic	91	86	94	86	89	79	5.2	5.2	71	70	7.8	7.2	60	58	22	23	90	89	88	88
Miami	29	79	72	66	52	47	4.6	6.7	76	77	9.9	8.9	61	65	10	42	96	97	86	86
Milwaukee	86	102	98	94	99	94	4.0	4.4	87	87	12.2	11.9	77	77	46	55	95	97	92	93
Nevada	81	94	98	94	98	93	3.9	4.5	84	85	13.8	14.5	73	71	50	47	99	99	97	97
NY City	60	89	91	84	90	82	6.1	6.0	80	78	9.1	9.2	61	60	8	27	94	95	82	79
Oakland	75	87	97	92	96	87	2.3	2.4	90	87	13.4	12.4	79	79	21	24	93	92	85	86
Portland	94	91	91	81	87	80	3.0	3.6	86	83	11.1	10.9	73	72	23	18	91	92	65	66
San Antonio	103	86	80	74	74	65	5.8	6.8	81	78	10.8	9.3	63	66	23	28	93	94	93	92
Stanford	64	96	97	95	95	93	3.1	4.1	88	86	11.0	10.8	68	74	55	57	98	97	82	83
Stony Brook	58	87	99	95	98	95	5.1	5.8	85	85	10.2	10.4	66	70	57	67	94	95	98	98
Torrance	71	84	91	83	90	78	6.0	6.0	82	83	10.3	10.9	68	69	49	42	99	98	81	82
Worcester	62	99	97	91	93	89	6.1	6.1	85	83	10.3	10.4	63	60	31	42	92	91	85	85

Note: Summary data is taken from the summary columns of the PMC Reports corresponding to the column headings, except DM Intervention cum. numbers from the previous month. These data are taken directly from that quarter's PMC report.

DM Intervention cum. Nov. 97 numbers are based on a weighted average of the AV1 FFQ and 4DFR, whereas the cum. Feb. 98 numbers are based on the average of the AV1 and AV2 FFQs.

Table 9.2 (continued)

Recruitment - VCC

	HRT[1]			DM[1]			CaD[2]			OS[3]			Age - HRT[4]			Age - DM[4]			Overall			
	% goal			% goal			% goal			% goal			% goal, 70 - 79			% goal, 70 - 79			weighted average*			
	Mar-May	June-Aug	cum., Aug 98	Mar-May	June-Aug	cum., Aug 98	Mar-May	June-Aug	cum., Aug 98	Mar-May	June-Aug	cum., Aug 98	Mar-May	June-Aug	cum., Aug 98	Mar-May	June-Aug	cum., Aug 98	Mar-May	June-Aug	cum., Aug 98	Rank
Atlanta	-	-	75	-	-	106	96	94	71	-	-	88	-	-	52	-	-	61	96	94	78	16
Birmingham	-	-	101	-	-	100	73	110	68	-	-	91	-	-	65	-	-	52	73	110	82	15
Bowman	-	-	101	-	-	102	141	492	65	-	-	100	-	-	75	-	-	54	141	492	84	14
Brigham	-	-	87	-	-	108	86	61	66	-	-	88	-	-	67	-	-	108	86	61	87	12
Buffalo	-	-	112	-	-	108	110	186	88	-	-	101	-	-	113	-	-	69	110	186	100	5
Chicago	-	-	93	-	-	115	82	182	70	-	-	85	-	-	102	-	-	99	82	182	94	6
Iowa	-	-	138	-	-	95	114	107	91	-	-	94	-	-	117	-	-	60	114	107	102	2
LaJolla	-	-	81	-	-	103	84	75	76	-	-	104	-	-	85	-	-	84	84	75	87	13
Memphis	-	-	100	-	-	96	96	77	80	-	-	91	-	-	93	-	-	63	96	77	89	10
Minneapolis	-	-	109	-	-	100	97	91	77	-	-	98	-	-	95	-	-	62	97	91	92	9
Newark	-	-	103	-	-	114	65	83	76	-	-	102	-	-	96	-	-	67	65	83	94	7
Pawtucket	-	-	91	-	-	108	72	69	77	-	-	92	-	-	80	-	-	73	72	69	88	11
Pittsburgh	-	-	108	-	-	111	126	109	75	-	-	86	-	-	90	-	-	63	126	109	92	8
Seattle	-	-	119	-	-	108	74	38	68	-	-	75	-	-	134	-	-	100	74	38	101	3
Tucson	-	-	99	-	-	107	86	77	70	-	-	99	-	-	135	-	-	119	86	77	101	4
UCDavis	-	-	111	-	-	132	99	58	83	-	-	101	-	-	126	-	-	127	99	58	112	1
*weights:		1			1			1			0.25			0.5			0.5					

[1] From WHIP1109. Distributed in CC Monthly Activity Reports. Can be run at CC as WHIP0770.

[2] Derived from WHIP1140, 1141 and 1125. Calculation used to determine % of goal is the Total # of CaD Randomizations / 70% of the Total # of DM and HRT AV1s Due, less the overlap.

[3] From WHIP1126. Distributed in CC Monthly Activity Reports. Can be run at CC as WHIP1139.

[4] Derived from WHIP0578. Available at CC as WHIP0775.

Table 9.2 (continued)

Recruitment - NCC

	HRT[1]			DM[1]			CaD[2]			OS[3]			Age - HRT[4]			Age - DM[4]			Overall			
	% goal			% goal			% goal			% goal			% goal, 70 - 79			% goal, 70 - 79			weighted average*			
	Mar-May	June-Aug	cum., Aug 98	Mar-May	June-Aug	cum., Aug 98	Mar-May	June-Aug	cum., Aug 98	Mar-May	June-Aug	cum., Aug 98	Mar-May	June-Aug	cum., Aug 98	Mar-May	June-Aug	cum., Aug 98	Mar-May	June-Aug	cum., Aug 98	Rank
Chapel Hill	-	-	103	-	-	105	85	86	73	-	-	94	-	-	98	-	-	53	85	86	89	11
Chi-Rush	-	-	177	-	-	177	84	95	89	-	-	185	-	-	122	-	-	101	84	95	141	1
Cincinnati	-	-	71	-	-	78	82	103	92	-	-	80	-	-	71	-	-	57	82	103	76	22
Columbus	-	-	99	-	-	108	72	84	81	-	-	100	-	-	98	-	-	68	72	84	93	9
Detroit	-	-	88	-	-	95	71	112	81	-	-	90	-	-	56	-	-	34	71	112	78	21
Gainesville	-	-	120	-	-	100	50	43	59	-	-	100	-	-	90	-	-	62	50	43	89	12
GWU-DC	-	-	90	-	-	105	82	89	76	-	-	101	-	-	90	-	-	50	82	89	86	17
Honolulu	-	-	68	-	-	104	65	59	68	-	-	87	-	-	54	-	-	52	65	59	74	23
Houston	-	-	76	-	-	85	80	79	67	-	-	96	-	-	43	-	-	41	80	79	69	24
Irvine	-	-	99	-	-	108	91	75	82	-	-	100	-	-	92	-	-	71	91	75	93	8
LA	-	-	100	-	-	119	82	83	81	-	-	98	-	-	116	-	-	92	82	83	101	3
Madison	-	-	108	-	-	102	94	77	90	-	-	89	-	-	96	-	-	65	94	77	95	6
Medlantic	-	-	100	-	-	105	136	91	80	-	-	98	-	-	67	-	-	43	136	91	86	18
Miami	-	-	93	-	-	102	101	29	72	-	-	63	-	-	39	-	-	68	101	29	79	20
Milwaukee	-	-	122	-	-	108	76	86	86	-	-	101	-	-	113	-	-	66	76	86	102	2
Nevada	-	-	107	-	-	101	83	81	85	-	-	98	-	-	97	-	-	65	83	81	94	7
NY City	-	-	99	-	-	98	61	60	69	-	-	102	-	-	101	-	-	73	61	60	89	13
Oakland	-	-	105	-	-	102	32	75	55	-	-	92	-	-	98	-	-	66	32	75	87	15
Portland	-	-	102	-	-	109	76	94	78	-	-	98	-	-	80	-	-	65	76	94	91	10
San Antonio	-	-	117	-	-	89	81	103	91	-	-	76	-	-	56	-	-	44	81	103	86	16
Stanford	-	-	93	-	-	104	89	64	87	-	-	97	-	-	111	-	-	88	89	64	96	5
Stony Brook	-	-	84	-	-	95	58	58	67	-	-	91	-	-	104	-	-	96	58	58	87	14
Torrance	-	-	71	-	-	106	82	71	80	-	-	90	-	-	67	-	-	90	82	71	84	19
Worcester	-	-	100	-	-	113	55	62	78	-	-	101	-	-	116	-	-	88	55	62	99	4
*weights:		1			1			1			0.25			0.5			0.5					

[1] From WHIP1109. Distributed in CC Monthly Activity Reports. Can be run at CC as WHIP0770.

[2] Derived from WHIP1140, 1141 and 1125. Calculation used to determine % of goal is the Total # of CaD Randomizations / 70% of the Total # of DM and HRT AV1s Due, less the overlap.

[3] From WHIP1126. Distributed in CC Monthly Activity Reports. Can be run at CC as WHIP1139.

[4] Derived from WHIP0578. Available at CC as WHIP0775.

Table 9.2 (continued)

Minority Randomization/Enrollment at Pool 1 Clinics

	% Non-white HRT/DM/OS[1]		
VCCs	cum., May 98	cum., Aug 98	Rank
Atlanta	25	24	10
Birmingham	35	34	6
LaJolla	26	25	8
Tucson	25	24	9
NCCs			
Chi-Rush	53	54	3
Detroit	28	28	7
Honolulu	75	75	1
Medlantic	60	58	2
Miami	43	43	4
San Antonio	43	43	5

[1] Derived from WHIP0960.
Can be run at CC as WHIP777.

Table 9.2 (continued)

HRT Follow-up - VCC

	6 Wk[1]	Semi-Annual 1[2]			Annual Visit 1[2]			Semi-Annual 2[2]			Annual Visit 2[2]			Semi-Annual 3[2]			Annual Visit 3[2]			Semi-Annual 4[2]			Annual Visit 4[2]					
	Cond	Conducted		+/-2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Overall		
	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	Rank
Atlanta	95	98	98	91	98	98	93	92	92	81	92	91	87	89	88	75	88	89	78	84	83	72		82	68	92	86	7
Birmingham	94	97	97	87	98	98	87	96	97	83	96	97	88	96	95	82	96	96	88	83	95	63	97	96	91	95	90	3
Bowman	95	97	97	85	96	96	77	92	93	74	93	94	79	90	91	77	94	94	77	88	91	73	84	94	76	92	86	5
Brigham	98	99	99	94	99	99	95	98	98	94	97	97	94	95	96	93	96	96	92	88	94	91	92	91	88	96	95	1
Buffalo	97	97	97	85	96	97	81	92	93	71	93	92	71	92	93	70	87	90	66	88	91	78	80	84	57	91	83	11
Chicago	89	96	96	66	95	96	57	92	93	68	91	92	58	89	90	68	91	92	72	89	90	76	80	89	74	90	80	13
Iowa	100	99	100	94	100	100	93	99	99	91	99	99	88	97	98	87	99	99	86	96	99	84	96	98	90	98	94	2
LaJolla	93	94	94	82	90	91	78	89	89	77	90	90	78	90	91	82	92	92	86	88	89	85	86	81	76	90	85	8
Memphis	93	97	97	82	97	97	87	91	91	74	94	94	81	94	93	68	91	92	81	89	88	60	92	92	77	93	85	9
Minneapolis	100	100	100	91	100	100	94	88	91	80	99	98	90	62	67	55	98	98	89	40	48	36	99	99	88	86	84	10
Newark	92	97	97	79	95	96	76	88	91	64	92	92	69	86	87	58	89	90	58	86	90	60	63	82	34	87	77	14
Pawtucket	97	98	98	86	97	97	75	93	93	77	93	93	78	91	91	81	90	91	74	87	87	79	85	88	80	92	86	6
Pittsburgh	97	99	99	48	97	97	54	95	95	65	96	97	30	94	94	58	93	93	51	95	94	25	93	95	77	95	75	15
Seattle	96	97	97	61	97	97	66	95	96	62	94	95	63	92	92	69	91	91	65	92	92	81	85	86	74	93	81	12
Tucson	86	95	95	64	93	92	67	90	90	55	86	86	42	87	86	50	84	84	51	87	88	51	81	86	61	88	73	16
UCDavis	98	99	99	86	96	96	79	94	95	85	94	94	80	93	92	85	90	91	83	86	89	85	79	83	73	91	88	4

[1] From WHIP1131. Can be run at CC as WHIP0781 or WHIP0786.

[2] From WHIP1141.

Notes: Conducted = % of visits due for which at least one task has been key-entered.

+/- 2 weeks = % of visits due that have been conducted within 2 weeks of the target date.

This report is reformatted this quarter in that cum., Nov. 97 columns have been deleted for +/- wks. This deletion affects the cum. Nov. 97 Overall Average versus last quarter.

Table 9.2 (continued)

HRT Follow-up - NCC

	6 Wk[1]	Semi-Annual 1[2]			Annual Visit 1[2]			Semi-Annual 2[2]			Annual Visit 2[2]			Semi-Annual 3			Annual Visit 3[2]			Overall		
	Cond	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks'	Conducted		+/- 2 wks			
	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	Rank
Chapel Hill	97	98	99	83	96	97	81	97	97	86	99	97	86	94	97	92		94	88	97	92	6
Chi-Rush	97	99	99	87	97	97	89	96	95	86	94	93	88	90	89	84				95	91	8
Cincinnati	97	99	99	87	95	95	80	91	90	72	89	83	67	89	90	70		83	71	93	83	17
Columbus	99	99	99	87	97	97	87	94	95	80	97	98	85	95	98	73				96	91	10
Detroit	78	88	89	63	82	86	32	72	69	36	69	70	32	47	51	19		46	38	72	55	24
Gainesville	99	99	99	90	96	97	85	95	96	82	96	95	84	91	93	87	96	94	81	96	91	11
GWU-DC	97	99	99	89	98	98	88	95	95	80	93	94	79	91	92	77		90	78	95	89	12
Honolulu	93	96	95	88	94	94	83	91	91	77	87	90	81	74	85	67		86	79	89	85	14
Houston	96	95	95	80	92	92	74	82	84	63	85	83	65	71	71	50	71	72	46	83	75	20
Irvine	83	92	93	70	84	85	60	76	79	62	76	83	69	69	76	53		82	73	79	74	21
LA	100	98	98	86	96	96	76	94	96	73	87	90	72	83	89	73		88	63	92	84	15
Madison	100	100	100	94	99	99	84	99	99	93	98	98	86	96	98	92		96	89	98	95	3
Medlantic	99	100	99	81	98	98	75	92	94	67	89	90	72	89	91	76		94	85	94	86	13
Miami	75	89	89	67	83	82	65	73	72	58	72	73	61	43	46	44		63	63	72	66	23
Milwaukee	100	99	99	94	99	99	91	98	98	87	98	97	87	98	97	87		96	89	98	94	5
Nevada	98	100	100	89	99	99	89	97	97	89	97	97	90	98	98	89		97	97	98	94	4
NY City	86	98	98	88	95	95	85	93	92	81	87	86	79	85	87	79		71	71	91	84	16
Oakland	97	99	99	91	98	99	88	97	97	86	96	98	88	93	93	85		88	82	97	92	7
Portland	98	98	98	77	94	96	74	92	94	72	90	93	67	82	89	66		68	58	91	81	19
San Antonio	76	86	86	70	84	87	69	77	78	61	78	83	70	77	77	56		78	72	80	74	22
Stanford	98	99	99	88	99	98	89	96	99	87	99	99	93	92	98	94				97	95	2
Stony Brook	100	100	100	98	99	99	95	99	99	94	99	100	93	100	95	88		95	84	99	95	1
Torrance	97	95	94	79	94	95	86	90	88	72	91	89	79	85	88	73		76	67	91	83	18
Worcester	100	99	100	85	98	98	88	98	97	81	94	96	79	95	94	84				97	91	9

[1] From WHIP1131. Can be run at CC as WHIP0781 or WHIP0786.

[2] From WHIP1141.

Notes: Conducted = % of visits due for which at least one task has been key-entered.
+/- 2 weeks = % of visits due that have been conducted within 2 weeks of the target date.

Table 9.2 (continued)

DM Follow-up - VCC

	Semi-Annual 1[1]			Annual Visit 1[1]			Semi-Annual 2[1]			Annual Visit 2[1]			Semi-Annual 3[1]			Annual Visit 3[1]			Semi-Annual 4[1]			Annual Visit 4			Overall		
	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks			
	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	Rank
Atlanta	94	94	75	96	96	91	91	91	75	90	91	80	88	87	68	88	89	78	80	79	58	84	86	64	89	81	9
Birmingham	99	99	85	98	99	87	97	97	83	96	97	86	94	96	80	94	95	88	83	93	62	96	93	88	95	89	2
Bowman	89	89	64	94	94	80	87	88	60	91	92	79	84	86	63	92	93	80	86	89	52	87	93	79	89	80	10
Brigham	99	98	80	97	98	91	95	94	73	96	96	87	93	94	70	94	94	86	89	90	66	90	92	88	94	87	3
Buffalo	97	97	75	96	96	79	94	94	77	93	94	69	93	93	75	87	90	61	91	93	79	71	86	50	90	82	7
Chicago	96	96	51	94	94	44	93	93	53	90	90	45	89	90	57	91	92	57	88	89	66	89	91	77	91	74	14
Iowa	99	99	92	99	99	92	99	99	91	98	99	90	98	98	84	98	98	87	96	98	87	98	96	90	98	94	1
LaJolla	93	94	71	93	93	83	91	91	74	88	90	78	88	89	77	89	89	82	87	87	78	90	85	75	90	83	6
Memphis	93	93	69	96	96	81	87	87	62	94	93	78	91	90	55	92	93	77	86	85	49	84	88	74	90	79	11
Minneapolis	85	87	67	99	99	90	90	91	73	99	98	88	65	68	45	98	98	91	14	28	20	98	95	88	81	77	12
Newark	92	93	61	91	92	68	82	84	55	83	84	57	75	79	52	82	80	51	73	78	46	48	63	27	78	67	16
Pawtucket	96	96	76	95	95	71	87	89	71	94	94	80	91	91	76	90	91	78	88	87	77	86	89	79	91	84	5
Pittsburgh	98	98	55	98	98	39	91	92	35	97	97	41	92	93	25	94	94	52	96	96	22	89	93	72	94	69	15
Seattle	97	97	53	96	97	63	94	94	64	95	96	59	95	95	64	97	97	70	95	95	89	92	90	83	95	82	8
Tucson	97	97	68	95	95	70	94	94	55	91	92	47	91	92	44	87	87	56	89	90	51	88	89	66	91	75	13
UCDavis	96	96	85	96	96	81	93	93	83	95	95	80	91	91	78	93	93	84	86	89	78	82	83	72	91	86	4

[1] From WHIP1140.

Notes: Conducted = % of visits due for which at least one task has been key-entered.
+/- 2 weeks = % of visits due that have been conducted within 2 weeks of the target date.

Table 9.2 (continued)

DM Follow-up - NCC

	Semi-Annual 1[1]			Annual Visit 1[1]			Semi-Annual 2[1]			Annual Visit 2[1]			Semi-Annual 3[1]			Annual Visit 3			Overall		
	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks	Conducted		+/- 2 wks			
	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	Rank
Chapel Hill	96	96	65	96	95	80	92	94	61	93	95	83	89	92	60		84	74	93	82	13
Chi-Rush	99	99	88	97	97	84	95	94	84	93	91	83	95	94	90		100	100	96	92	6
Cincinnati	95	95	74	96	96	79	90	90	69	88	84	66	85	87	63	72	73	59	88	78	18
Columbus	95	95	50	96	96	77	85	87	65	96	98	82	86	90	71		89	74	92	81	14
Detroit	89	89	67	61	70	34	75	76	58	53	59	34	53	61	41		41	29	66	55	23
Gainesville	99	99	89	96	96	83	94	95	79	94	96	80	92	94	82	93	93	83	95	89	7
GWU-DC	99	99	82	98	98	88	96	95	76	93	95	84	92	89	69	80	90	68	93	86	10
Honolulu	93	93	77	94	95	84	85	84	69	91	93	80	66	78	59	86	98	85	86	83	11
Houston	88	88	53	78	79	44	77	77	51	77	75	46	64	63	37	42	61	36	71	59	22
Irvine	89	92	47	92	92	60	75	83	44	80	81	59	72	80	36		80	63	82	68	19
LA	91	89	59	89	90	71	82	84	52	76	78	58	69	73	41		67	50	81	68	20
Madison	99	100	95	98	98	87	98	98	90	98	98	86	96	97	91		93	86	98	93	4
Mediantic	94	95	67	95	95	69	89	90	65	84	86	63	83	83	62	86	89	84	89	79	16
Miami	60	65	29	80	82	63	53	54	34	47	56	43	23	24	21		47	41	52	47	24
Milwaukee	100	100	90	99	99	92	99	99	87	97	97	89	98	98	86		97	91	99	94	2
Nevada	99	100	82	99	99	90	98	98	83	98	98	88	98	98	92		98	95	98	93	3
NY City	96	97	83	95	94	82	93	91	76	87	86	78	77	78	71		78	68	90	82	12
Oakland	96	97	67	98	98	84	94	95	69	95	96	85	90	91	65	100	98	93	96	87	9
Portland	97	98	86	96	97	70	94	96	76	92	93	65	76	85	45	70	89	62	87	80	15
San Antonio	83	85	50	83	85	51	68	71	49	75	77	59	63	67	53	71	77	62	74	65	21
Stanford	99	99	87	98	98	91	96	97	84	94	96	91	91	94	83		96	96	95	93	5
Stony Brook	100	100	98	98	98	95	97	97	92	99	98	91	98	98	89		96	83	98	95	1
Torrance	92	92	75	94	94	76	91	88	70	88	87	71	83	84	64		76	65	90	78	17
Worcester	98	98	80	98	97	85	96	97	80	94	96	80	96	95	86	77	92	81	93	89	8

[1] From WHIP1140.

Notes: Conducted = % of visits due for which at least one task has been key-entered.
+/- 2 weeks = % of visits due that have been conducted within 2 weeks of the target date.

Table 9.2 (continued)

Retention - VCC

	HRT[1]				DM[2]				CaD[3]				OS		Overall		
	% Stopping Intervention		% Stopping Followup		% Stopping Intervention		% Stopping Followup		% Stopping Intervention		% Stopping Followup		% Stopping Followup				
	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	Rank
Atlanta	22.6	24.9	1.9	2.3	2.1	2.3	1.8	2.1	16.2	16.3	0.9	1.0	-	-	7.6	8.2	11
Birmingham	18.5	19.4	2.1	2.3	6.2	6.4	1.9	2.2	10.8	10.3	1.2	1.4	-	-	6.8	7.0	6
Bowman	25.5	27.3	3.1	3.2	5.9	8.0	3.3	3.8	15.6	17.2	0.6	0.6	-	-	9.0	10.0	16
Brigham	15.3	16.1	1.2	1.1	3.8	4.1	1.0	1.0	17.7	17.5	0.3	0.1	-	-	6.6	6.7	5
Buffalo	27.6	28.5	1.0	1.2	4.2	4.6	2.0	2.2	13.6	12.9	0.2	0.3	-	-	8.1	8.3	12
Chicago	21.0	23.4	1.8	1.9	2.3	2.7	2.4	2.4	17.3	17.3	0.5	0.5	-	-	7.6	8.0	10
Iowa	9.0	10.4	0.5	0.5	1.0	1.3	0.9	1.2	3.7	4.4	0.3	0.4	-	-	2.6	3.0	1
LaJolla	23.3	24.9	4.4	4.6	5.2	4.9	4.1	4.2	12.0	12.2	1.5	1.6	-	-	8.4	8.7	14
Memphis	17.7	20.1	2.0	2.5	6.0	7.4	1.8	2.2	20.5	19.6	0.9	1.0	-	-	8.2	8.8	15
Minneapolis	14.2	16.2	0.5	0.6	2.4	2.4	1.3	1.2	10.5	8.7	0.2	0.2	-	-	4.9	4.9	2
Newark	12.4	14.5	2.0	2.7	1.5	1.7	0.9	1.4	13.1	13.9	0.3	0.7	-	-	5.0	5.8	4
Pawtucket	19.3	21.4	2.4	2.5	4.1	4.7	1.6	1.8	15.4	15.1	0.8	0.9	-	-	7.3	7.7	8
Pittsburgh	15.6	16.8	2.3	2.3	1.5	1.5	1.3	1.3	10.8	10.7	0.4	0.4	-	-	5.3	5.5	3
Seattle	24.5	26.0	2.3	2.5	1.3	1.5	2.1	2.2	13.5	14.9	0.5	0.5	-	-	7.4	7.9	9
Tucson	19.8	21.7	3.8	4.1	2.3	3.3	2.5	2.8	19.1	19.2	0.8	0.7	-	-	8.1	8.6	13
UCDavis	17.3	19.1	2.7	2.8	6.0	6.6	2.3	2.5	12.2	12.7	1.0	1.0	-	-	6.9	7.5	7

[1] From report WHIP0745.

[2] From report WHIP0748.

[3] From report WHIP0744.

Table 9.2 (continued)
Retention - NCC

	HRT[1]				DM[2]				CaD[3]				OS				
	% Stopping Intervention		% Stopping Followup		% Stopping Intervention		% Stopping Followup		% Stopping Intervention		% Stopping Followup		% Stopping Followup		Overall		
	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	Rank
Chapel Hill	9.1	10.2	0.7	0.8	0.5	2.0	0.5	1.3	5.6	5.7	0.4	0.9	-	-	2.8	3.5	3
Chi-Rush	13.1	14.2	2.3	2.4	2.3	2.6	1.6	1.9	4.7	6.9	0.4	0.5	-	-	4.1	4.8	9
Cincinnati	12.1	14.1	2.4	3.1	3.9	4.3	1.4	1.5	10.5	11.0	1.2	1.1	-	-	5.3	5.9	15
Columbus	12.2	15.1	1.5	1.5	4.8	6.1	1.6	1.7	11.4	12.3	0.4	0.3	-	-	5.3	6.2	20
Detroit	6.7	9.1	1.9	3.2	5.7	7.3	3.3	3.8	5.8	4.6	1.4	1.2	-	-	4.1	4.9	10
Gainesville	17.0	19.5	2.3	2.8	4.5	3.9	1.6	2.2	10.4	11.6	0.5	0.6	-	-	6.1	6.8	24
GWU-DC	17.4	18.5	2.6	2.7	7.2	1.1	2.2	2.1	11.3	11.2	0.9	0.6	-	-	6.9	6.0	18
Honolulu	7.8	8.0	1.5	1.5	0.2	0.9	0.5	0.6	4.9	5.8	0.2	0.2	-	-	2.5	2.8	2
Houston	12.5	14.4	0.9	0.9	5.3	5.5	0.7	1.4	6.4	6.3	0.5	0.7	-	-	4.4	4.9	10
Irvine	17.8	19.6	1.6	2.0	0.2	0.4	1.2	1.3	8.5	9.9	1.2	1.4	-	-	5.1	5.8	13
LA	7.0	8.1	1.4	1.6	1.9	2.9	0.9	1.2	12.0	11.8	0.7	0.8	-	-	4.0	4.4	6
Madison	14.6	16.2	1.1	1.5	6.0	6.7	1.4	1.7	9.0	11.0	0.3	0.5	-	-	5.4	6.3	21
Medlantic	10.9	12.9	1.6	2.0	4.3	4.5	1.6	2.0	10.4	8.4	2.4	1.5	-	-	5.2	5.2	12
Miami	13.4	19.0	1.8	3.4	4.8	6.8	1.0	1.6	5.7	8.0	0.8	1.5	-	-	4.6	6.7	22
Milwaukee	13.9	15.7	0.6	0.5	1.1	1.5	0.4	0.6	7.6	7.9	0.3	0.3	-	-	4.0	4.4	7
Nevada	14.2	17.0	0.9	1.2	0.9	0.7	0.8	0.7	6.6	7.3	0.0	0.1	-	-	3.9	4.5	8
NY City	14.0	14.7	2.5	2.4	2.1	2.1	1.8	1.8	15.0	13.9	1.1	1.1	-	-	6.1	6.0	17
Oakland	6.0	7.0	0.8	0.8	1.4	1.6	1.2	1.1	4.1	3.9	0.0	0.2	-	-	2.3	2.4	1
Portland	7.0	9.4	0.9	0.8	0.9	1.1	1.4	1.4	7.4	8.6	0.6	0.5	-	-	3.0	3.6	4
San Antonio	12.6	15.0	2.3	2.4	7.1	9.7	2.2	2.8	9.5	9.5	1.3	1.1	-	-	5.8	6.8	23
Stanford	10.8	12.3	0.1	0.7	1.5	2.9	0.6	0.9	5.6	7.0	0.1	0.5	-	-	3.1	4.1	5
Stony Brook	15.1	17.3	0.6	0.8	3.5	3.7	0.8	1.1	10.1	11.5	0.3	0.5	-	-	5.1	5.8	14
Torrance	16.9	17.0	2.5	2.2	7.1	7.4	2.0	1.9	7.0	6.8	0.5	0.4	-	-	6.0	6.0	16
Worcester	14.7	14.7	0.9	0.8	3.5	4.4	1.2	1.2	15.9	14.9	0.6	0.6	-	-	6.1	6.1	19

[1] From report WHIP0745.
[2] From report WHIP0748.
[3] From report WHIP0744.

Table 9.2 (continued)

HRT Intervention - VCC

	AV1						AV2						AV3								Overall		
	% with Pill Count at AV1[1]		% ≥ 80% Adherent at AV1[2]		Adherence Summary at AV1[3]		% with Pill Count at AV2[1]		% ≥ 80% Adherent at AV2[2]		Adherence Summary at AV2[3]		% with Pill Count at AV3[1]		% ≥ 80% Adherent at AV3[2]		Adherence Summary at AV3[3]		% Blinding[4]		Weighted ave*		Rank
	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	
Atlanta	91	91	81	81	71	71	78	79	80	80	57	58	72	70	82	82	52	51	91	90	75	75	15
Birmingham	91	90	87	87	78	78	82	80	86	85	69	67	76	76	87	87	66	66	92	92	81	80	9
Bowman	90	90	79	79	69	69	83	81	88	85	68	65	77	76	81	83	57	57	90	89	78	77	12
Brigham	91	90	88	88	79	79	84	86	88	88	74	75	80	77	89	89	70	68	91	91	83	83	5
Buffalo	89	89	85	85	73	73	78	78	85	86	63	62	75	73	82	82	55	55	85	84	76	76	13
Chicago	91	90	89	89	77	76	82	81	86	87	65	64	80	80	92	92	68	68	90	90	82	81	8
Iowa	95	95	92	92	87	87	92	92	93	93	86	86	87	89	94	94	83	84	90	88	90	90	1
LaJolla	90	90	84	84	66	67	80	79	83	82	58	58	69	70	84	86	53	55	91	90	75	75	14
Memphis	92	92	87	86	77	77	84	85	88	86	70	69	83	81	88	87	67	65	93	93	82	82	7
Minneapolis	93	94	87	88	81	82	86	86	90	91	76	77	78	78	87	90	68	70	93	93	83	84	3
Newark	92	92	85	86	73	74	86	87	80	80	63	63	83	83	72	75	55	57	93	93	77	78	11
Pawtucket	91	90	89	90	78	78	82	83	91	92	70	71	73	73	94	93	64	63	90	88	82	82	6
Pittsburgh	95	95	89	89	83	82	87	88	89	89	77	77	82	82	86	88	67	68	96	96	85	85	2
Seattle	92	92	89	89	79	79	83	83	85	86	66	68	69	70	87	84	55	54	92	91	79	79	10
Tucson	82	83	84	84	64	64	76	75	76	77	50	50	71	69	75	77	45	44	96	96	71	71	16
UCDavis	92	91	89	90	79	79	85	84	90	89	72	71	82	81	88	90	67	68	87	86	83	83	4
*Weights	1		1		1		1		1		1		1		1		1		0.5				

[1] % of AVs conducted that include study pill collections or estimates. From WHIP1141.

[2] % of ppts adherent as measured by pill count or estimate at AVs, excluding ERT -> PERT ppts. From data\ analysis not yet routinely distributed to CCs.

[3] % of ppts due for the AV who took at least 80% of their study pills.

[4] % of ppts for whom no unblinding occurred. From DSMB report not distributed to CCs.

Table 9.2 (continued)

HRT Intervention - NCC

	AV1						AV2						AV3								Overall		
	% with Pill Count at AV1[1]		% ≥ 80% Adherent at AV1[2]		Adherence Summary at AV1[3]		% with Pill Count at AV2[1]		% ≥ 80% Adherent at AV2[2]		Adherence Summary at AV2[3]		% with Pill Count at AV3[1]		% ≥ 80% Adherent at AV3[2]		Adherence Summary at AV3[3]		% Blinding[4]		Weighted ave*		
	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	Rank
Chapel Hill	95	93	89	90	81	80	93	92	93	91	85	82		100		80		75	93	91	90	87	2
Chi-Rush	91	90	77	80	68	70	82	83	80	82	63	65							95	95	78	80	16
Cincinnati	92	92	90	91	78	78	87	87	95	94	74	69		80		88		58	92	90	87	82	13
Columbus	92	92	84	85	75	75	81	76	81	83	64	62							96	95	81	80	15
Detroit	93	92	87	86	67	67	94	94	81	77	53	51		83		50		17	93	93	80	70	23
Gainesville	91	92	91	91	80	81	86	82	94	94	77	74	78	84	94	94	71	74	93	93	85	85	6
GWU-DC	89	90	88	88	76	77	83	81	86	88	66	67		68		87		53	87	85	82	78	18
Honolulu	97	97	87	86	79	78	88	89	87	86	67	69		100		100		86	88	88	84	88	1
Houston	94	95	92	92	80	80	82	81	86	87	60	58	80	77	100	89	57	49	95	94	82	79	17
Irvine	91	90	87	87	66	66	78	78	83	86	48	55		56		100		46	95	95	77	75	22
LA	96	96	84	85	77	77	89	89	91	88	70	70		71		100		56	89	89	85	82	14
Madison	93	93	89	90	82	83	87	86	94	93	81	79		77		90		69	91	89	88	85	9
Medlantic	88	89	70	72	60	62	73	73	73	73	48	48		73		75		52	98	97	71	70	24
Miami	88	88	82	80	60	57	80	82	84	81	49	49		90		100		56	98	98	76	77	21
Milwaukee	95	94	90	90	85	83	85	85	91	91	75	75		85		100		82	90	89	87	87	4
Nevada	92	92	84	84	77	77	84	86	91	90	74	77		82		96		79	89	89	84	85	8
NY City	90	90	83	83	71	71	82	82	86	87	62	62		82		85		48	93	92	80	78	20
Oakland	97	96	92	93	88	89	92	93	93	92	83	85		80		92		65	88	87	90	87	3
Portland	93	94	91	91	80	82	84	86	92	91	70	73		92		83		53	95	94	86	83	11
San Antonio	93	91	91	91	70	71	86	85	83	83	55	58		74		90		52	95	94	81	78	19
Stanford	93	93	92	92	83	83	83	83	96	91	79	74							90	88	88	86	5
Stony Brook	91	91	89	89	79	79	88	84	87	86	76	72		83		100		79	89	88	85	85	7
Torrance	91	90	89	89	76	75	86	87	85	87	64	66		94		93		67	89	89	82	83	12
Worcester	90	90	92	90	80	79	84	82	88	85	69	68							95	95	85	83	10
*Weights	1		1		1		1		1		1		1		1		1		0.5				

[1] % of AVs conducted that include study pill collections or estimates. From WHIP1141.

[2] % of ppts adherent as measured by pill count or estimate at AVs, excluding ERT -> PERT ppts. From data\ analysis not yet routinely distributed to CCs.

[3] % of ppts due for the AV who took at least 80% of their study pills.

[4] % of ppts for whom no unblinding occurred. From DSMB report not distributed to CCs.

Table 9.2 (continued)

VCC- DM Intervention - Participation, Adherence, and Retention[1]

	Session Participation						Fat Gram Scores Session 12						% Stop Inter % Stop FU[8]		AV1 w/o Inter[9]		[C-I] % Fat AV1& AV2[10]			
	% Attendance Session 12[2]		% Completion Session 12[3]		% Missed 3 Consecutive Sessions[4]		% Submitted w/Fat Score[5]		% ≤ goal[6]		(% ≤ goal) * (% collected)[7]		FU	Interv			FFQ AV1	FFQ AV2		
	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., Aug 98	Average	Rank[11]
Atlanta	69	70	92	92	13	13	85	85	72	70	61	59	2.1	2.3	1.2	1.4	10.4	9.1	9.8	11
Birmingham	66	67	91	91	15	17	84	85	66	67	56	57	2.2	6.4	5.6	5.4	8.0	7.2	7.6	16
Bowman	66	67	82	83	27	22	64	67	70	70	45	47	3.8	8.0	6.0	6.0	10.6	9.2	9.9	10
Brigham	75	74	94	92	11	10	87	86	71	71	62	61	1.0	4.1	5.4	5.2	10.6	10.0	10.3	8
Buffalo	73	73	94	94	7	2	81	81	60	60	48	48	2.2	4.6	2.2	2.4	10.4	8.8	9.6	12
Chicago	77	77	90	92	11	10	90	91	71	71	64	64	2.4	2.7	5.0	5.1	11.2	10.0	10.6	6
Iowa	75	74	99	99	3	4	96	96	78	78	75	75	1.2	1.3	3.0	3.0	12.9	11.9	12.4	1
LaJolla	73	73	88	87	16	15	79	80	66	66	52	52	4.2	4.9	4.1	3.7	10.0	7.1	8.6	15
Memphis	73	73	92	91	15	14	86	86	72	72	62	62	2.2	7.4	4.4	4.9	10.8	10.6	10.7	5
Minneapolis	78	78	94	93	14	14	91	90	71	70	64	63	1.2	2.4	1.1	1.3	12.5	10.9	11.7	4
Newark	68	68	86	86	20	21	76	76	67	67	51	51	1.4	1.7	3.5	4.5	11.1	10.1	10.6	6
Pawtucket	69	69	88	89	10	12	85	83	69	69	58	57	1.8	4.7	3.0	2.4	10.4	8.6	9.5	13
Pittsburgh	74	74	95	95	9	8	86	86	81	81	69	69	1.3	1.5	0.8	0.8	12.9	10.6	11.8	3
Seattle	74	74	92	92	15	16	80	80	77	77	62	62	2.2	1.5	1.3	1.3	12.7	11.0	11.9	2
Tucson	64	64	91	91	14	14	81	81	68	68	55	55	2.8	3.3	4.0	3.9	10.1	8.5	9.3	14
UCDavis	68	68	92	92	11	13	82	82	69	69	57	57	2.5	6.6	2.9	2.9	10.5	9.6	10.1	9

[1] Group dynamics also influence participation. Group dynamics for which we have reports include Timeliness of group formation (WHIP1110 & WHIP1118) distributed in Monthly Activity Reports.

[2] # women who attended session 12 / # women for whom session data have been key-entered. From WHIP0588. Available to CCs through WHIP0427.

[3] % women attending group sessions or completing make-up activities. From WHIP0588.

[4] % women who missed 3 consecutive sessions (completion) out of # women who have been assigned through Session 18. From WHIP1162.

[5] % of evaluated women who submitted a fat score at Session 12. From WHIP0588.

[6] % of women with fat scores = or < their fat gram goals. From WHIP0588.

[7] (% of women with fat scores = or < their fat gram goals) * (% women with fat scores recorded): % < goal assuming those not reporting a fat score are not meeting the fat gram goal.

[8] From WHIP748. Not dependent on each other; may stop intervention or follow-up independently.

[9] % AV1 without Intervention - % of women who have reached AV1 without having started intervention. From WHIP1134.

[10] [Control-Intervention] % fat FFQ AV1 and FFQ AV2. Difference between Control and Intervention % fat from FFQ based on AV1 and AV2 raw data, unadjusted for participant characteristics. Design assumption = 15% at AV1; goal as of AGM 1996 = 13%. FFQs are averaged. Data not yet routinely distributed.

[11] Rank based on [C-I] average.

Table 9.2 (continued)

NCC- DM Intervention - Participation, Adherence, and Retention[1]

	Session Participation						Fat Gram Scores Session 12						% Stop Inter % Stop FU[8]		AV1 w/o Inter[9]		[C-I] % Fat AV1& AV2[10]			
	% Attendance Session 12[2]		% Completion Session 12[3]		% Missed 3 Consecutive Sessions[4]		% Submitted w/Fat Score[5]		% ≤ goal[6]		(% ≤ goal) * (% collected)[7]		FU	Interv			FFQ AV1	FFQ AV2	Average	Rank [11]
	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., Aug 98	cum., Aug 98		
Chapel Hill	64	63	86	83	12	10	72	70	65	65	47	46	1.3	2.0	7.2	6.2	9.5	9.0	9.3	21
Chi-Rush	64	64	87	85	14	16	68	67	70	71	47	48	1.9	2.6	11.5	11.4	9.8	11.8	10.8	12
Cincinnati	68	68	90	91	11	10	83	83	64	61	53	51	1.5	4.3	4.4	4.3	11.0	9.4	10.2	17
Columbus	67	68	85	88	11	9	81	83	67	66	54	55	1.7	6.1	2.8	3.0	12.2	12.9	12.6	2
Detroit	62	62	84	84	10	11	73	73	61	61	44	45	3.8	7.3	3.3	4.7	11.0	8.6	9.8	19
Gainesville	71	68	91	88	15	14	88	80	80	75	71	61	2.2	3.9	6.1	6.4	12.1	10.9	11.5	9
GWU-DC	74	73	96	96	4	5	89	89	74	74	66	66	2.1	1.1	4.4	3.9	12.5	10.6	11.6	8
Honolulu	67	66	83	84	20	20	71	70	61	59	43	41	0.6	0.9	8.3	8.4	9.9	10.2	10.1	18
Houston	65	64	89	88	19	13	83	81	65	67	54	54	1.4	5.5	3.1	2.7	11.5	10.0	10.8	14
Irvine	71	72	85	86	9	13	76	78	73	75	56	59	1.3	0.4	4.2	4.1	12.7	10.6	11.7	6
LA	66	65	89	89	15	20	80	81	74	75	59	60	1.2	2.9	3.2	3.7	11.8	13.3	12.6	2
Madison	73	73	97	98	1	3	92	92	65	66	60	61	1.7	6.7	1.0	0.9	12.7	10.5	11.6	7
Mediantic	55	53	81	76	17	14	73	70	61	63	45	44	2.0	4.5	20.6	19.9	8.1	6.2	7.2	24
Miami	57	57	84	88	11	12	73	76	73	71	54	54	1.6	6.8	24.2	24.3	7.9	9.9	8.9	23
Milwaukee	77	77	95	96	5	6	90	91	75	75	67	68	0.6	1.5	1.3	3.8	12.4	11.3	11.9	5
Nevada	74	74	91	93	12	13	90	92	83	84	75	77	0.7	0.7	1.0	1.8	14.8	14.1	14.5	1
NY City	67	68	90	88	9	15	85	85	64	65	54	56	1.8	2.1	6.6	7.1	8.8	9.5	9.2	22
Oakland	79	80	94	94	6	7	85	85	75	74	64	63	1.1	1.6	7.1	6.8	12.2	12.5	12.4	4
Portland	79	79	99	99	0	0	91	92	69	68	63	62	1.4	1.1	2.6	2.3	11.7	10.1	10.9	10
San Antonio	57	55	75	73	22	24	67	64	65	65	43	41	2.8	9.7	16.2	15.8	8.8	9.8	9.3	20
Stanford	75	74	91	90	9	9	83	83	67	68	56	57	0.9	2.9	3.6	3.6	11.9	9.7	10.8	12
Stony Brook	71	68	95	90	7	7	92	85	62	62	57	52	1.1	3.7	10.6	11.8	10.7	10.0	10.4	15
Torrance	65	65	84	87	9	11	69	76	77	75	53	57	1.9	7.4	6.5	6.0	11.8	9.9	10.9	11
Worcester	75	74	91	88	9	6	84	81	74	73	62	59	1.2	4.4	8.9	5.7	11.2	9.5	10.4	15

[1] Group dynamics also influence participation. Group dynamics for which we have reports include Timeliness of group formation (WHIP1110 & WHIP1118)

[2] # women who attended session 12 / # women for whom session data have been key-entered. From WHIP0588. Available to CCs through WHIP0427.

[3] % women attending group sessions or completing make-up activities. From WHIP0588.

[4] % women who missed 3 consecutive sessions (completion) out of # women who have been assigned through Session 18. From WHIP1162.

[5] % of evaluated women who submitted a fat score at Session 12. From WHIP0588.

[6] % of women with fat scores = or < their fat gram goals. From WHIP0588.

[7] (% of women with fat scores = or < their fat gram goals) * (% women with fat scores recorded): % < goal assuming those not reporting a fat score are not meeting the fat gram goal.

[8] From WHIP748. Not dependent on each other; may stop intervention or follow-up independently.

[9] % AV1 without Intervention - % of women who have reached AV1 without having started intervention. From WHIP1134.

[10] [Control-Intervention] % fat FFQ AV1 and FFQ AV2. Difference between Control and Intervention % fat from FFQ based on AV1 and AV2 raw data, unadjusted for participant characteristics. Design assumption = 15% at AV1; goal as of AGM 1996 = 13%. FFQs are averaged. Data not yet routinely distributed.

[11] Rank based on [C-I] average.

Table 9.2 (continued)

CaD Intervention - VCC

	SAV2						AV2						AV3						AV4						Overall		
	% with Pill Count at SAV-2[1]		% ≥ 80% Adherent at SAV- 2[2]		Adherence Summary at SAV-2[3]		% with Pill Count at AV-2[1]		% ≥ 80% Adherent at AV- 2[2]		Adherence Summary at AV-2[3]		% with Pill Count at AV-3[1]		% ≥ 80% Adherent at AV- 3[2]		Adherence Summary at AV-3[3]		% with Pill Count at AV-3[1]		% ≥ 80% Adherent at AV- 4[2]		Adherence Summary at AV-4[3]		Average		Rank
	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	
Atlanta	93	93	55	55	49	49	84	84	66	66	53	53	74	75	69	69	48	49	71	68	80	71	53	43	66	65	11
Birmingham	90	87	43	44	38	38	88	87	60	60	52	51	84	83	63	61	51	50	87	83	77	65	67	52	67	63	12
Bowman	92	93	58	60	52	54	85	85	69	72	56	60	79	78	72	70	55	53	85	81	73	69	57	54	69	69	6
Brigham	88	89	64	64	57	56	86	87	73	73	58	59	76	77	75	74	57	56	73	77	63	66	44	48	68	69	7
Buffalo	92	91	64	64	56	57	85	86	66	67	54	55	80	79	72	73	53	54	86	78	84	85	62	62	71	71	4
Chicago	69	73	65	67	44	47	72	75	69	70	46	48	69	73	70	69	46	48	52	66	63	66	31	43	58	62	13
Iowa	98	98	68	69	66	67	94	94	74	74	68	69	92	93	72	73	65	67	92	94	80	76	71	69	78	79	1
LaJolla	90	90	64	65	56	58	87	88	72	72	59	60	80	80	68	70	53	54	85	73	73	73	59	50	71	69	5
Memphis	92	92	52	53	45	46	79	80	63	64	47	49	66	68	64	63	40	41	74	69	73	70	48	44	62	61	14
Minneapolis	91	91	75	75	67	68	90	90	75	76	65	67	81	83	77	78	62	64	74	76	92	86	67	64	76	77	2
Newark	74	76	54	54	37	38	86	87	59	59	43	45	72	73	52	51	34	33	79	74	60	56	29	31	57	56	16
Pawtucket	92	92	57	60	49	53	84	85	62	65	50	53	80	79	67	68	50	51	80	76	67	74	49	52	66	67	9
Pittsburgh	90	91	64	66	56	58	92	92	68	70	61	62	87	87	71	72	60	60	86	86	78	77	63	65	73	74	3
Seattle	80	81	65	66	51	52	86	86	73	74	60	61	80	80	67	67	53	53	77	80	65	69	47	53	67	68	8
Tucson	68	69	56	58	36	38	72	74	69	69	45	47	66	67	68	67	42	41	62	60	89	74	52	42	60	59	15
UCDavis	91	92	58	59	52	53	86	86	67	69	56	58	78	80	63	66	47	50	61	70	74	69	40	45	64	66	10

[1] % of visits conducted that include study pill collections or estimates. From WHIP1143.

[2] % of ppts adherent as measured by pill count or estimate at visit. From data analysis not yet routinely distributed to CCs.

[3] % of ppts due for the visit who took at least 80% of their study pills. From data analysis not yet routinely distributed to CCs.

Table 9.2 (continued)

CaD Intervention - NCC

	SAV2						AV2						AV3						Overall		
	% with Pill Count at SAV 2[1]		% ≥ 80% Adherent at SAV- 2[2]		Adherence Summary at SAV-2[3]		% with Pill Count at AV-2[1]		% ≥ 80% Adherent at AV- 2[2]		Adherence Summary at AV-2[3]		% with Pill Count at AV-3[1]		% ≥ 80% Adherent at AV- 3[2]		Adherence Summary at AV-3[3]		Average		Rank
	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	
Chapel Hill	71	73	65	66	45	47	92	93	74	77	62	67		90		51		40	68	67	15
Chi-Rush	98	97	65	67	64	63	92	92	69	66	63	61	73		75		40		71	74	3
Cincinnati	86	88	58	60	48	50	84	84	63	65	48	48		74		66		39	64	64	18
Columbus	94	94	65	70	58	62	84	85	71	73	57	60		69		89		62	71	74	4
Detroit	77	80	54	55	35	37	88	90	68	67	42	44		92		55		26	61	61	21
Gainesville	94	96	63	65	58	62	84	85	72	72	59	59	74	78	61	73	43	56	67	72	8
GWU-DC	87	89	60	62	52	55	86	85	69	69	56	56	90	82	61	66	42	51	67	68	14
Honolulu	83	86	62	63	47	51	89	91	74	75	61	65	83	94	50	69	39	65	65	73	6
Houston	90	88	70	70	54	52	90	90	77	76	59	57	77	84	80	71	42	43	71	70	12
Irvine	35	38	52	60	15	21	78	86	77	80	51	60		76		77		56	51	62	20
LA	67	72	56	60	35	41	67	75	70	75	40	49		79		68		37	56	62	19
Madison	95	95	61	62	58	59	84	86	67	69	56	59		77		73		54	70	70	11
Mediantic	87	91	51	49	44	44	86	87	51	54	42	45		79		43		33	60	58	24
Miami	91	90	49	49	40	39	89	90	54	52	42	39		87		85		52	61	65	17
Milwaukee	94	93	68	67	64	62	88	91	79	76	67	67		87		83		70	77	77	2
Nevada	94	98	61	60	57	58	86	88	75	75	64	66		81		65		53	73	71	9
NY City	88	87	46	49	40	41	78	78	67	69	49	50		64		67		39	61	60	23
Oakland	97	98	75	75	72	73	92	92	72	75	66	68		89		78		66	79	79	1
Portland	90	90	67	69	59	62	84	84	75	73	60	58		84		72		55	73	72	7
San Antonio	92	93	58	63	43	50	84	83	68	68	49	49	88	81	50	64	35	44	63	66	16
Stanford	53	59	78	79	40	46	92	91	79	81	69	70		93		79		65	68	74	5
Stony Brook	95	96	59	60	55	57	81	83	61	65	48	53		83		76		59	66	70	10
Torrance	92	94	58	60	52	54	86	89	66	61	53	50		79		81		55	68	69	13
Worcester	91	91	56	57	50	51	84	85	55	59	44	49		62		60		32	63	60	22

[1] % of visits conducted that include study pill collections or estimates. From WHIP1143.

[2] % of ppts adherent as measured by pill count or estimate at visit. From data analysis not yet routinely distributed to CCs.

[3] % of ppts due for the visit who took at least 80% of their study pills. From data analysis not yet routinely distributed to CCs.

Table 9.2 (continued)

Outcomes Analysis - VCC

	Form 33 Collection						Documentation						Local Adjudication						Overall Timeliness		
	Form 33: % Collected for CT		Form 33: % Collected for OS[1]		Form 33D: % Collected[2]		% Provider visits for which documents requested[3]		% Cases assigned to local adjudication[4]		% Cases assigned within 6 weeks[5]		% Assigned cases adjudicated		% Adjudicated within 14 days[6]		% Agreement with Central Adj.		% Cases closed within 14 weeks of Form 33[7]		Rank[8]
	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	
Atlanta	91	91	87	85	92	88	98	98	67	73	49	40	92	96	84	82			30	27	12
Birmingham	95	97	77	82	93	96	91	94	62	71	35	39	77	85	90	93			13	20	16
Bowman	90	91	94	95	96	97	99	99	77	86	44	41	93	95	44	53			38	39	11
Brigham	96	96	95	94	99	99	98	100	80	86	45	40	89	97	46	52			24	22	15
Buffalo	92	93	93	93	98	99	100	99	91	92	70	69	99	99	86	88			62	75	1
Chicago	91	91	93	94	74	66	93	93	58	71	32	37	98	96	94	90			30	26	13
Iowa	98	99	95	96	95	97	100	99	88	91	59	61	93	96	47	51			48	55	6
LaJolla	90	90	83	86	98	96	100	100	96	95	81	80	69	69	47	46			55	55	5
Memphis	89	89	83	86	84	90	96	99	60	69	72	49	90	95	74	81			24	24	14
Minneapolis	86	87	85	88	88	91	99	99	83	86	58	60	98	99	54	56			39	44	8
Newark	85	86	91	89	80	86	99	99	74	75	56	56	94	97	58	62			36	44	9
Pawtucket	93	93	86	90	92	95	98	99	92	89	70	69	99	99	70	73			55	59	3
Pittsburgh	94	94	80	79	91	97	98	100	85	88	63	61	99	99	94	95			40	44	10
Seattle	95	95	95	96	96	99	98	98	87	92	50	54	99	100	92	93			49	57	4
Tucson	91	91	91	90	98	97	98	98	84	85	55	54	97	97	60	63			47	47	7
UCDavis	93	93	94	94	98	99	100	100	95	92	57	59	100	100	97	97			58	63	2

[1] Initial Form 33 mailings from CCC to OS participants was delayed approximately 6 months. From WHIP1257.

[2] Only Form 33, ver. 3 starting March 1996 require Form 33D. From WHIP1257.

[3] Excludes closed cases for which no documents were requested. Derived from WHIP1258.

[4] % cases assigned of those for which documents were requested. Derived from WHIP 1263.

[5] % cases assigned within 6 weeks or have been waiting less than 6 weeks but not yet sent to local adjudication. Derived from WHIP1263 and WHIP1264.

[6] % adjudicated within 14 days or have been waiting less than 14 days but have not yet been adjudicated. Derived fromWHIP1263 and WHIP1264.

[7] % closed within 14 weeks of Form 33 or have been waiting less than 14 weeks from Form 33. Derived from WHIP1262 and WHIP1266.

[8] Rank based on overall timeliness.

Table 9.2 (continued)

Outcomes Analysis - NCC

	Form 33 Collection						Documentation						Local Adjudication						Overall Timeliness		
	Form 33: % Collected for CT		Form 33: % Collected for OS[1]		Form 33D: % Collected[2]		% Provider visits for which documents requested[3]		% Cases assigned to local adjudication[4]		% Cases assigned within 6 weeks[5]		% Assigned cases adjudicated		% Adjudicated within 14 days[6]		% Agreement with Central Adj.		% Cases closed within 14 weeks of Form 33[7]		Rank[8]
	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	
Chapel Hill	94	95	90	91	92	99	100	100	53	64	30	26	99	100	85	90			46	42	12
Chi-Rush	97	96	78	79	98	98	96	99	83	67	67	53	70	84	47	63			50	48	9
Cincinnati	89	88	87	84	76	82	92	96	50	65	34	36							37	36	17
Columbus	93	93	96	95	90	94	99	99	56	75	21	37	85	93	57	68			34	40	15
Detroit	70	72	85	86	69	77													35	36	16
Gainesville	96	96	91	93	91	95	99	100	78	81	47	49	97	96	85	87			64	60	4
GWU-DC	97	96	90	88	89	93	97	100	64	75	44	44	97	97	96	98			50	54	8
Honolulu	89	89	91	92	97	98	96	97	81	89	61	56	94	93	84	79			58	58	5
Houston	80	79	88	85	57	64	95	97	25	49	37	36	98	75	98	78			13	30	18
Irvine	80	84	84	86	82	90	98	99		28	33	18							62	28	19
LA	87	88	94	93	98	98	98	99	78	83	47	45	100	99	81	81			63	65	3
Madison	98	98	97	96	99	99	95	97	89	94	72	76	96	96	58	60			76	82	1
Mediantic	91	92	74	78	83	98	95	98	45	53	44	43	92	84	50	68			22	23	23
Miami	66	68	78	76	14	23	94	96	38	57	36	40	80	74	45	74			10	42	14
Milwaukee	98	97	98	95	98	100	96	100	85	86	40	48	85	90	99	100			46	55	7
Nevada	98	98	96	96	99	100	96	97	67	73	29	23	89	89	61	63			50	47	10
NY City	92	92	79	78	76	85	99	99	38	66	32	15	95	71	63	46			8	27	21
Oakland	96	96	93	90	95	99	98	98	77	76	15	24	90	93	44	52			21	24	22
Portland	92	92	90	89	84	92	98	98	29	41	31	28	56	71	49	60			23	18	24
San Antonio	77	78	87	85	88	94	99	99	48	63	23	28	91	94	78	81			23	28	20
Stanford	97	97	84	94	91	98	99	98	78	79	29	36	94	98	86	87			55	57	6
Stony Brook	98	98	94	92	95	99	99	100	81	91	41	52	97	100	87	88			57	67	2
Torrance	90	89	92	89	94	90	99	99	75	77	41	32	96	92	74	72			49	42	13
Worcester	96	97	91	94	100	99	100	100	91	93	23	33	93	97	96	95			31	42	11

[1] Initial Form 33 mailings from CCC to OS participants was delayed approximately 6 months. From WHIP1257.

[2] Only Form 33, ver. 3 starting March 1996 require Form 33D. From WHIP1257.

[3] Excludes closed cases for which no documents were requested. Derived from WHIP1258.

[4] % cases assigned of those for which documents were requested. Derived from WHIP 1263.

[5] % cases assigned within 6 weeks or have been waiting less than 6 weeks but not yet sent to local adjudication. Derived from WHIP1263 and WHIP1264.

[6] % adjudicated within 14 days or have been waiting less than 14 days but have not yet been adjudicated. Derived fromWHIP1263 and WHIP1264.

[7] % closed within 14 weeks of Form 33 or have been waiting less than 14 weeks from Form 33. Derived from WHIP1262 and WHIP1266.

[8] Rank based on overall timeliness.

Table 9.2 (continued)

Central Laboratory - VCC

	ECGs % grades 1 - 3[1]		Blood % Complete[2]		4DFRs % < 4 Errors[3]		Summary Average		Rank
	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	
Atlanta	92	94	92	93	99	99	94	95	11
Birmingham	96	98	93	92	99	99	96	96	7
Bowman	95	97	97	97	100	100	97	98	2
Brigham	95	96	96	96	97	96	96	96	9
Buffalo	96	92	93	93	96	96	95	94	13
Chicago	92	96	96	96	99	99	96	97	3
Iowa	91	88	98	98	100	100	96	95	10
LaJolla	93	97	98	98	98	95	96	97	5
Memphis	91	93	90	90	97	97	93	94	15
Minneapolis	98	99	100	100	99	99	99	99	1
Newark	96	93	97	97	99	99	97	96	6
Pawtucket	91	91	93	92	98	98	94	94	14
Pittsburgh	96	94	98	98	100	99	98	97	4
Seattle	95	93	96	96	96	95	95	94	12
Tucson	90	83	94	94	94	93	93	90	16
UCDavis	95	95	98	98	96	95	96	96	8

[1] % ECGs of acceptable quality (grades 1 - 3). Derived from WHIP1023.

[2] % Complete blood aliquots, based on aliquots required for visit type. From WHIP1044.

[3] % archived 4DFRs with < 4 errors, cum. from Jan. 1, 1995. Derived from WHIP0935. Distributed to CCs quarterly.

Table 9.2 (continued)
Central Laboratory - NCC

	ECGs		Blood		4DFRs				
	% grades 1 - 3[1]		% Complete[2]		% < 4 Errors[3]		Summary		
							Average		
	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	cum., May 98	cum., Aug 98	Rank
Chapel Hill	89	90	95	95	99	99	94	95	15
Chi-Rush	98	99	93	93	93	94	95	95	10
Cincinnati	95	86	87	87	96	96	92	90	23
Columbus	94	98	91	91	97	97	94	95	11
Detroit	85	96	91	91	94	93	90	93	18
Gainesville	96	94	94	96	91	91	94	94	17
GWU-DC	86	88	98	98	98	98	94	95	12
Honolulu	94	90	98	99	99	99	97	96	9
Houston	98	92	81	80	98	98	92	90	22
Irvine	95	97	95	97	96	94	95	96	8
LA	96	97	94	95	100	100	97	98	3
Madison	93	99	99	99	100	100	97	99	1
Medlantic	93	94	91	91	84	83	90	89	24
Miami	94	96	96	96	99	99	96	97	6
Milwaukee	93	97	95	95	98	99	95	97	7
Nevada	97	97	99	99	100	100	99	99	2
NY City	92	95	98	98	92	92	94	95	13
Oakland	87	84	93	93	99	99	93	92	19
Portland	92	96	82	83	98	96	91	92	20
San Antonio	92	92	93	94	95	96	93	94	16
Stanford	97	96	96	96	100	100	98	97	5
Stony Brook	90	91	93	93	100	100	94	95	14
Torrance	100	97	96	96	100	100	99	98	4
Worcester	91	86	93	94	91	92	92	91	21

[1] % ECGs of acceptable quality (grades 1 - 3). Derived from WHIP1023.

[2] % Complete blood aliquots, based on aliquots required for visit type. From WHIP1044.

[3] % archived 4DFRs with < 4 errors, cum. from Jan. 1, 1995. Derived from WHIP0935. Distributed to CCs quarterly.

Table 9.2 (continued)

Data Management - VCC

	Timeliness of key-entry[1]		
	cum., May 98	cum., Aug 98	Rank
Atlanta	93	91	5
Birmingham	73	72	15
Bowman	92	93	3
Brigham	74	76	14
Buffalo	97	97	1
Chicago	81	82	10
Iowa	94	94	2
LaJolla	92	93	4
Memphis	70	70	16
Minneapolis	90	88	7
Newark	83	84	9
Pawtucket	80	80	11
Pittsburgh	85	86	8
Seattle	79	79	12
Tucson	91	91	6
UCDavis	76	77	13

[1] Timeliness = % data entered within two weeks. From WHIP1112. Can be run by CC as WHIP0774.

Table 9.2 (continued)

Data Management - NCC

	Timeliness of key-entry[1]		
	cum., May 98	cum., Aug 98	Rank
Chapel Hill	79	80	19
Chi-Rush	80	82	18
Cincinnati	77	78	22
Columbus	86	86	11
Detroit	78	78	21
Gainesville	96	97	4
GWU-DC	96	97	4
Honolulu	89	89	8
Houston	86	87	10
Irvine	65	66	23
LA	81	82	17
Madison	98	98	1
Medlantic	88	88	9
Miami	86	86	12
Milwaukee	92	93	6
Nevada	97	97	3
NY City	82	79	20
Oakland	85	86	13
Portland	65	66	23
San Antonio	93	92	7
Stanford	82	83	15
Stony Brook	98	98	2
Torrance	81	82	16
Worcester	85	85	14

[1] Timeliness = % data entered within two weeks. From WHIP1112. Can be run by CC as WHIP0774.

10. 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 10.1 - Publications presents current and planned publications that have been approved by the Publications and Presentations Committee.

Table 10.2 - 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.

Table 10.1
Publications

Name of Manuscript	Writing Group	Data Focus	Stage	Publisher
Informed consent in the Women's Health Initiative clinical trial and observational study	**McTiernan**, Franzi, Johnson, Manson, Nevitt, Rossouw, Taylor, Carleton	Gen.	10	Journal of Womens's Health 4(5):519-29, 1995
The Women's Health Initiative: overview of the nutrition component	**Tinker**, Rupp, Burrows, Henry, Patterson, Van Horn	Gen.	10	Nutrition and Womens Health, pp. 510-542
Women Health Initiative: Why now? What is it? What's new?	**Matthews**, Shumaker, Hunt, Bowen, Klesges, Kaplan, Ritenbaugh, Langer, Weiss	Gen.	10	American Psychlogist. 52(2):101-116, 1997 Feb.
Low-fat diet practices of older women: prevalence and implication for dietary assessment"	**Patterson**, Caggiula, Coates, Kristal, Ritenbaugh, Snetselaar, Stern, Tylavsky, Van Horn	Gen.	10	Journal of the American Dietetic Association. 96(7):670-9, 1996 Jul.
The evolution of the Women's Health Initiative: perspectives from the NIH	**Rossouw**, Finnegan, Harlan, Pinn, Clifford, McGowan	Gen.	10	Journal of the Americal Medical Womens Association. 50(2):50-5, 1995 Mar-Apr
Design of the WHI clinical trial and observational study	**Prentice**, Rossouw, Furberg, Johnson, Henderson, Cummings, Manson, Freedman, Oberman, Kuller	Gen.	10	Controlled Clinical Trials 19:61-109, 1998
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.
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
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
Measurement characteristics of the WHI food frequency questionnaire	**Patterson**, Bolton, Carter, Kristal, Tinker, Agurs-Collins	Gen.	10	
The Women's Health Initiative: Goals, rationale, and current status	**Liu**	Gen.	10	Menopausal medicine
Factors associated with insurance status among participants in the WHI	**Hsia**, Sofaer, Lillington, Zapaka, Limacher, Kiefe, Sennott-Miller, Mason, Bowen, Kemper	Gen.	9	

Table 10.1 (continued)

Name of Manuscript	Writing Group	Data Focus	Stage	Publisher
Statistical methods adjusting for restricted population and measurement error	**Wang**, Anderson, Prentice	Gen.	9	
Unresolved issues regarding HRT: The WHI and its relevance to practicing physicians	**Hall**, Howard	CT	9	
WHI halfway paper (100K paper)	**Langer**, Lewis, Trevisan, Kotchen, Hendrix, Elmer, Daugherty, Adams-Campbell	Gen.	9	
Post-menopausal bone loss and its relationship to oral bone loss	**Jeffcoat**, Redford, Reddy, Lewis, Wang	Gen.	9	Periodontics 2000
A comprehensive data management system for multicenter studies	**Anderson**, Davis, Koch	Gen.	8	
Depression as mediated by social support, life events, and sexual activity in postmemopausal non-hispanic white and latina women	**Larisch**, Talavera, Langer, Velasquez, Elder	Gen.	8	
Completeness of purchase mailing lists for identifying older women	**Falkner**, Trevisan, Wactawski-Wende	CT	8	
Health insurance as a determinant of cancer screening in WHI OS participants	**Hsia**, Limacher, Zapka, Sofaer, Bowen, Mason, Kiefe, Kemper, Lillington	OS	7	
Body weight and anthropometric measures of adiposity	Manson, Kotchen, Perri, Lewis, Johnson, Freed, Hall, Allen, Foreyt, Tinker, Noonan, Stefanick	Gen.	6	
Patterns of antihypertensive treatment and control among postmenopausal women	Wassertheil-Smoller, Manson, Wong, Lasser, Kotchen, Langer, Grimm, Black, Psaty, Anderson	OS	6	
Women's Health and the Women's Health Initiative	**Cochrane**, Hunter, Johnson, Matthews, Strickland, Wactawski-Wende, Woods	Gen.	5	
Cardiovascular and other physiological correlates of depression	**Wassertheil-Smoller**, Talavera, Campbell, Shumaker, Ockene, Robbins, Dunbar, Greenland, Cochrane	Gen.	5	
Psychosocial and behavioral correlates of moderate alcohol consumption in women	**Powell**, Hymowitz, Criqui, Ockene, Finnegan, Castro, Trevisan, Curb, Hunt, Noonan	CT	5	

Table 10.1 (continued)

Name of Manuscript	Writing Group	Data Focus	Stage	Publisher
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	Gen.	5	
Comparisons between never smokers, former smokers, and current smokers in the WHI	**Hymowitz**, Ockene, Bowen, Robbins, Brunner, Shikany, Wagenknecht, Noonan	OS	5	
The relationship between smoking status, body weight, and waist-to-hip ratio: the WHI	**Johnson**, Klesges, Cousins, Manson, Curb, Black, Liu	Gen.	5	
Patterns of use and characteristics associated with hormone replacement therapy among postmenopausal women	**Dunn**, Greenland, Lowe, LaCroix	Gen.	5	
Regional differences in stroke morbidity at baseline in the WHI	**Johnson**, Hays, Sheps, Schenken, Oberman, Limacher, Hulka, Hall, Burke, Baum, Anderson, Jeppson	Gen.	5	
Self-reported urogenital symptoms in postmenopausal women aged 50-79: WHI	**Pastore**, Wells, Hulka	Gen.	5	
Correlates of serum lypocene in older women	**Casso**, Agurs-Collins, Haines, Patterson, White	CT	5	
Labeling as a predictor of dietary maintenance	**Hopkins**	CT	5	
Correlates of serum a- and g-tocopherol in the WHI	**White**, Chen, Wilson, Shikany, Mares-Perlman, Caan, Masaki	CT	5	
Innovative Strategies for monitoring and enhancing clinic performance in the WHI clinical trial: the creation of the Performance Monitoring Committee	**Pottern**, Lund, Naughton, Trevisan, Tinker, Shumaker, Rossouw, Prentice, Brinson, Anderson, Nance, Bonk, McTiernan, Feddersen, Furberg, Kotchen, Limacher	Gen.	5	
A comparison of health behaviors and health status among lesbian, bisexual and heterosexual women enrolled in the WHI	**Valanis**, Whitlock, Charney, Bassford, Bowen, Carter	CT	4	
Correlates of endogenous sex hormone concentrations in WHI	**McTiernan**, Wactawski-Wende, Chen, Meilahn, LaVelleur, Cummings, Hiatt, Baum, Hulka, Wang	CT	4	
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	Gen.	4	

Table 10.1 (continued)

Name of Manuscript	Writing Group	Data Focus	Stage	Publisher
Determinants of fasting hyperinsulinemia	**Manson**, Weidner, LaCroix, Haan, Rodrigues, Wagenknecht, Johnson, Allen, Hendrix	Gen.	4	
The relationship of quality of social support to frequency of cancer screening behaviors among postmenopausal women	**Lane**, Frishman, Taylor, Glanz, Elam, Klaskala, Powell, Messina	Gen.	4	
Are antioxidants associated with bone mineral density in older women?	**Seeley**, LaCroix, Wactawski-Wende, Wang, Stefanick, Kritchevsky, Jackson, Haan, Csuka, Caan, Cauley	CT	3	
The relationship of dietary phytoestrogens menopausal to symptoms and major morbidity in postmenopausal women	**San Roman**, Liu, Assaf, Woods, Patterson, Judd, Caggiula, Brzyski, Burke	CT	3	
Prevalence of pelvic organ prolapse and urinary incontinence in women	**Clark**, Harris, Maddox, McTiernan, Hendrix, Varner, Chang, Barnabei, Francis	CT	3	
Hormone replacement therapy effects on the resting ECG	**Greenland**, Schwartz, Limacher, Kadish, Daugherty, Frishman	CT	3	
Special populations recruitment for the WHI: success and limitations	**Fouad**, Strickland, Wang, Thompson, Talavera, Lakin, Howard, Young, Mouton	Gen.	3	
Prevalence of silent MI	**Sagar**, Kotchen, Hoffman, Wong, Greattinger, Burke Van Voorhees, Oberman, Taylor	CT	3	
The relationship of selected dietary components and risk of adenoma and colorectal cancer among postmenopausal women: WHI	**Frank**, Garland, Agurs-Collins, Wylie-Rosette, Paskett, Khandekar, Gams, Shikany	Gen.	3	
Interactions among hormone replacement therapy and dietary fat intake on heart disease risk factors in postmenopausal women	**Chlebowski**, Stefanick, Wagenknecht, Frid, Cain, Mossavar-Rahmani, Fouad	Gen.	3	
The health impact of domestic violence in older women	**Mouton**, Rovi, Schulthiess, Payne, Furniss, Lasser	OS	3	
Risk of bacterial endocarditis in postmenopausal women undergoing endometrial biopsy	**Limacher**, Barnabei, Smith Bassford, Schatz, Linn, McNeeley	CT	3	
Sleep complaints: correlates and co-morbidities	**Kripke**, Freeman, Masaki, Brunner, Jackson, Hendrix	CT	3	

Table 10.1 (continued)

Name of Manuscript	Writing Group	Data Focus	Stage	Publisher
Effect of hysterectomy with ovarian preservation on cardiovascular morbidity and mortality	**Brzyski**, Barnabei, Barad, Giudice, Satterfield, Margolis, McNeeley, Taylor	CT	3	
Does bone mineral density predict breast cancer in an ethnically diverse population of women recruited into WHI?	**Cauley**, Chen, Johnson, Khandekar, Wactawski-Wende	Gen.	3	
Nutrient intake of women with diabetes in the WHI observational study cohort	**Tinker**, Rosal, West, Smith, Lee, Gams, Caggiula, Snetselaar	Gen.	3	
Dietary, physical activity, and exercise patterns among diabetics	**Agurs-Collins**, Adams-Campbell, Hannah, Howard	Gen.	3	
Current treatment patterns in women with hypercholesterolemia	**Manson**, Chae, Freed	Gen.	3	
The WHI sleep disturbance scale: scoring and psychometric evaluation	**Levine**, Bowen, Kaplan, Kripke, Naughton, Shumaker	Gen.	3	
Psychometric evaluation of the urinary incontinence scale	**Levine**, Bowen, Shumaker, Naughton, Kaplan	Gen.	3	
Reliability and physiologic correlates of the physical activity questionnaire in the WHI	**White**, Rodrigues, Wang, Strickland, Siscovick, Rebar, Going, Frid, Cauley, Casso, Stefanick	CT	3	
Do ethnic differences in lean and fat mass contribute to ethnic differences in bone mineral density (BMD)?	**Cauley**, Margolis, Nevitt, Snetselaar, McGowan, LaCroix, Jackson, Lewis, Ko	CT	3	
Socio-demographic determinants of folic acid intake	**Beresford**	Gen.	2	
Relationship between adherence to a low fat diet and mental health in women	**Pleuss**, Schectman, Hoelscher, Bowen, Thomson	Gen.	2	
Is a "too low" fat diet a marker of health or disease	**Gilligan**	CT	2	
Influence of race and sunlight exposure on distribution of bone density among postmenopausal women in the southeast	**Oberman**, Burke, Schenken, Limacher, Lewis, Johnson, Hulka, Hall, Baum, Hays	Gen.	2	
Baseline characteristics of the WHI-OS breast cancer survivor cohort	**Paskett**, Sherman, Anderson	OS	2	
Databased tracking and statistical models of the clinical trial recruitment process	**Creech**	CT	2	
Insulin resistance and weight change in postmenopausal black and white women	**Howard**, Passaro, Adams-Campbell	Gen.	2	

Table 10.1 (continued)

Name of Manuscript	Writing Group	Data Focus	Stage	Publisher
Physical activity and CVD in women: the role of moderate vs. vigorous exercise	**McTiernan**	OS	2	
Association of yogurt consumption and selected food groups to colorectal cancer among WHI participants in the OS	**Mossavar-Rahmani**	OS	2	
Research staff turnover and participant adherence in the WHI	**Jackson**, Chlebowski	CT	2	
Update on the WHI Clinical Trial	**Johnson**	CT	2	
Estimating normal hemogram values for post-menopausal women	**Carleton**		2	

Stage
2= Approved
3= Analysis proposed
4= Analysis in progress
5= Draft manuscript
6= Final manuscript submitted to P&P Committee
7= Final manuscript approved and sent to WHI Project Office
8= Submitted
9= In press
10= Published

Table 10.2
Ancillary Studies

Study ID	Title	Study's Principal Investigator(s)	WHI Investigator	Initial D&A Approval	Initial NIH PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Speci-mens?	Start Date	Duration	Status
1	Arterial Disease Artherosclerosis Prevention Trial	John Crouse	Greg Burke	Approved	NA	5 CCs	DM	4000	NA	NA	5 years	dropped
4	Dietary Modification and Prostate Cancer in WHI Husbands	James Shikany	Al Oberman	Approved	yes	ALL	DM Partners	10922	NA	4/1/96	5 years	dropped
5	Explanations for the Development of Fat Distaste	Pamela Green	Deb Bowen	Approved	NA	none	DM	160	NA	4/1/95	1.5 years	dropped
6	Incidence and Impact of Arthritis in Older Women	Susan Hughes	Phil Greenland	Approved	NA	none	OS	1200	NA	1/1/96	5 years	dropped
7	Effect of HRT on Cardiovascular Morbidity and Mortality in Postmenopausal Women with a low Ankle/Arm BPI	Lewis Kuller	Lewis Kuller	Approved	NA	12, 14, 16, 22, 24, 25, 45	HRT	6500	NA	asap	9 years	dropped
8	Partner's Health Study	Robert Langer	Robert Langer	Approved	NA	none	WHI Partners	1500	NA	7/1/94	15 mos.	dropped
10	Urinary Estrogen Metabolites and Breast Cancer Risk	Elaine Meilahn	Lewis Kuller	Approved	yes	All	DM	80000	NA	7/1/95	5 years	dropped
12	Empowerment/Nutritional Counseling	Charles Mouton	Norman Lasser	Declined	NA	1 CC	DM	360	NA	7/1/95	4 years	dropped
16	Lower Extremity Atherosclerotic Disease	Mary McDermott	Phil Greenland	Approved	NA	7 CCs	OS	5500	NA	7/1/95	5 years	dropped
18	WHI:FSMP DM follow-up	Jim Grizzle	Deb Bowen	Approved	yes	12,19,64	WHI women	120	NA	11/1/96	4 years	dropped
19	Coagulation Proteins, Anticardiolipin Antibodies and Stroke in Women	Anthony Orencia	Phil Greenland	Approved	NA	21,22,60	OS	782	1.2 ml	NA	4 years	dropped
20	Coronary Screening of Postmenopausal Women Using EBCT	Robert Detrano	Rowan Chlebowski	Approved	NA	63	OS	2666	NA	2/1/96	2 years	dropped
21	Effect of DM, HRT and CaD Admin on Progression of Coronary Atherosclerosis Assessed by EBCT	Robert Detrano	Rowan Chlebowski	Approved	NA	2 CCs	CT	2666	NA	NA	5 years	dropped
22	Vascular Compliance as a Predictor of Cardiovascular Disease in Postmenopausal Women	Jennifer Robinson	Richard Grimm	Approved	NA	none	CT	500	NA	NA	9 years	dropped
26	HRT and Knee/Hip Osteoarthritis	James Cerhan	Robert Wallace	Approved	yes	ALL	HRT	11374	NA	4/1/96	5 years	dropped
27	Vitamin D, Calcium, and Breast Cancer	Barbara Hulka	David Sheps	Approved	yes	ALL	ALL	2600	1.5 ml	12/1/97	5 years	dropped
28	Perspectives on Aging	S. Wassertheil-Smoller	S. Wassertheil-Smoller	Approved	yes	none	OS	NA	1.5 ml	NA	5 year follow-up	dropped
29	HRT and Cardiovascular Biomarkers Related to Oxidation Status and Platelet Function	Michael Gaziano/JoAnn Manson	JoAnn Manson	Approved	yes	none	HRT	300	NA	9/1/95	6 months	dropped
30	The Role of Endocrine Factors in the Etiology of Lung Cancer in Women	Geoffrey Kabat	S. Wassertheil-Smoller	Approved	yes	ALL	OS	67000	2.5 ml	6/1/96	4 years	dropped
32	Recruitment Techniques in getting Minority Women to participate in Breast Cancer Clinical Trials	Kathryn Boe	Robert Langer	Approved		none	NA	400	NA	NA		dropped
35	Risk Factors for Fatigue in Women Ages 50 to 75	Arthur Hartz	Jane Kotchen	Approved	yes	21	CT	1200	NA	1/1/96	3.5 years	dropped
36	Hormone Replacement Therapy and Changes in Mammographic Density	Barbara Hulka	Anne McTiernan	Approved	yes	ALL	HRT	NA	NA		9 years	active
37	Lipid Markers of Atherosclerotic Disease in Post Menopausal Women	JoAnn Manson	JoAnn Manson	Declined	NA	12,15,22	OS	NA	NA	9/1/96	NA	dropped
38	Hemostatic/Thrombotic and Genetic Markers for Coronary Disease in Postmenopausal Women	Paul Ridker	JoAnn Manson	Declined	NA	12,15,22	OS	NA	NA	9/1/96	NA	dropped
41	Metabolism of Lipoprotein and HRT	Joel Morrisett	John Foreyt	Declined	NA	none	All	24	blood	10/1/95	5 years	dropped
42	Impact of Insurance Status on Health Outcomes and Health Services Utilization in the WHI	Judith Hsia/Shoshanna Sofaer	Vallery Miller	Declined	NA	ALL	OS	All	NA	NA		dropped

Table 10.2 (continued)

Study ID	Title	Study's Principal Investigator(s)	WHI Investigator	Initial D&A Approval	Initial NIH PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Speci-mens?	Start Date	Duration	Status
43	Decrease of Bone Mass in Older Women	William Goodman	Howard Judd	Declined	NA	none	CT	362	blood, urine	10/1/95	4 years	dropped
45	Response Set Biases in Dietary Self-Report in the WHI DM	James R. Hebert	James R. Hebert	Approved	yes	14, 16, 21, 30, 48, 49, 50, 53, 65, 67,	DM	1350	NA	8/1/96	2 yesrs	dropped
46	Prostate & Colorectal Cancer in WHI Dietary Arm Husbands	Albert Oberman	Al Oberman	Approved	yes	All	DM Partners	34200	NA	12/1/96	5 yesrs	dropped
49	Applying Creative Self-Monitoring in the WHI	Yasmin Rahmani	Yasmin Rahmani	Declined	NA	none	DM		NA		NA	dropped
51	Cross-Sectional & Longitudinal Evaluation of Bone Quality	Adrian LeBlanc	John Foreyt	Declined	NA	none	OS	400				dropped
53	A Prospective Study of Diet and Hormones in the Development of Prostate Cancer	Geoffrey Kabat	S. Wassertheil-Smoller	Declined	NA	20	OS	17500	blood, urine	4/1/97	4 yesrs	dropped
54	Women & Minority Recruitment / Retention: A Community-Based Intervention	Mona Fouad	Al Oberman	Declined	NA	none	DM	400	N/A	10/1/96	4 yesrs	dropped
55	Predictors of Participation Among Latinos in Clinical Trials	Gregory Talavera	Gregory Talavera	Approved	yes	4	All	17270	N/A	9/1/96	4 yesrs	dropped
61	Longitudinal Assessment of Memory Functioning in the WHI Clinical Trial	Beth Ober	Mary Haan	Approved	yes		HRT	110	N/A		6 years	dropped
64	Examine Mammography Sensitivity in WHI Women	John Foreyt		Declined			CT	600			3 years	dropped
66	Quantitative, Patient-Specific serially comparable (QPS) mammography	Joel D. Morrisett/Paul E. Sovelius	John Foreyt	Declined		none	All	5409	10ml	4/1/97	5 years	dropped
59	Prevalence and Natural History of Autoimmune Thyroid Disease (AITD) in Postmenopausal Women	Margita Zakarija		Declined		none	OS	2200	5ml	10/1/96	9 years	dropped
77	HRT Decision Project	David Kerner	Robert Langer	Declined		none	OS	160	N/A			dropped
9	Osteoporosis and Oral Bone Loss	Cora E. Lewis	Al Oberman	Approved	NA	none	OS	650	NA	7/1/95	7 years	funded
11	Validation and Exploration of Sleep and Mood Predictors	Daniel Kripke	Robert Langer	Approved	NA	none	OS	600	urine	7/1/94	5 years	funded
13	Prevalence and Correlates of Lumbar Spinal Stenosis	Lewis Kuller	Lewis Kuller	Approved	NA	none	CT	150	NA	ASAP	12 years	funded
14	High Density Lipoprotein Metabolism	Scott Going, Tamsen Bassford	Tom Moon	Approved	NA	none	OS	200	NA	7/1/94	2 years	funded
15	The Relationship between Osteopenia and Periodontitis	Jean Wactawski-Wende	Maurizio Trevisan	Approved	yes	none	OS	1300	NA	NA	4 years	funded
17	Domestic Violence in Older Women	Charles Mouton	Norman Lasser	Approved	yes	none	OS	1000	NA	10/25/94	2 years	funded
24	Cross-ethnic Comparisons of Skeletal Health of Postmenopausal Women in San Diego County	Diane Schneider	Robert Langer	Approved	yes	none	OS	168	NA	1/3/95	2 years	funded
25	Ankle-Arm Blood Pressure Index Measurement	Kamal Masaki	David Curb	Approved	yes	none	OS	2700	NA	7/1/95	2 years	funded
31	Eye Care Use	Robert Kleinstein	Al Oberman	Approved	yes	none	OS	300	NA	NA		funded
33	The Association of HRT with Abdominal and Total Body Fat in Postmenopausal Women	Charlotte Mayo	Al Oberman	Approved	yes	none	OS	690	NA	7/31/95	6-8 months	funded
34	Femoral Morphology: Ethnic Differences and Effect of HRT	Dorothy Nelson	Susan Hendrix	Approved	yes	none	CT	400	NA	5/1/96	4 years	funded
39	The Effects of HRT on the Development and Progression of Dementia	Sally Shumaker	Curt Furberg	Approved	yes	all except #18	HRT	4800	NA	3/1/96	6 years	funded

Table 10.2 (continued)

Study ID	Title	Study's Principal Investigator(s)	WHI Investigator	Initial D&A Approval	Initial NIH PO Approval	IDs of Other Participating Clinics	Study Population	Sample Size	Specimens?	Start Date	Duration	Status
40	Ethnic and age differences in use of Mammography	S. Wassertheil-Smoller	S. Wassertheil-Smoller	Approved	yes	none	All	All	NA	NA	NA	funded
44	Estrogen and Vaginal pH	Anthony Schaeffer	Phil Greenland	Approved	yes	none	HRT	100	vaginal fluid	asap	NA	funded
47	Effect of diet intervention on motivation to make other health-related changes	Langer/Lo	Robert Langer	Approved	yes	none	DM	150	NA	5/1/96	1 year	funded
48	Prostate Ca Survey of Spouses of WHI Screened Women	Sylvia Smoller	S. Wassertheil-Smoller	Approved	yes	none	All	1607	NA	2/1/96	5 / Mo.	funded
50	Nutrition Practice Guidelines for Maintaining Low-Fat Dietary Change in Post Menopausal Women	Beth Burrows	Ross Prentice	Approved	yes	none	DM	200	NA	10/1/96	1 yr	funded
56	Behavioral and psychosocial predictors of dietary change in postmenopausal women	Joan Pleuss	Alice Thomson	Approved	yes	none	DM	260	N/A	9/1/96	2 yesrs	funded
57	Hispanic Women's Advocacy and Retention Strategies	Cheryl Kitenbaugh	Cheryl Ritenbaugh	Approved	yes	none	OS	120	N/A	9/1/96	2 yesrs	funded
67	Prevalence and Natural History of Autoimmune Thyroid Disease is Postmenopausal Women	Marjita Zakarija	Marianna Baum	Approved	NA	none	OS					funded
60	Fat Intake in Husbands of WHI Dietary Arm Participants	James Shikany	Al Oberman	Approved	yes	none	DM Partners					funded
65	Incidence of Benign breast disease in the DM CT - Pilot	Tom Rohan	Anne McTiernan	Approved	yes	all	DM	200	N/A		1.5 years	funded
70	The Prevalence & Prognostic Importance of Myocardial Ischemia During Daily Life, & its Relationship to Migraine Status:WHI	David Sheps	David Sheffield	Approved	yes	10	OS	3200		7/1/97	3 years	funded
78	Community Strategy to Retain Women Enrolled in Research	Mona Fouad		Approved		none	DM+HRT	40	N/A	7/1/97	3 months	funded
68	Coronary artery calcification detected with Ultrafast CT as an indication of CAD in OS participants	Judith Hsia	Judith Hsia	Approved	yes	51	OS	782		1/1/97	8 years	Not an AS
62	Prevention of age-related maculopathy in the WHI HRT CT: WHI-SE	Mary Haan	Mary Haan	Approved	yes		HRT	3300	N/A		9 years	dropped
69	Birth Place and CVD Risk in Women	Judy Wylie-Rosett		Approved		none	OS					pending submission
71	Assessing Stages of Change in Postmenopausal Women Enrolled in the Dietary Modification Arm if the WHI	Amy Brewer	William Applegate	Declined		5	DM	250		7/1/97	8 years	dropped
72	Ethnicity, Body Composition, Bone Density and Breast Cancer	Zhoa Chen	Cheryl Ritenbaugh	Approved	yes	none	OS	800		9/1/97	5 years	pending submission
73	Psychosocial and Cultural Determinants of NIDDM in Latinas	Deborah Parra-Medina	Robert Langer	Approved	yes	3	OS	228	1 drop	5/1/97	1 year	pending submission
74	The Effectiveness of Individual Versus Group Behavioral Strategies to Increase Participants Adherence	Lois Wodarski	Maurizio Trevisian	Approved	yes	none	DM	50		7/1/97	3 months	pending submission
52	Endogenous Sex Hormones and Breast Cancer in Older Women	Anne McTiernan	Anne McTiernan	Approved	yes	All	OS	782	2ml	2/1/97	4 yesrs	under review
58	Enrollment of Hispanic Women in Prevention Trials	Edward Trapido	Marianna Baum	Approved	yes	none	All	120	N/A	9/1/96	3 yesrs	under review
63	Development and Evaluation of Eating Style Index	Pam Haines		Approved	yes		OS	800		9/30/96	2 years	under review

Table 10.2 (continued)

Study ID	Title	Study's Principal Investigator(s)	WHI Investigator	Initial D&A Approval	Initial NIH PO Approval	IDRs of Other Participating Clinics	Study Population	Sample Size	Speci-mens?	Start Date	Duration	Status
75	Adherence to Dietary Modification in the WHI	Milagros C. Rosal	Judith Ockene	Approved		6	DM	480		9/1/97	5 years	under review
76	Tailored Messages to Enhance Adherence of Older Women to Dietary Programs for Breast Cancer control	Rowan Chlebowski	Linda Lillington	Approved	yes	none	DM	28	N/A			under review
79	How a Low Fat Diet is Related to Adiposity and Body Fat Distribution	Judith Wylie-Rosett	S. Wassertheil-Smoller	declined		none	OS	300	N/A			under review
80	Combine Effect of HRT and Heritable Prothrombotic Mutations on the Risk of Deep Venous Thrombosis (DVT) and Pulmonary Embolus (PE)	Bruce Psaty	Bruce Psaty	Approved	declined	none	HRT	1000	1 Aliquot	4/1/97	2 years	dropped
81	Abnormal Androgeneic Hair Growth in Postmenopausal Women	Ruth Freeman	S. Wassertheil-Smoller	Declined		none	DM+HRT+OS	500	N/A			dropped
82	Extension of Bone Mineral Density Assessment in WHI Native American Women	Zhao Chen	Cheryl Ritenbaugh	Approved	yes	none	OS	200	N/A		4 years	under review
83	Hemostatic, Thrombotic, and Genetic Markers for Coronary Events in Post Menopausal Women	Paul Ridker	David Siscovick	declined	yes	none	OS	1300	2ml		5 years	dropped
84	Apollpoprotein E genotype, ERT use, and fat-soluble vitamin intake: Effects on Cognitive Function in Older Women	Julie E. Dunn	Phil Greenland	Approved	yes	none	DM+OS	260	30ml	11/1/97	1 year	funded
85	Brain Imaging with (F-18)-Fluorometatyrosine in Post-Menopausal Women on or off Hormonal Replacement Therapy - Implications for Schizophrenia	Thomas E. Nordahl										
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									
87	The Effect of Dietary Change on Blood Flavonold and F2-Isoprostane Levels	Michael Simon	Susan Hendrix	declined	declined	none	DM	236	1ml x 2	12/1/98	2 years	dropped
88	Cholesterol distribution in lipoprotein particles in WHI Dietary Modification Intervention participants consuming a low-fat dietary pattern compared to Comparison participants consuming their usual fat intake	Lesley Tinker	Ross Prentice	declined	declined	12	DM	30	1ml x 2			dropped
89	Effect of HRT on plasma homocysteine concentration	Selhub and Manson	JoAnn Manson	declined	declined	none	HRT	700	.6ml x 2	7/98	5 years	dropped
90	Biochemical and genetic determinants of fracture in postmenopausal women	Cummings and Jamal	Charles Kooperberg	approved	approved	none	OS	910	1.8ml x2	2/1/98	3 years	pending
91	Alterations in calcium and calcitropic hormone levels in 4 ethnic groups in response to CaD supplementation: Possible effect modulation by VDR phenotype	Gayle Lester		declined	declined		CT					dropped
92	Fasting glucose in baseline plasma from all CT participants	Barbara Howard					CT					
93	The Epidemiology of Venous Disease	Michael Criqui		approved	declined		OS	725		4/1/98	1 year	

Table 10.2 (continued)

Study ID	Title	Study's Principal Investigator(s)	WHI Investigator	Initial D&A Approval	Initial NIH PO Approval	ID#s of Other Participating Clinics	Study Population	Sample Size	Speci-mens?	Start Date	Duration	Status
94	The Effect of Lowfat Dietary Modification on Markers of Bone Turnover and Bone Mineral Density	Rebecca Jackson		declined			DM	80				dropped
95	Work organization, psychological distress, and health among minority older women	Beatriz Rodriguez		Approved		none	OS	500		1/1/98	1 year	pending
96	Longitudinal Insulin Sensitivity and Postmenopausal HRT	Daryl Cottrell		declined		none	OS	75				pending
97	Modeling serum markers for cost-effective ovarian cancer screening	Garnet Anderson		Approved	yes	all	OS	720	.5ml	4/1/99	4 years	under review
98	Bone mineral density as a predictor for periodontitis	Jean Wactawski-Wende		Approved		none	OS	1000	2T	5/1/99	3 years	pending
99	GENNID Study	Rowan Chlebowski		Approved	yes	none	ALL	40	40 ml	9/1/98	15 months	pending
100	Genetic, Biochemical and Behavioral Determinants of Obesity	Jennifer Hays		Approved	yes							
101	Women's Health Oral History Project	Catherine (Kit) Allen		Approved	yes							

OVERVIEW OF MEASURES ON FORMS 37 AND 38 WOMEN'S HEALTH INITIATIVE

This document provides an overview of the measures in Forms 37 and 38 for the Women's Health Initiative. More detailed documentation is available upon request. Investigators should be aware that most of the measures in Forms 37 and 38 were designed for analysis through aggregate scores. Thus, multiple items yield single scores for analyses. Analysis and interpretation of individual items is not appropriate. The CCC staff has detailed information for scoring for all scales. Following are brief descriptions of the concepts and measures. Not all measures described here have defined algorithms.

Depression

Depression is more common among women than among men, but population based studies of depression in postmenopausal women are rare. Measures of depression were included in the WHI to determine whether there is an association between depression, morbidity and mortality. In addition, depression may occur as a consequence of chronic illness. Further, depression may be associated with retention in the study.

Depression is measured in two different ways. In Form 37, there are nine items taken from the medical outcome study, Short Form 36 (Burnman et al, 1988). These items present a brief screening test for depression and mood disorders that have been validated in a large study of office-based practices. In Form 37, these are items 101.1-102.1. In Form 38 they are items 55.1-57.1. These items are a shortened version of the Center for Epidemiological Studies Depression Scale (CES-D). The CES-D has been used in population based studies and has been shown to be a valid and reliable measure of depressed mood (Weissman et al, 1977).

Cognitive Functioning

Cognitive functioning is measured with a modified mini-mental state exam (MMSE). The measurement of cognitive functioning is important because of the keen interest in declines in mental performance with age. Hormone replacement therapy may prevent mental changes in older women although studies are inconsistent. In addition, the complex demands of participation in the WHI may be difficult for women with cognitive limitations. The MMSE is an 18-item interviewer administered test that appears as Items 1-18 in Form 39. The MMSE is commonly used in clinical research studies. It assesses serious problems in mental performance but has less accuracy to detect variations among adults without central nervous dysfunction. This form is only used in women 65 years and older participating in HRT. For more information contact the WHI-MS investigators.

Life Events

A variety of studies have shown that people who have experienced life changes may be more susceptible to chronic illness and to death. Life events are an indicator of life stress. In order to evaluate life events, the WHI includes measures from the Alameda County

Epidemiologic Study (Berkman and Syme, 1979). These items were later modified for the Beta Blocker Heart Attack Trial (BHAT), a study of the post-MI patients (Ruberman et al, 1984). In order to evaluate life events, 11 items with three-point intensity rating were included. These appear as Items 89-99 in Form 37 and Items 44-54 in Form 38.

Social Support

Supportive interpersonal relationships have been shown to be an important predictor of morbidity and mortality. Social support may work in at least two different ways. First, those with good support systems may be more protected from chronic illnesses. The second possibility is that social support may "buffer" stress from life events (Shumaker and Hill, 1991). In order to evaluate social support, a questionnaire from the Medical Outcomes Study has been included in Form 37 (Items 1-9). The questionnaire is designed to assess the amount of social support the patient has available. The nine questions ask respondents to indicate how often each of nine different types of support is available to them. Responses are scored on a five-point scale ranging from "none of the time" to "all of the time." The nine questions form an overall score and four subscales: emotional/informal support, affection, tangible support, and positive social interaction (Sherbourne and Stewart, 1991).

Social Integration

Items 10-14 of Form 37 measure the number and identity of people in one's life and provide an index of how connected the respondent is with other people. Item 10 has seven subcomponents that assess living arrangements. In total there are 12 different questions. The items will be used to evaluate the relationship between social integration and morbidity and mortality. The items were derived from a California Human Population Laboratory, Alameda County study (Berkman, 1984, 1986).

Care Giving

Care giving may be a particular source of social strain and stress for women. As the population ages, more of the women in the study may be assuming care giving roles. Care giving items were included to determine whether these responsibilities predict morbidity and mortality independently of other stress and social support measures. The care giving items were obtained from the Cardiovascular Health Survey (Brown et al, 1990). The information is obtained from a single two-part item in Form 37 (15).

Social Strain

Social relationships may have either positive or negative effects. Social strain is often called "negative social support." For women, strain on existing support systems might interfere with social support and could have a negative effect on health status. Social strain is measured by Items 16-19 in Form 37. The items were obtained from a measure of negative aspects of social relationships developed by Antonucci and colleagues (1989).

Optimism

Optimism represents a cluster of constructs, including perceived control, positive expectations, empowerment, fighting spirit, and lack of helplessness. Some evidence suggests that optimistic people have better outcomes from cardiovascular diseases and cancer. An optimism measure was included in the WHI to evaluate the role of optimistic outlook upon morbidity and mortality. Optimism is measured using a Life Orientation Test-Revised which is a six item scale that appears as Items 20-25 on Form 37 (Scheier and Carver, 1985).

Lack of Expression and Negative Emotions

Some evidence suggests that individuals who are unable to express negative emotions may be more prone to the development or progression of cancer and cardiovascular diseases. In order to assess the relationship between negative emotion and health outcomes, items from the Ambivalence Over Emotional Expression Questionnaire (AEQ) and Emotional Expressiveness Questionnaire (EEQ) are included as Items 26-32 in Form 37 (King and Emmons, 1990).

Hostility

The relationship between hostility and cardiovascular disease has been demonstrated in a variety of studies (Cook and Medley, 1954). Research on the type-A personality has given way to a focus on cynicism and hostility which may be the active components of personality related to heart disease. Hostility is measured using the 13-item cynicism subscale of the Cook-Medley Questionnaire (Cook and Medley, 1954) which appears as Items 33-45 on Form 37. Higher scores on the scale indicate greater levels of hostility (Barefoot et al, 1989).

Quality of Life/Functional Status

Quality of life will be evaluated using a general health status measure. The measure, SF-36 was developed for the medical outcomes study. The SF-36 is perhaps the most widely used health questionnaire in the world today. It has gone through very extensive validity and reliability evaluation. The SF-36 appears as Items 46-83 of Form 37 and as Items 1-38 on Form 38. The SF-36 provides eight quality of life subscales. These include physical functioning (Items 50-59), role limitations due to physical health (Items 63-66), role limitations due to emotional problems (Items 67-69), energy/fatigue (Items 74-78, 80-82), emotional well being (Items 75-77, 79-81), social functioning (Items 60-83), pain (Items 61, 62), and general health (Items 38, 70-73). In each of these subscales, higher scores indicate better health (Ware and Sherbourne, 1992).

Activities of Daily Living

Measures of activities of daily living describe functional independence on a variety of different domains. For the WHI study, four items describing basic activities are included. These appear as Items 84-87 on Form 37 and as Items 39-42 on Form 38.

Symptoms

Much of the minor variation in wellness is captured by reports of symptoms. The WHI questionnaires include lists of symptoms that might be reported by participants. The lists were obtained from the PEPI (Postmenopausal Estrogen/Progestin Intervention) study and from other national health surveys. Thirty-four symptoms are included as Items 88.1-88.34 in Form 37 and Items 43.1-43.34 in Form 38. For scoring, symptoms will be aggregated in several ways. Overall symptoms scores might be calculated. In addition, specific subscores might be used to create an index for HRT and DMT related symptoms (PEPI, 1995; Matthews et al, 1994).

Sleep Disturbance

The aging process is associated with changes in sleep patterns. It is also possible that sleep patterns change as a function of HRT. Sleep is also an important variable in predicting health outcomes and an important aspect of depression in older adults. In the WHI study, sleep is evaluated by Items 103-112 of Form 37 and Items 58-67 of Form 38.

Urinary Incontinence

Urinary incontinence is a significant health problem for older women. Some evidence suggests that estrogen replacement therapy may reduce or eliminate this problem. In order to evaluate urinary incontinence, seven items from the Hormone and Estrogen Replacement Study (HERS) were included. These items appear as number 113-119 on Form 37 and as Items 68-74 on Form 38.

Sexual Functioning

Sexual functioning may be affected by hormonal changes associated with the menopause. Some evidence suggests improvements in vaginal dryness with estrogen replacement therapy. In order to evaluate this issue, five items measuring sexual activity and satisfaction were included. These items appear as number 120-124 on Form 37 and numbers 75-79 on Form 38. The items ask about involvement with a partner, sexual activity, satisfaction, frequency of activity, and worries.

Sexual Orientation

The WHI study includes a single item (Number 125 on Form 37) that assesses sexual orientation. Sexual orientation is included for several reasons. For example, there have been some concerns that women whose sexual partners are primarily other women are at higher risk for breast cancer than are heterosexual women.

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