Women's Health Initiative
Clinical Trial and Observational Study

Semi-Annual Progress Report
September 1, 1998 to January 31, 1999

Prepared by
WHI Clinical Coordinating Center
Fred Hutchinson Cancer Research Center

Ross Prentice, Principal Investigator

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WHI Semi-Annual Progress Report

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Executive Summary

This report marks the successful completion of recruitment into all 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 68,135 women into the Clinical Trial (CT) and 93,726 into the Observational Study (OS).

The final CT enrollment has 27,321 women (99% of goal) in the Clinical Trial 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 32,234 (74% of cumulative goal). Current projections suggest a final CaD sample size of 35,000 to 40,000.

The age distribution of the recruited population is close to target, particularly in HRT. 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. Approximately 9.9% of HRT women have discontinued study hormones after one year and 18.5% 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 nearing their planned completion with the emphasis turning to maintenance and targeted special assistance. 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: 11.0% at Year 1, 9.9% at Year 2 and 9.7% 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 women with significant potential to further improve their adherence.

Adherence to CaD supplements is of concern as it is clearly lower than expected, with a drop-out rate of 11.7% at one year of follow-up and 18.5% at Year 2. The new tablet formulation has provided more improvement in these rates from the previous year's report of 12.4% and 20% 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 selected 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 again 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 August 31, 1998 to January 31, 1999 as well as the cumulative experience. Topics include recruitment, follow-up, intervention monitoring, safety, outcomes, data quality, study timeline, design related issues and specialized 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 in September 1998.
- Successful completion of OS recruitment on December 31, 1998.
- Continued recruitment into the CaD trial including randomizations through the second-year of follow-up.
- Implementation of an outcomes "sweep" process every six months to coincide with this reporting cycle. For example, all outcomes cases reported as of August 31 of a given year being adjudicated and closed by February 28 of the next year, to improve the timeliness of event reporting for DSMB monitoring.
- Implementation of a plan to speed reporting of deaths and adjudication of cause of death.
- Concerted efforts to formulate a plan to enhance the DM intervention with a motivational interviewing component and additional training of nutritionists.
- Attention to adherence as a continuing concern, including intensive work by the PMC to review CC performance and provide assistance to improve adherence and retention.
- Establishment of a Genetics and Biomarkers Taskforce to make recommendations about technical, ethical, and scientific aspects of performing these tests in WHI women.
- Nomination and election of WHI advisory committee chairs and members and commencement of work under the reorganized committee structure.
- Commencement of analytic work with the full baseline CT and OS dataset.
- Continued emphasis on safety monitoring and quality assurance by the PMC and the QA visit teams.

All reports summarize Clinical Center (CC) data provided to the CCC by January 31, 1999. 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 two changes in Clinical Center leadership in the past six months. Dr. Barbara Hulka, Principal Investigator of the NCC at the University of Chapel Hill has retired. Dr. Gerardo Heiss has assumed the PI role for this site. Dr. William Applegate has recently left the University of Tennessee. Dr. Karen Johnson is now the Principal Investigator in Memphis.

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	Karen Johnson, 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	Gerardo Heiss, 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 Hays, 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 MPH
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 68,135 women into the CT, 6% more than our design projection of 64,500, and 93,726 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.

2.2 HRT Recruitment

Table 2.1 – Component-Specific Enrollment status. Enrollment in the HRT trial is now complete with randomization of 27,348 women, which is 99.4 percent of our goal of 27,500.

Approximately 40% of HRT participants have had a prior hysterectomy, somewhat less than the projected proportion of 45%. Power calculations reflecting this final distribution have been conducted (see Section 3 of 1998 Annual Report). The higher prevalence of CHD risk factors in women without a uterus should partially compensate for the smaller sample size in this arm of the HRT trial.

2.3 DM Recruitment

Table 2.1 – Component-Specific enrollment status. DM recruitment ended with 48,837 women randomized as of August 31, 1998, 105% of goal.

2.4 CaD Recruitment

Table 2.1 – Component-Specific enrollment status and *Figure 2.1 - Projected and Actual CaD Randomizations at All CCs and CaD Randomizations per Quarter at All CCs.* CaD recruitment as of January 31, 1999 had reached 74% of overall goal with 32,234 women randomized. In the last six months, recruitment of women to the CaD trial has fallen off somewhat compared to the previous year. However, recruitment during the holiday period December 1998-January 1999, traditionally a difficult period for study recruitments, was similar to the previous holiday season. We now anticipate that between 35,000 and 40,000 will be randomized by the end of recruitment in August 2000. Power calculations have been repeated with updated assumptions regarding adherence and outcomes rates using projected sample sizes of 35,000 and 40,000 (Section 5, Table 5.4).

2.5 OS Recruitment

Table 2.1 – Component-Specific Enrollment Status and *Figure 2.2 - Projected and Actual OS Enrollments at All CCs and OS Enrollments per Quarter at All CCs.* Final recruitment into the OS was 93,726 which was 94% of the original goal of 100,000. The latter was set arbitrarily based on projections of the numbers of women screened but not enrolled in the CT who might be enlisted in the OS. Thus, nearly 94,000 women in the OS will be more than sufficient to support a multitude of analytic projects.

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% aged 50-54, 20% aged 55-59, 45% aged 60-69 and 25% aged 70-79 years. To facilitate adherence to these goals on a local level, recruitment to HRT and DM was closed as each age group target was met. In the HRT trial, this resulted in an age distribution that was very close to the design assumption target. The closing of younger age cells did not occur until DM targets had already exceeded goal in those cells. Therefore, the age distribution in DM is skewed towards the younger age groups, and the actual percent of women aged 70-79 is 8 percent lower than the design assumption of 25%. The same is true for the CaD trial at this time, but the age distribution in CaD may improve as the older women recruited later in the process reach their first and second annual visits and are eligible for randomization in CaD. Power calculations for all study components using the observed values were presented in Sections 3, 4 and 5 of the 1998 Annual Report.

2.7 Minorities

Table 2.3 – Ethnic-Specific Recruitment by Study Component. Nearly 28,000 minority women were recruited in the Women's Health Initiative: 12,464 (18.3% of all women) in the Clinical Trial and 15,437 (16.5% of all women) in the Observational Study. This accomplishment is attributed to concerted efforts by all Clinical Centers to reach minority participants throughout the recruitment process and focused, intensive attention on minority recruitment towards the latter months of recruitment. Over 14,000 African American, 6500 Hispanic, 700 American Indian or Eskimo and 4100 Asian or Pacific Islander were enrolled in the WHI Program, which makes the WHI an unprecedented opportunity to advance knowledge about minority women's health.

Table 2.1
Component-Specific Enrollment Status

Data as of: January 31, 1999

Study Component	N	% of Overall Goal
CT	68135	
HRT	27348	99%
Without Uterus	10739	87%
With Uterus	16609	110%
DM	48837	105%
CaD	32234	74%
OS	93726	94%

Table 2.2
Age - Specific Recruitment by Study Component

Data as of: January 31, 1999

	Total Randomized	% of Overall Goal	Age Distribution	Design Assumption
HRT (Overall)				
50-54	3426	125%	13%	10
55-59	5402	99%	20%	20
60-69	12364	100%	45%	45
70-79	6156	90%	23%	25
HRT without Uterus				
50-54	1398	114%	13%	10
55-59	1910	78%	18%	20
60-69	4851	88%	45%	45
70-79	2580	84%	24%	25
HRT with uterus				
50-54	2028	135%	12%	10
55-59	3492	116%	21%	20
60-69	7513	111%	45%	45
70-79	3576	95%	22%	25
DM				
50-54	6958	149%	14%	10
55-59	11042	118%	23%	20
60-69	22714	108%	47%	45
70-79	8123	70%	17%	25
CaD				
50-54	5070	116%	16%	10
55-59	7908	90%	25%	20
60-69	13912	71%	43%	45
70-79	5344	49%	17%	25
OS				
50-54	12384		13%	
55-59	17327		18%	
60-69	41219		44%	
70-79	22796		24%	

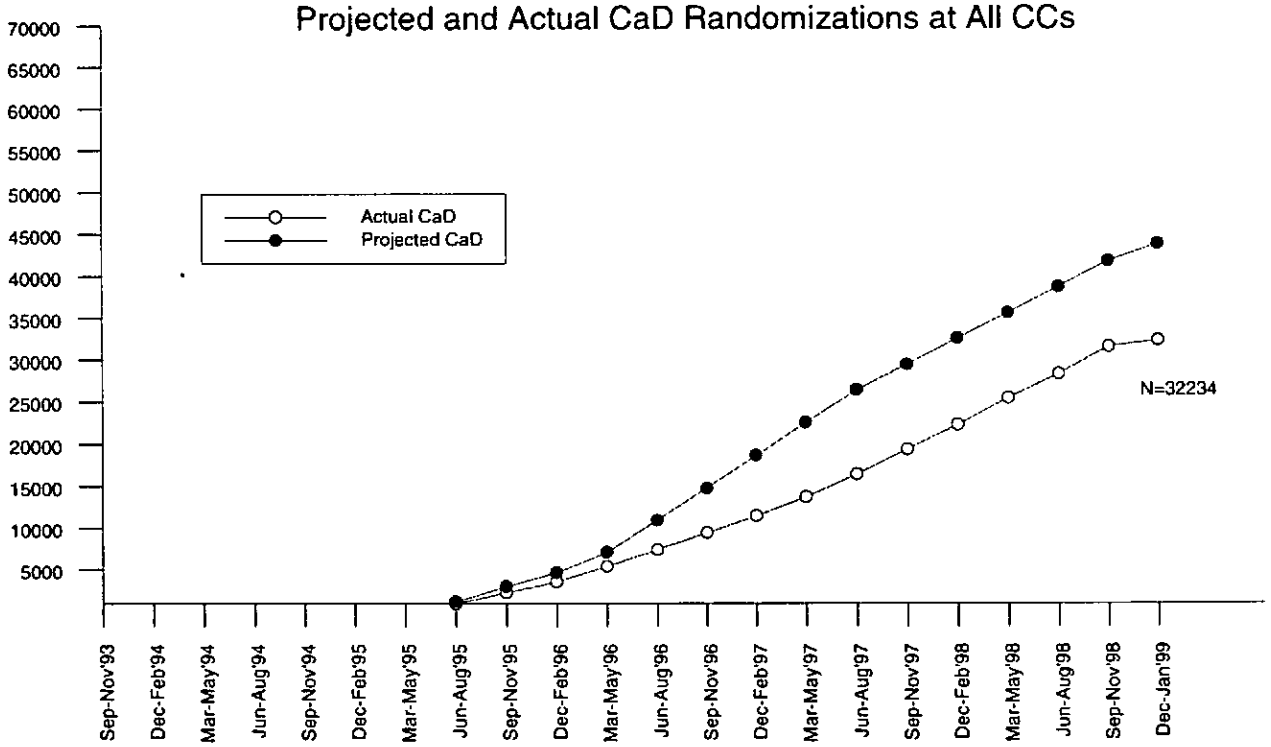
Table 2.3
Ethnic-Specific Recruitment by Study Component

Data as of: January 31, 1999

	CT		OS		Overall	
Minorities	**N**	**%**	**N**	**%**	**N**	**%**
Total Minorities	12464	18.3%	15437	16.5%	27901	17.2%
American Indian or Eskimo	293	0.4%	425	0.5%	718	0.4%
Asian or Pacific Islander	1520	2.2%	2673	2.9%	4193	2.6%
Black or African American	6988	10.3%	7644	8.2%	14632	9.0%
Hispanic	2889	4.2%	3658	3.9%	6547	4.0%
Other	774	1.1%	1037	1.1%	1811	1.1%
Whites	55520	81.5%	78014	83.2%	133534	82.5%
Unknown	151	0.2%	275	0.3%	426	0.3%
Total	68135	100.0%	93726	100.0%	161861	100.0%

Figure 2.1

Projected and Actual CaD Randomizations at All CCs



CaD Randomizations per Quarter at All CCs

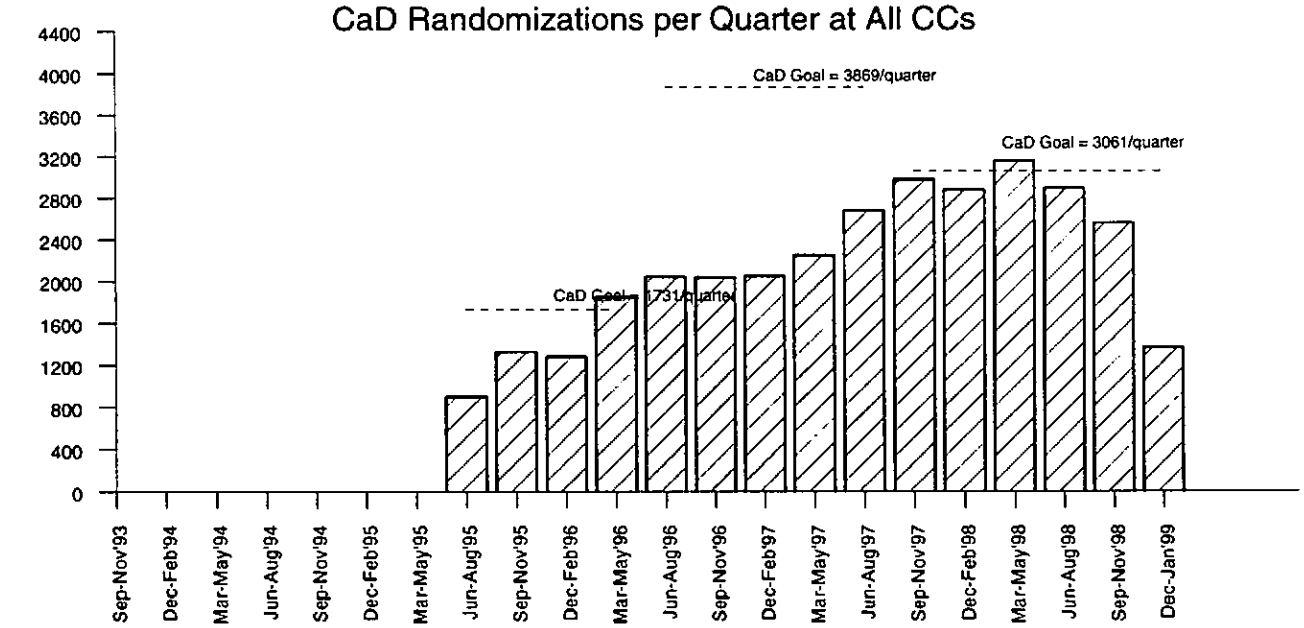
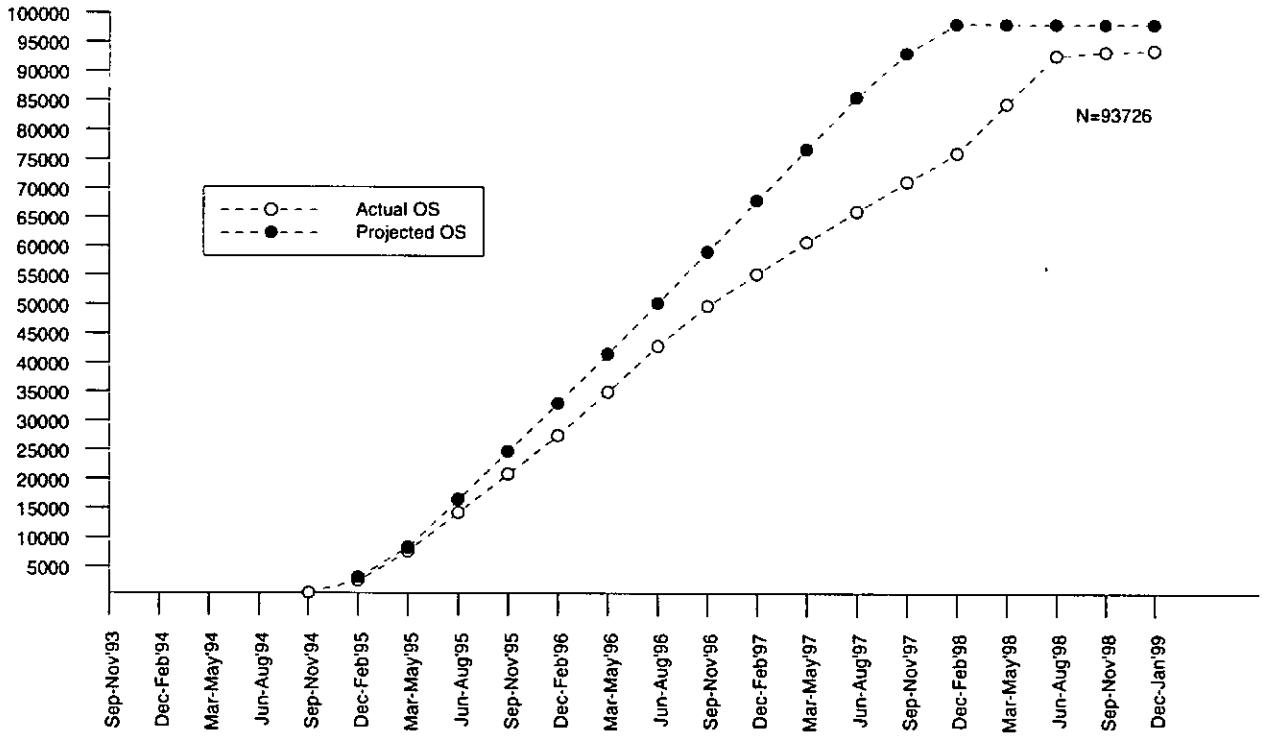
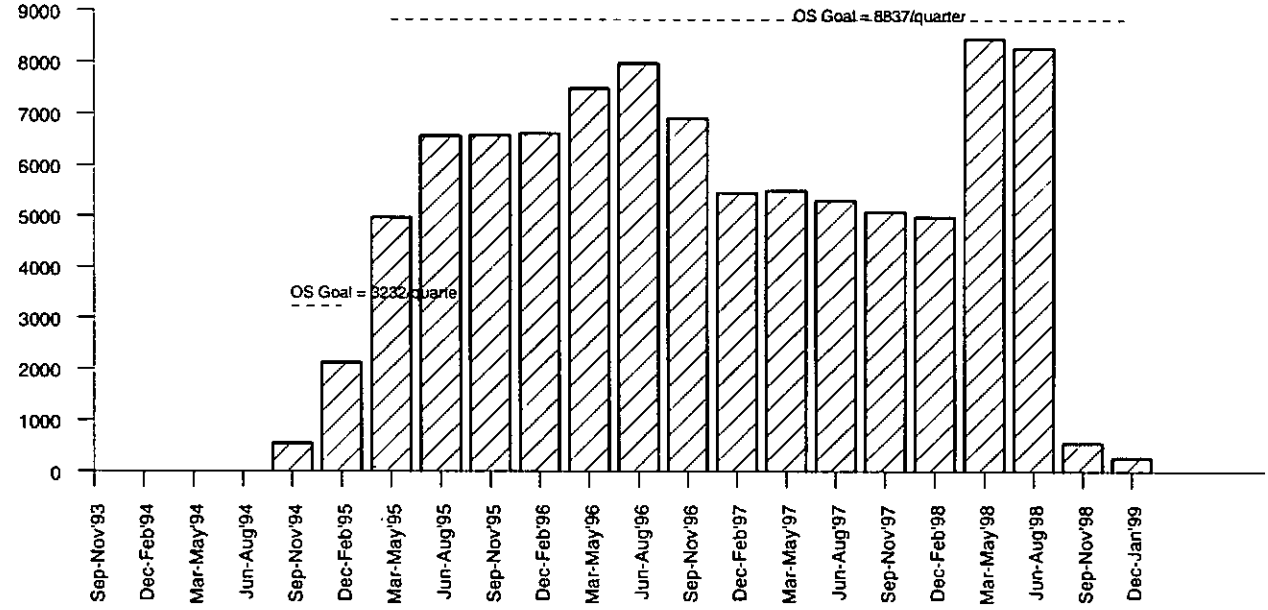


Figure 2.2

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, address possible adherence and retention issues, ascertain outcomes and promote bonding. Calculated adherence data from these telephone 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 protocol-assigned medications are shown by treatment arm for each interval for which we have adherence data. For stopping intervention and medication rates we excluded the 331 who were moved from ERT to PERT in early 1995 after our protocol change since their experience is unique in the trial. The final column is the adherence summary 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 for 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 9.9%, and our estimate for drop-out between AV-1 and AV-2 is 9.5% 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 2.5% per year; in women with a uterus it averages 1.7% per year.

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 as a binary variable indicating adherence (taking 80% or more of pills) in the preceding time interval (included in this report are the intervals from AV-1 to AV-2 and AV-2 to AV-3).

Tables 3.4 and *3.5* show numbers of HRT women, summary odds ratios (OR), separately by baseline uterine status for the time periods between AV-1 and AV-2, and between AV-2 and AV-3, as a function of various factors. Included in these analyses are only those women who were reported to be taking 80% or more of their HRT pills at the beginning of the specified interval. For brevity, analyses for randomization to SAV-1 and SAV-1 to AV-1 are not included in this report. These analyses have not changed appreciably since the last report.

Adherence among both women with a uterus and hysterectomized women is somewhat better for women having a higher family income and is noticeably poorer if the woman is of racial/ethnic minority status. Among hysterectomized women, increasing age is associated with better adherence.

Previous logistic regression analyses of HRT medication adherence have included reported breast changes. These analyses found an increased risk for non-adherence between SAV-1 and AV-1 in all women who reported breast changes at 1 year only and between AV-1 and AV-2 for hysterectomized women who reported breast changes at 1 year only. However, for AV-2 to AV-3, reported breast changes were not significantly associated with adherence. Studies of hormone replacement therapy have consistently shown breast tenderness to be a common, troublesome side effect associated with compliance.[1-3] Therefore, the current analyses included reported severity of breast tenderness at AV-1 (Form 38) rather than breast changes. *Tables 3.4* and *3.5* show that reported breast tenderness at AV-1 is significantly associated with HRT medication adherence for both hysterectomized women and women with an intact uterus during the interval from AV-1 to AV-2 and for hysterectomized women during the interval from AV-2 to AV-3. In fact, adherence at both intervals generally decreases as reported breast tenderness severity worsens, even though this factor was ascertained only at AV-1.

Table 3.4 shows that women with a uterus who reported bleeding at 1 year from randomization, or at all data collection points in the first year, have lower medication adherence for the time period between AV-1 and AV-2. Note that compared to earlier time intervals (previously reported), adherence among women receiving the six week phone call is not significantly different from those who do not receive the call.

Table 3.5 examines adherence in the time period AV-2 to AV-3 in relation to these and other

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[1] Denke MA. Effects of continuous combined hormone-replacement therapy on lipid levels in hypercholesterolemic postmenopausal women. American Journal of medicine 1995;99(1):29-35.

[2] Marsh MS, Whitcroft S, and Whitehead MI. Paradoxical effects of hormone replacement therapy on breast tenderness in postmenopausal women. Maturitas 1994;1992):97-102.

[3] Nand SL et al for the Ogen/Provera Study Group. Menopausal symptom control and side effects on continuous estrone sulfate and three doses of medroxyprogesterone acetate. Climacteric 1998;1(3):211-218.

factors. Although the data are still sparse, among women with a uterus adherent to medication during the interval from AV-1 to AV-2, bleeding pattern was not strongly related to adherence except for those women who reported bleeding at 6 weeks and 6 months (associated with higher adherence). All other factors (except breast tenderness as described above) for women with a uterus and hysterectomized women seem important primarily in the earlier months after randomization.

Baseline psychosocial variables (Form 37) were also examined in relation to medication adherence up to SAV-1 and between SAV-1 and AV-1. Psychosocial variables ascertained 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 3.6*. These analyses also include body mass index and the demographic factors listed in *Table 3.4* as control variables. The left side of *Table 3.6* 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. 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 3.6* 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 baseline factors were also examined in relation to HRT adherence. 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 3.7 - Reasons for Stopping HRT summarizes the frequency of reported reasons for stopping interventions by hysterectomy status. For all women "health problems or symptoms from the WHI intervention" is the most frequently reported reason for stopping HRT study pills.

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 (although for this current report, "breast tenderness" rather than "breast changes" were included in the logistic regression model). Reports of bleeding and breast changes by contact type are shown in *Tables 3.8* and *3.9*, 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 3.10 - 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 2177 biopsies, 85 (3.9%) yielded an abnormal result: 39 cystic, 6 adenomatous, 13 atypia and 4 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), open-label conjugated equine estrogen (CEE 0.3 mg), or a cyclic regimen as an option for short-term management of bleeding after the first 6 months. Among women with breast tenderness, adherence may increase with focused support for management of this change. We are developing additional guidelines and management strategies for women with breast tenderness. Women do receive routine materials and clinician guidance for managing breast tenderness. To further guide management, more frequent collection of data about breast tenderness is also being explored.

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. Principal Investigators, Consulting Gynecologists, and other clinicians are providing information to local health care providers about the study (via letters, presentations, and phone calls) to encourage collaborative relationships and therefore provide appropriate proactive and responsive study considerations when addressing women's individual healthcare needs.

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 during the critical first year 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 Adherence and Retention Workshops presented to all Clinical Centers in April/May 1998 and at the Special Populations Adherence and Retention Workshop in November 1998.

Table 3.1
HRT Adherence Summary

Data as of: January 31, 1999

	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]
Contact	N	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	%
6 Week	26275	24889	95	21021	80													
Semi-Annual Visit-1	27070	26359	98	22533	83	1408	5	1541	6	25163	94	988	4	1857	7	22318	89	84
Without Uterus	10627	10295	97	8677	82	528	5	685	7	9923	94	404	4	804	8	8715	88	82
With Uterus	16443	16064	98	13856	84	880	6	856	5	15240	95	584	4	1053	7	13603	89	85
Annual Visit-1	24348	23397	96	19570	81	1169	5	1368	6	21026	94	891	4	1786	9	18349	87	77
Without Uterus	9588	9151	95	7653	80	505	5	611	7	8331	93	362	4	782	9	7187	86	75
With Uterus	14760	14246	97	11917	81	664	5	757	6	12695	94	529	4	1004	8	11162	88	78
Annual Visit-2	15279	14170	93	11684	76	1411	10	1495	11	11589	89	381	3	1096	10	10112	87	68
Without Uterus	6080	5558	91	4569	75	606	10	657	12	4626	88	142	3	489	11	3995	86	66
With Uterus	9199	8612	94	7115	77	805	9	838	11	6963	89	239	3	607	9	6117	88	69
Annual Visit –3	7242	6626	91	5474	75	460	7	525	10	4914	90	163	3	453	9	4298	88	63
Without Uterus	2916	2623	90	2171	74	208	7	236	11	2004	90	63	3	213	11	1728	86	60
With Uterus	4326	4003	93	3303	76	252	6	289	9	2910	91	100	3	240	8	2570	88	65
Annual Visit –4	2657	2427	91	2069	78	152	7	161	9	1544	91	55	4	123	8	1366	89	59
Without Uterus	1117	1001	90	855	77	67	6	78	10	705	90	22	3	61	9	622	88	56
With Uterus	1540	1426	93	1214	79	85	7	83	9	839	91	33	4	62	7	744	89	62

[1] Medication rate calculated as number of pills taken divided by number of days since bottle(s) were dispensed.

[2] Adherence summary calculated as number of women consuming ≥ 80% of pills / # due for visit.

Note: Deceased women are excluded from all medication adherence calculations, but are included in the number "Due."

Table 3.2
HRT Drop-Out and Drop-In Rates by Follow-Up Time
(Design-specified values in parentheses)

Data as of: January 31, 1999

	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)	9.9%	(8.8)	9.9%	(8.8)
AV-2	10.0%	(5.9)	19.0%	(14.2)	9.1%	(5.9)	18.1%	(14.2)	9.5%	(5.9)	18.5%	(14.2)
AV-3	7.2%	(5.9)	24.9%	(19.2)	6.4%	(5.9)	23.3%	(19.2)	6.7%	(5.9)	24.0%	(19.2)
AV-4	6.2%	(5.9)	29.5%	(24.0)	7.1%	(5.9)	28.7%	(24.0)	6.6%	(5.9)	29.0%	(24.0)
Drop-Ins[4]												
AV-1	2.9%	(1.5)	2.9%	(1.5)	2.0%	(1.5)	2.0%	(1.5)	2.4%	(1.5)	2.4%	(1.5)
AV-3	4.6%	(2.9)	7.4%	(4.4)	3.3%	(2.9)	5.2%	(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 and Incidence Rate 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% per year thereafter; Drop-in rate of 2.5% per year.

Table 3.4
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[1,2]

Data as of: January 31, 1999

	HRT (N=11392)					
	Without Uterus (N=4526)			With Uterus (N=6866)		
	Non-Adherent Participants (N=851)	Adherent Participants[3] (N=3675)	OR for adherence (>80%)[4]	Non-Adherent Participants (N=1188)	Adherent Participants[3] (N=5678)	OR for adherence (>80%)[4]
Age:						
50-54[5]	189	629	1.00	231	945	1.00
55-59	182	731	1.22	291	1341	1.09
60-69	313	1534	1.38**	445	2423	1.23*
70-79	167	781	1.35*	221	969	1.05
Ethnicity:						
White	567	2926	1.00	943	4965	1.00
Black	169	464	0.62**	124	301	0.56**
Hispanic	85	158	0.47**	79	229	0.73*
Other Minority	28	119	0.88	41	165	0.84
Education:						
0-8 Yrs	34	87	1.00	30	89	1.00
Some H.S./Diploma	242	1043	0.99	253	1282	1.22
Post H.S.	568	2514	1.02	899	4277	1.09
Income:						
<20K	287	1025	1.00	304	1134	1.00
20-35K	235	1015	1.04	308	1531	1.23*
35-50K	129	732	1.35*	206	1185	1.44**
>50K	176	827	1.17	344	1724	1.29*
DM Randomized:						
No	559	2355	1.00	806	3951	1.00
Yes	292	1320	1.10	382	1727	0.94
HRT Washout:						
No	732	3142	1.00	1098	5200	1.00
Yes	119	533	1.11	90	478	1.26
Marital Status:						
Married	434	2099	1.00	675	3465	1.00
Not Married	409	1561	0.89	507	2199	0.97
Hormones Ever:						
No	323	1438	1.00	679	3357	1.00
Yes	528	2237	0.89	509	2321	0.88

(continues)

[1] Excludes ERT to PERT participants.

[2] * P-value <=.05 from Wald test.
** P-value <=.01 from Wald test

[3] Adherence defined as participants who took at least 80% of HRT medications. If a participant does not have a pill collection, she was considered non-adherent.

[4] Assuming asymptotic normality for parameter estimates

[5] Underlined levels are reference categories

Table 3.4 (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[1,2]

Data as of: January 31, 1999

	HRT (N=11392)					
	Without Uterus (N=4526)			With Uterus (N=6866)		
	Non-Adherent Participants (N=851)	Adherent Participants[3] (N=3675)	OR for adherence (>80%)[4]	Non-Adherent Participants (N=1188)	Adherent Participants[3] (N=5678)	OR for adherence (>80%)[4]
6 wk phone call						
No[5]	71	244	1.00	79	297	1.00
Yes	780	3431	0.99	1109	5381	1.12
Breast tenderness						
No tenderness	508	2597	1.00	756	4014	1.00
Mild	181	747	0.82*	270	1182	0.87
Moderate	56	181	0.68*	65	231	0.69*
Severe	15	20	0.27**	16	39	0.52*
On-Study bleeding						
No bleeding at 6 weeks				728	3658	1.00
Bleeding at 6 weeks only				36	135	0.75
Bleeding at 6 months only				67	335	1.10
Bleeding at 6 wks and 6 mnths				76	460	1.22
Bleeding at 1 year only				46	137	0.62 **
Bleeding at 6 wks and 1 year				9	33	0.83
Bleeding at 6 months and 1 year				46	232	1.11
Bleeding at 6 wks, 6 mnths, 1 yr				150	552	0.75**

[1] Excludes ERT to PERT participants.

[2] * P-value <=.05 from Wald test.
** P-value <=.01 from Wald test

[3] Adherence defined as participants who took at least 80% of HRT medications. If a participant does not have a pill collection, then she was considered non-adherent.

[4] Assuming asymptotic normality for parameter estimates

[5] Underlined levels are reference categories

Table 3.5
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[1,2]

Data as of: January 31, 1999

	HRT (N=4689)					
	Without Uterus (N=1910)			With Uterus (N=2779)		
	Non-Adherent Participants (N=347)	Adherent Participants[3] (N=1563)	OR for adherence (>80%)[4]	Non-Adherent Participants (N=415)	Adherent Participants (N=2364)[3]	OR for adherence (>80%)[4]
Age:						
50-54[5]	76	261	1.00	71	400	1.00
55-59	69	312	1.33	104	562	0.91
60-69	128	668	1.48*	160	1063	1.13
70-79	74	322	1.22	80	339	0.76
Ethnicity:						
White	267	1277	1.00	347	2104	1.00
Black	59	191	0.79	35	119	0.66
Hispanic	18	53	0.58	21	77	0.71
Other Minority	3	42	3.51*	12	64	0.91
Education:						
0-8 Yrs	9	43	1.00	11	42	1.00
Some H.S./Diploma	92	440	0.76	98	529	1.29
Post H.S.	244	1065	0.76	303	1783	1.44
Income:						
<20K	92	426	1.00	96	476	1.00
20-35K	99	455	0.92	120	625	0.94
35-50K	64	308	0.90	83	498	1.08
>50K	82	343	0.84	110	729	1.19
DM Randomized:						
No	220	980	1.00	281	1572	1.00
Yes	127	583	1.02	134	792	1.02
HRT Washout:						
No	312	1374	1.00	388	2193	1.00
Yes	35	189	1.37	27	171	1.18
Marital Status:						
Married	186	912	1.00	234	1456	1.00
Not Married	158	643	0.81	180	901	0.93
Hormones Ever:						
No	130	626	1.00	234	1401	1.00
Yes	217	937	0.84	181	963	0.89

(continues)

[1] Excludes ERT to PERT participants.

[2] * P-value <=.05 from Wald test.
** P-value <=.01 from Wald test

[3] Adherence defined as participants who took at least 80% of HRT medications. If a participant does not have a pill collection, then she was considered non-adherent.

[4] Assuming asymptotic normality for parameter estimates

[5] Underlined levels are reference categories

Table 3.5 (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[1,2]

Data as of: January 31, 1999

	HRT (N=4689)					
	Without Uterus (N=1910)			With Uterus (N=2779)		
	Non-Adherent Participants (N=347)	Adherent Participants[3] (N=1563)	OR for adherence (>80%)[4]	Non-Adherent Participants (N=415)	Adherent Participants (N=2364)[3]	OR for adherence (>80%)[4]
6 wk phone call						
No[5]	30	125	1.00	32	145	1.00
Yes	317	1438	0.93	383	2219	0.99
Breast tenderness						
No tenderness	225	1138	1.00	291	1665	1.00
Mild	84	299	0.70*	76	487	1.15
Moderate	23	69	0.58*	22	110	0.89
Severe	1	12	3.39	5	18	0.58
On-Study bleeding						
No bleeding at 6 weeks				266	1541	1.00
Bleeding at 6 weeks only				16	59	0.70
Bleeding at 6 months only				26	142	0.95
Bleeding at 6 wks and 6 mnths				23	214	1.63*
Bleeding at 1 year only				7	38	0.99
Bleeding at 6 wks and 1 year				4	17	0.76
Bleeding at 6 months and 1 year				17	74	0.77
Bleeding at 6 wks, 6 mnths, 1 yr				42	229	0.88

[1] Excludes ERT to PERT participants.

[2] * P-value <=.05 from Wald test.
** P-value <=.01 from Wald test

[3] Adherence defined as participants who took at least 80% of HRT medications. If a participant does not have a pill collection, then she was considered non-adherent.

[4] Assuming asymptotic normality for parameter estimates

[5] Underlined levels are reference categories

Table 3.6
Logistic Regression Analysis[1] of Psychosocial and Behavioral Measures on HRT Adherence[2]

Data as of : January 31, 1999

	Without Uterus			With Uterus		
	HRT Adherence from[3]:					
	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[4]	Baseline Variables[5]		AV-1 Variables[5]	Baseline Variables[5]		AV-1 Variables[5]
Number of Women	10608	7821	4526	16096	12177	6866
(a higher score indicates...)						
Social Support Construct (greater support)	1.11 *	1.02		1.04	1.10 *	
Social Strain Construct[6] (less strain)	1.07 *	1.07 *		1.09 *	1.08 *	
Optimism Construct (more optimism)	1.10 *	1.06		1.06 *	1.04	
Negative Emotional Expressiveness[6] (less negative expressiveness)	1.10 *	1.15 *		1.04	1.04	
Ambivalent Emotional Expressiveness[6] (less ambivalence)	1.05	1.03		1.01	1.03	
Hostility Construct[6] (less hostility)	1.02	1.06		1.07 *	1.07 *	
Overall Quality of Life (higher perceived quality)	1.08 *	1.02	1.08	1.07 *	1.07 *	1.10 *
Satisfaction with Quality of Life (more satisfaction)	1.10 *	1.04	1.09 *	1.10 *	1.10 *	1.10 *
Physical Functioning Construct (less limitations)	1.07 *	1.09 *	1.10 *	1.10 *	1.08 *	1.17 *
Limitations Due to Physical Health Construct (less limitations)	1.08 *	1.12 *	1.16 *	1.07 *	1.10 *	1.14 *
Limitations Due to Emotional Problems Construct (less limitations)	1.13 *	1.16 *	1.13 *	1.12 *	1.11 *	1.09 *
Health Interference with Social Activities (less interference)	1.10 *	1.13 *	1.14 *	1.07 *	1.09 *	1.11 *
Downhearted and Blue (less feeling blue)	1.15 *	1.10 *	1.11 *	1.10 *	1.08 *	1.05
Feel Worn Out (less worn out)	1.09 *	1.12 *	1.10 *	1.09 *	1.05	1.08 *
Pain Construct (less pain)	1.08 *	1.13 *	1.11 *	1.04 *	1.11 *	1.09 *
General Health Construct (better health)	1.07 *	1.09 *	1.16 *	1.07 *	1.08 *	1.16 *
Daily Living Activities Construct[6] (less disability)	0.99	1.00	1.06	1.03	1.04	1.04
Overall Symptom Construct[6] (fewer symptoms)	1.15 *	1.14 *	1.16 *	1.08 *	1.13 *	1.24 *
Life Event Construct[6] (fewer and less upsetting life events)	1.14 *	1.06	1.07	1.11 *	1.14 *	1.05
CES-D/DIS Depression Construct[6] (less depression)	1.08 *	1.09 *	1.12 *	1.07 *	1.10 *	1.04
Worried that sex will affect health[6] (less worried)	1.04	0.99	1.05	1.06 *	1.04	1.07 *

[1] The following demographic variables were included in the regression model: age, ethnicity, education, income, body mass index, hysterectomy status, and DM randomized.

[2] * Denotes statistical significance at the 0.05 level (from regression t-test)

[3] 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

[4] For descriptions of the psychosocial behavioral constructs, see Appendix A

[5] Indicates the timeframe for the psychosocial behavioral constructs used in the model.

[6] The sign of the parameter was reversed to reflect the description of the scoring.

Table 3.7
Reasons for Stopping HRT

Data as of January 31, 1999

Reasons[1]	Without Uterus (N =2260)		With Uterus (N =3342)	
Personal	159	(7%)	194	(6%)
Travel	86	(4%)	92	(3%)
Study Procedures	37	(2%)	61	(2%)
Health	914	(40%)	1206	(36%)
Experiencing health problems or symptoms not due to intervention	362	(16%)	439	(13%)
Worried about health effects of medical tests	9	(<1%)	12	(<1%)
Worried about costs if adverse effects occur	11	(<1%)	2	(<1%)
Advised not to participate by health care provider	406	(18%)	584	(17%)
Study conflicts with health care needs	341	(15%)	445	(13%)
Expected more care	5	(<1%)	9	(<1%)
Intervention	591	(26%)	1151	(34%)
Reports health problems or symptoms from WHI intervention	470	(21%)	967	(29%)
Problem with Clinic Practitioner or other CC staff	3	(<1%)	11	(<1%)
Doesn't like taking pills	57	(3%)	62	(2%)
Doesn't like DM requirements	1	(<1%)	4	(<1%)
Problems with DM group nutritionist or group members	1	(<1%)	1	(<1%)
Doesn't like DM eating patterns	1	(<1%)	2	(<1%)
Doesn't like randomized nature of intervention	46	(2%)	80	(2%)
Expected some benefit from intervention	28	(1%)	30	(1%)
Won't participate in safety procedures.	26	(1%)	35	(1%)
Other	712	(32%)	1082	(32%)
Not Given	238	(11%)	359	(11%)

[1] Multiple reasons may be reported for a woman

Table 3.8
Reports of Bleeding

Data as of: January 31, 1999

Contact	With Uterus
6 Week HRT Phone Call	
Number with an HRT Safety Interview	15650
Number with Bleeding	3577 (22.9%)
Semi-Annual Contact 1	
Number Having Contact	16064
Number with Bleeding	4626 (28.8%)
Annual Visit 1	
Number Having Visit	14246
Number with Bleeding	2630 (18.5%)
Semi-Annual Contact 2	
Number Having Contact	11446
Number with Bleeding	1446 (12.6%)
Annual Visit 2	
Number Having Visit	8612
Number with Bleeding	915 (10.6%)
Semi-Annual Contact 3	
Number Having Contact	5764
Number with Bleeding	464 (8.0%)
Annual Visit 3	
Number Having Visit	4003
Number with Bleeding	291 (7.3%)
Semi-Annual Contact 4	
Number Having Contact	2342
Number with Bleeding	120 (5.1%)
Annual Visit 4	
Number Having Visit	1426
Number with Bleeding	87 (6.1%)
Semi-Annual Contact 5	
Number Having Contact	571
Number with Bleeding	21 (3.7%)
Annual Visit 5	
Number Randomized	37
Number with Bleeding	2 (5.4%)
Non Routine Contact	
Number Randomized	16609
Number with Bleeding	1377 (8.3%)

Table 3.9
Other HRT Symptoms

Data as of: January 31, 1999

Contact	Without Uterus	With Uterus
6 Week HRT Phone Call		
Number with an HRT Safety Interview	10075	15650
Number with Breast Changes	603 (6.0%)	1075 (6.9%)
Semi-Annual Contact 1		
Number Having Contact	9881	15505
Number with Breast Changes	465 (4.7%)	897 (5.8%)
Annual Visit 1		
Number Having Visit	8811	13796
Number with Breast Changes	344 (3.9%)	553 (4.0%)
Semi-Annual Contact 2		
Number Having Contact	6693	10581
Number with Breast Changes	195 (2.9%)	324 (3.1%)
Annual Visit 2		
Number Having Visit	5057	7868
Number with Breast Changes	169 (3.3%)	249 (3.2%)
Semi-Annual Contact 3		
Number Having Contact	3211	4997
Number with Breast Changes	97 (3.0%)	124 (2.5%)
Annual Visit 3		
Number Having Visit	2217	3458
Number with Breast Changes	83 (3.7%)	115 (3.3%)
Semi-Annual Contact 4		
Number Having Contact	1214	1850
Number with Breast Changes	29 (2.4%)	41 (2.2%)
Annual Visit 4		
Number Having Visit	758	1128
Number with Breast Changes	25 (3.3%)	46 (4.1%)
Semi-Annual Contact 5		
Number Having Contact	279	409
Number with Breast Changes	9 (3.2%)	11 (2.7%)
Annual Visit 5		
Number Randomized	23	39
Number with Breast Changes	3 (13.0%)	3 (7.7%)
Non Routine Contact		
Number Randomized	10739	16609
Number with Breast Changes	63 (0.6%)	198 (1.2%)

Table 3.10
Endometrial Aspiration Results

Data as of: January 31, 1999

		Number with Abnormal Results[1]				
Months since randomized	**N of aspirations[2,3]**	**Cystic**	**Adenomatous**	**Atypia**	**Cancer**	**Total[4]**
0-6	102	5	1	0	0	1
6-12	666	12	2	4	0	6
12-18	588	9	2	2	3	7
18-24	311	10	1	3	0	4
24-36	171	1	0	0	0	0
36-42	165	0	0	2	1	3
42-48	113	1	0	2	0	2
48-54	35	1	0	0	0	0
54-60	20	0	0	0	0	0
60-66	6	0	0	0	0	0
Total	2177	39	6	13	4	23

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

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

[3] ERT-TO-PERT removed.

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

4. DM Status

4.1 Adherence

Nutrient intake data for adherence monitoring are presented in *Tables 4.1-4.3*. Studywide, the mean difference between Intervention and Comparison women is 11.0% energy from fat at AV-1, 9.9% at AV-2, 9.7% at AV-3, and 8.1% at AV-4. 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 and subsequent decline of 0.25% per year. The lower than anticipated value of C-I at AV-1 will reduce the overall power of the study but the size of the impact depends considerably on the degree of adherence throughout the remaining years of follow-up. The new power calculations shown in *Table 4.4* 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.

At AV-2 and AV-3, the C-I difference is larger for women who have reduced fat gram goals than the original goals. By the end of recruitment, approximately 80% of DM Intervention participants will have the reduced fat gram goals. Presently, nearly 80% of DM Intervention participants have reduced fat gram goals at AV-1, while only about 70% with an AV-2 FFQ, and 35% at AV-3 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*). Multivariate analyses were conducted to identify factors associated with C-I differences in percentage energy from fat (*Tables 4.5-4.6*). Participant characteristics associated with a poorer C-I difference include being older, a minority, or having a higher BMI (*Table 4.5*). 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 4.6*).

Figures 4.1 - 4.4 illustrate the positive, near linear, relationship of session attendance and fat score monitoring with C-I for both minority and non-minority Clinical Centers. For example, *Figure 4.1* indicates that women who attended 12 or more sessions at AV1 achieved a C-I that approximates the design assumptions. However, in some Clinical Centers, rather large numbers of women (up to 50 percent) attended less than 12 sessions at AV1 (*Table 4.7*). As shown in *Figures 4.2-4.3*, the negative impact of poor session attendance continues to be apparent at the AV2 C-I. *Figure 4.5* addresses the issue of a possible cohort effect in the DM. Although women randomized in 1993-94 appear to have somewhat lower C-I than women randomized in other years, the effect is modest.

During the past six months, the WHI investigators and staff have undertaken a number of activities addressing adherence. A Special Populations workshop was conducted on November 9, 1998. Attendees discussed issues in diversity, barriers of cultural differences to the conduct of clinical trials, as well as role-played specific adherence and retention scenarios. In December 1998, pilot study results of the DM Intensive Intervention Program were sent to Clinical Centers and the WHI Committees. Results showed improvement in C-I after DM Intervention participants received three motivational interviewing contacts compared to the usual additional assistance contacts. (Data not shown.) Efforts are underway to develop a proposal to submit to the WHI Steering Committee to implement a more intensive additional assistance contact schedule using motivational interviewing among DM Intervention participants.

4.2 Adherence to Follow-up

Table 4.8 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. There is some suggestion of a reduction in follow-up adherence after AV-4, which will be carefully monitored.

Table 4.1
Nutrient Intake Monitoring

Data as of: January 31, 1999

	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]	16178	25.0	7.5	23868	36.0	6.9	11.0	0.1	0.00
FFQ Year 2[4]	3524	25.8	7.5	5148	35.7	7.1	9.9	0.2	0.00
FFQ Year 3[5]	623	26.2	7.2	802	35.9	7.0	9.7	0.4	0.00
FFQ Year 4[6]	208	28.0	7.8	298	36.1	6.7	8.1	0.6	0.00
4DFR Baseline	891	32.8	6.4	1342	33.0	6.8	0.2	0.3	0.50
4DFR Year 1	672	21.7	7.4	974	32.9	6.8	11.2	0.4	0.00
24 Hr Recall, Post-baseline	227	22.9	9.2	264	32.1	7.6	9.2	0.8	0.00
24 Hr Recall, Year 1	156	22.1	7.8	209	32.5	7.9	10.4	0.8	0.00
24 Hr Recall, Year 2	74	22.6	9.9	118	32.6	8.5	10.0	1.3	0.00
24 Hr Recall, Year 3	40	24.9	8.6	46	33.9	8.4	9.0	1.8	0.00
24 Hr Recall, Year 3 Cohort	226	24.4	8.2	347	32.3	6.9	7.9	0.6	0.00
Total Energy (kcal)									
FFQ Baseline	19542	1789	713	29295	1789	707	0.0	6.6	0.92
FFQ Year 1	16178	1474	530	23868	1584	642	110.0	6.1	0.00
FFQ Year 2	3524	1494	524	5148	1573	617	79.0	12.7	0.00
FFQ Year 3	623	1508	526	802	1564	639	56.0	31.6	0.36
FFQ Year 4	208	1509	550	298	1561	596	52.0	52.2	0.52
4DFR Baseline	891	1707	454	1342	1712	455	5.0	19.6	0.80
4DFR Year 1	672	1431	365	974	1625	439	194.0	20.6	0.00
24 Hr Recall, Post-baseline	227	1519	417	264	1651	520	132.0	43.0	0.00
24 Hr Recall, Year 1	156	1550	411	209	1648	498	98.0	49.0	0.08
24 Hr Recall, Year 2	74	1487	415	118	1620	567	133.0	76.2	0.22
24 Hr Recall, Year 3	40	1436	344	46	1770	525	334.0	97.3	0.00
24 Hr Recall, Year 3 Cohort	226	1479	404	347	1688	488	209.0	39.0	0.00
Total Fat (g)									
FFQ Baseline	19542	77.9	35.3	29295	77.8	34.7	0.1	0.3	0.86
FFQ Year 1	16178	41.2	21.4	23868	64.3	31.7	23.1	0.3	0.00
FFQ Year 2	3524	42.9	20.7	5148	63.5	30.5	20.6	0.6	0.00
FFQ Year 3	623	44.4	21.8	802	63.4	31.1	19.0	1.5	0.00
FFQ Year 4	208	47.1	24.0	298	63.5	30.3	16.4	2.5	0.00
4DFR Baseline	891	63.0	23.6	1342	63.7	24.5	0.7	1.0	0.67
4DFR Year 1	672	34.4	14.9	974	60.2	23.3	25.8	1.0	0.00
24 Hr Recall, Post-baseline	227	39.6	21.9	264	60.5	27.0	20.9	2.2	0.00
24 Hr Recall, Year 1	156	38.0	17.5	209	60.9	26.1	22.9	2.4	0.00
24 Hr Recall, Year 2	74	37.3	20.5	118	60.5	30.2	23.2	4.0	0.00
24 Hr Recall, Year 3	40	40.3	18.4	46	68.4	31.6	28.1	5.7	0.00
24 Hr Recall, Year 3 Cohort	226	40.7	18.9	347	62.3	25.1	21.6	2.0	0.00

(continues)

[1] Absolute difference.

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

[3] 4532 (28%) Itervention women had <=20% energy from fat at year 1.

[4] 822 (23%) Intervention women had <=20% energy from fat at year 2.

[5] 122 (20%) Intervention women had <=20% energy from fat at year 3

[6] 29 (14%) Intervention women had <=20% energy from fat at year 4.

Table 4.1 (continued)
Nutrient Intake Monitoring

Data as of: January 31, 1999

	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]	16178	14.1	8.0	23868	22.5	11.9	8.4	0.1	0.00
FFQ Year 2[4]	3524	14.7	7.7	5148	22.1	11.4	7.4	0.2	0.00
FFQ Year 3[5]	623	15.1	8.1	802	22.4	11.8	7.3	0.6	0.00
FFQ Year 4[6]	208	16.1	8.4	298	22.0	11.3	5.9	0.9	0.00
4DFR Baseline	891	20.6	8.9	1342	20.9	9.2	0.3	0.4	0.67
4DFR Year 1	672	10.8	5.4	974	19.4	8.2	8.6	0.4	0.00
24 Hr Recall, Post-baseline	227	12.9	7.9	264	20.0	9.6	7.1	0.8	0.00
24 Hr Recall, Year 1	156	12.2	6.7	209	20.1	10.5	7.9	1.0	0.00
24 Hr Recall, Year 2	74	11.8	6.8	118	19.6	10.7	7.8	1.4	0.00
24 Hr Recall, Year 3	40	13.1	6.8	46	23.5	11.9	10.4	2.1	0.00
24 Hr Recall, Year 3 Cohort	226	12.9	6.6	347	20.6	9.2	7.7	0.7	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	16178	7.8	4.3	23868	12.5	6.7	4.7	0.1	0.00
FFQ Year 2	3524	8.1	4.2	5148	12.2	6.4	4.1	0.1	0.00
FFQ Year 3	623	8.4	4.4	802	11.9	6.1	3.5	0.3	0.00
FFQ Year 4	208	9.2	5.3	298	12.3	6.5	3.1	0.5	0.00
4DFR Baseline	891	13.1	5.8	1342	13.4	6.1	0.3	0.3	0.38
4DFR Year 1	672	7.4	3.5	974	12.7	6.2	5.3	0.3	0.00
24 Hr Recall, Post-baseline	227	8.2	5.0	264	12.5	7.3	4.3	0.6	0.00
24 Hr Recall, Year 1	156	7.9	4.4	209	12.7	6.4	4.8	0.6	0.00
24 Hr Recall, Year 2	74	8.2	6.0	118	12.9	8.5	4.7	1.1	0.00
24 Hr Recall, Year 3	40	8.2	4.9	46	14.4	8.0	6.2	1.5	0.00
24 Hr Recall, Year 3 Cohort	226	8.7	4.9	347	12.9	6.7	4.2	0.5	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	16257	5.1	2.3	24021	3.8	2.0	1.3	0.0	0.00
FFQ Year 2	3688	5.2	2.4	5386	3.9	2.0	1.3	0.0	0.00
FFQ Year 3	664	5.2	2.4	887	3.9	2.0	1.3	0.1	0.00
FFQ Year 4	215	5.0	2.3	314	4.0	2.0	1.0	0.2	0.00

[1] Absolute difference.

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

[3] 4532 (28%) Intervention women had <=20% energy from fat at year 1.

[4] 822 (23%) Intervention women had <=20% energy from fat at year 2.

[5] 122 (20%) Intervention women had <=20% energy from fat at year 3

[6] 29 (14%) 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: January 31, 1999

	Intervention[1]			Control[2]			Difference		
	N	Mean	SD	N	Mean	SD	Mean[3]	SE	p-value[4]
% Energy from Fat									
FFQ Baseline	15855	38.8	5.0	23754	38.8	4.9	0.0	0.1	0.49
FFQ Year 1	12754	25.2	7.6	18871	36.2	6.9	11.0	0.1	0.00
FFQ Year 2	2474	25.9	7.6	3495	36.1	7.1	10.2	0.2	0.00
FFQ Year 3	230	26.8	7.5	290	37.0	6.6	10.2	0.6	0.00
4DFR Baseline	690	32.4	6.5	1029	33.0	6.9	0.6	0.3	0.06
4DFR Year 1	489	21.6	7.6	695	33.0	7.0	11.4	0.4	0.00
24 Hr Recall, Post-baseline	186	23.4	9.4	206	32.1	7.7	8.7	0.9	0.00
24 Hr Recall, Year 1	107	21.5	7.6	140	32.6	7.9	11.1	1.0	0.00
24 Hr Recall, Year 2	36	20.2	7.8	57	32.8	8.9	12.6	1.8	0.00
Total Energy (kcal)									
FFQ Baseline	15855	1780	701	23754	1786	706	6.0	7.2	0.46
FFQ Year 1	12754	1467	529	18871	1588	645	121.0	6.9	0.00
FFQ Year 2	2474	1483	524	3495	1576	618	93.0	15.3	0.00
FFQ Year 3	230	1493	498	290	1599	667	106.0	52.8	0.13
4DFR Baseline	690	1688	455	1029	1712	463	24.0	22.6	0.30
4DFR Year 1	489	1410	376	695	1617	435	207.0	24.3	0.00
24 Hr Recall, Post-baseline	186	1499	418	206	1640	529	141.0	48.5	0.01
24 Hr Recall, Year 1	107	1576	422	140	1680	519	104.0	61.6	0.14
24 Hr Recall, Year 2	36	1494	384	57	1576	534	82.0	102.6	0.81
Total Fat (g)									
FFQ Baseline	15855	77.4	34.6	23754	77.6	34.6	0.2	0.4	0.61
FFQ Year 1	12754	41.3	21.6	18871	64.8	32.0	23.5	0.3	0.00
FFQ Year 2	2474	42.7	21.1	3495	64.1	30.7	21.4	0.7	0.00
FFQ Year 3	230	44.8	20.6	290	66.7	32.9	21.9	2.5	0.00
4DFR Baseline	690	61.6	23.4	1029	63.8	24.9	2.2	1.2	0.10
4DFR Year 1	489	33.9	15.5	695	60.2	23.6	26.3	1.2	0.00
24 Hr Recall, Post-baseline	186	39.7	22.0	206	60.2	27.8	20.5	2.6	0.00
24 Hr Recall, Year 1	107	37.4	16.5	140	62.4	26.8	25.0	2.9	0.00
24 Hr Recall, Year 2	36	33.1	15.1	57	59.2	30.2	26.1	5.4	0.00

(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: January 31, 1999

	Intervention[1]			Control[2]			Difference		
	N	Mean	SD	N	Mean	SD	Mean[3]	SE	p-value[4]
Saturated Fat (g)									
FFQ Baseline	15855	27.2	13.2	23754	27.2	13.1	0.0	0.1	0.81
FFQ Year 1	12754	14.1	8.0	18871	22.6	12.0	8.5	0.1	0.00
FFQ Year 2	2474	14.6	7.9	3495	22.3	11.4	7.7	0.3	0.00
FFQ Year 3	230	15.3	7.7	290	23.4	12.5	8.1	0.9	0.00
4DFR Baseline	690	20.0	8.8	1029	20.8	9.4	0.8	0.5	0.14
4DFR Year 1	489	10.5	5.6	695	19.1	8.2	8.6	0.4	0.00
24 Hr Recall, Post-baseline	186	13.0	8.0	206	19.9	9.7	6.9	0.9	0.00
24 Hr Recall, Year 1	107	11.9	6.2	140	20.7	10.9	8.8	1.2	0.00
24 Hr Recall, Year 2	36	9.9	4.8	57	18.6	9.5	8.7	1.7	0.00
Polyunsaturated Fat (g)									
FFQ Baseline	15855	15.1	7.4	23754	15.1	7.4	0.0	0.1	0.53
FFQ Year 1	12754	7.8	4.3	18871	12.5	6.7	4.7	0.1	0.00
FFQ Year 2	2474	8.1	4.3	3495	12.4	6.5	4.3	0.1	0.00
FFQ Year 3	230	8.5	4.3	290	12.7	6.2	4.2	0.5	0.00
4DFR Baseline	690	12.8	5.7	1029	13.5	6.2	0.7	0.3	0.05
4DFR Year 1	489	7.4	3.5	695	12.9	6.6	5.5	0.3	0.00
24 Hr Recall, Post-baseline	186	8.3	5.0	206	12.4	7.4	4.1	0.6	0.00
24 Hr Recall, Year 1	107	7.8	4.3	140	12.8	6.2	5.0	0.7	0.00
24 Hr Recall, Year 2	36	8.0	4.8	57	12.7	8.6	4.7	1.6	0.00
Fruits and Vegetables (servings)									
FFQ Baseline	15814	3.6	1.8	23708	3.6	1.8	0.0	0.0	0.40
FFQ Year 1	12865	5.0	2.4	19050	3.9	2.0	1.1	0.0	0.00
FFQ Year 2	2646	5.1	2.4	3734	3.9	2.1	1.2	0.1	0.00
FFQ Year 3	275	5.3	2.5	382	4.0	2.2	1.3	0.2	0.00

[1] Intervention group is defined as women randomized to Intervention after 6/15/95 that have revised fat gram goals.

[2] Control group is defined as women randomized to Control after 6/15/95.

[3] Absolute difference.

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

Table 4.3
Nutrient Intake Monitoring in Minority Women

Data as of: January 31, 1999

	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]	2754	27.5	8.2	3986	36.5	7.3	9.0	0.2	0.00
FFQ Year 2[4]	577	28.0	8.0	843	36.1	7.4	8.1	0.4	0.00
FFQ Year 3[5]	84	29.2	8.0	116	36.0	7.0	6.8	1.1	0.00
FFQ Year 4[6]	28	30.1	7.4	27	36.2	8.4	6.1	2.1	0.01
4DFR Baseline	451	33.0	6.4	675	33.4	6.8	0.4	0.4	0.35
4DFR Year 1	320	23.2	7.9	440	33.4	6.9	10.2	0.5	0.00
24 Hr Recall, Post-baseline	40	24.6	10.7	44	30.7	7.6	6.1	2.0	0.00
24 Hr Recall, Year 1	23	22.0	7.8	31	30.2	7.5	8.2	2.1	0.00
24 Hr Recall, Year 2	13	25.9	13.0	23	31.0	9.9	5.1	3.8	0.19
24 Hr Recall, Year 3	6	28.1	9.3	1	33.9				
24 Hr Recall, Year 3 Cohort	57	25.8	7.7	81	32.9	6.7	7.1	1.2	0.00
Total Energy (kcal)									
FFQ Baseline	3628	1762	811	5348	1757	825	5.0	17.6	0.49
FFQ Year 1	2754	1412	621	3986	1510	775	98.0	17.7	0.00
FFQ Year 2	577	1431	622	843	1512	748	81.0	37.8	0.15
FFQ Year 3	84	1473	611	116	1519	806	46.0	104.7	0.88
FFQ Year 4	28	1478	658	27	1361	547	117.0	163.5	0.66
4DFR Baseline	451	1670	480	675	1688	470	18.0	28.8	0.42
4DFR Year 1	320	1384	386	440	1589	459	205.0	31.6	0.00
24 Hr Recall, Post-baseline	40	1470	492	44	1612	419	142.0	99.4	0.08
24 Hr Recall, Year 1	23	1524	371	31	1490	390	34.0	105.1	0.67
24 Hr Recall, Year 2	13	1363	532	23	1491	510	128.0	179.7	0.67
24 Hr Recall, Year 3	6	1191	227	1	1331				
24 Hr Recall, Year 3 Cohort	57	1486	452	81	1580	398	94.0	72.8	0.13
Total Fat (g)									
FFQ Baseline	3628	77.8	39.8	5348	77.7	40.2	0.1	0.9	0.65
FFQ Year 1	2754	43.5	25.7	3986	62.4	37.5	18.9	0.8	0.00
FFQ Year 2	577	44.8	24.3	843	62.0	36.7	17.2	1.7	0.00
FFQ Year 3	84	49.2	27.7	116	62.1	39.0	12.9	5.0	0.01
FFQ Year 4	28	48.1	22.9	27	55.7	26.8	7.6	6.7	0.37
4DFR Baseline	451	61.8	23.2	675	63.8	25.8	2.0	1.5	0.33
4DFR Year 1	320	35.8	16.8	440	60.0	24.4	24.2	1.6	0.00
24 Hr Recall, Post-baseline	40	40.0	22.8	44	55.9	21.9	15.9	4.9	0.00
24 Hr Recall, Year 1	23	36.8	14.8	31	51.7	21.3	14.9	5.2	0.01
24 Hr Recall, Year 2	13	42.3	33.5	23	52.6	27.9	10.3	10.4	0.20
24 Hr Recall, Year 3	6	37.0	12.6	1	50.1				
24 Hr Recall, Year 3 Cohort	57	43.1	20.2	81	59.3	21.9	16.2	3.7	0.00

(continues)

[1] Absolute difference.

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

[3] 510 (19%) Intervention women had <=20% energy from fat at year 1.

[4] 99 (17%) Intervention women had <=20% energy from fat at year 2.

[5] 11 (13%) Intervention women had <=20% energy from fat at year 3

[6] 1 (4%) Intervention women had <=20% energy from fat at year 4.

Table 4.3 (continued)
Nutrient Intake Monitoring in Minority Women

Data as of: January 31, 1999

	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]	2754	14.3	9.0	3986	20.6	13.1	6.3	0.3	0.00
FFQ Year 2[4]	577	14.7	8.7	843	20.6	13.0	5.9	0.6	0.00
FFQ Year 3[5]	84	16.1	9.3	116	21.1	14.2	5.0	1.8	0.01
FFQ Year 4[6]	28	16.4	8.2	27	18.2	9.2	1.8	2.3	0.53
4DFR Baseline	451	19.5	8.5	675	20.3	9.4	0.8	0.6	0.24
4DFR Year 1	320	11.0	6.0	440	18.6	8.0	7.6	0.5	0.00
24 Hr Recall, Post-baseline	40	12.4	7.5	44	18.1	8.6	5.7	1.8	0.00
24 Hr Recall, Year 1	23	11.9	6.6	31	15.0	6.5	3.1	1.8	0.05
24 Hr Recall, Year 2	13	12.8	10.6	23	15.2	7.8	2.4	3.1	0.30
24 Hr Recall, Year 3	6	11.2	5.9	1	9.1				
24 Hr Recall, Year 3 Cohort	57	12.9	6.6	81	19.2	8.5	6.3	1.3	0.00
Polyunsaturated Fat (g)									
FFQ Baseline	3628	15.9	8.6	5348	15.8	8.6	0.1	0.2	0.53
FFQ Year 1	2754	8.6	5.3	3986	12.7	8.0	4.1	0.2	0.00
FFQ Year 2	577	8.9	5.2	843	12.4	7.5	3.5	0.4	0.00
FFQ Year 3	84	9.9	6.1	116	12.0	7.1	2.1	1.0	0.02
FFQ Year 4	28	9.0	4.9	27	11.6	6.4	2.6	1.5	0.17
4DFR Baseline	451	13.4	6.0	675	13.7	6.5	0.3	0.4	0.48
4DFR Year 1	320	7.8	3.8	440	13.2	6.8	5.4	0.4	0.00
24 Hr Recall, Post-baseline	40	8.9	5.3	44	11.8	6.1	2.9	1.3	0.01
24 Hr Recall, Year 1	23	7.8	3.3	31	12.6	6.0	4.8	1.4	0.01
24 Hr Recall, Year 2	13	9.5	8.7	23	13.0	10.2	3.5	3.4	0.15
24 Hr Recall, Year 3	6	7.7	2.0	1	19.3				
24 Hr Recall, Year 3 Cohort	57	9.6	5.8	81	12.4	6.0	2.8	1.0	0.00
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	2770	4.5	2.5	4021	3.4	2.0	1.1	0.1	0.00
FFQ Year 2	587	4.7	2.6	855	3.5	2.1	1.2	0.1	0.00
FFQ Year 3	86	4.7	2.5	127	3.6	2.2	1.1	0.3	0.00
FFQ Year 4	28	4.8	2.8	28	3.3	2.2	1.5	0.7	0.03

[1] Absolute difference.

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

[3] 510 (19%) Intervention women had <=20% energy from fat at year 1.

[4] 99 (17%) Intervention women had <=20% energy from fat at year 2.

[5] 11 (13%) Intervention women had <=20% energy from fat at year 3

[6] 1 (4%) Intervention women had <=20% energy from fat at year 4.

Table 4.4
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-1 % Energy from fat: 13% at AV-1, 11% at year 10

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

[4] Design values

Table 4.5
Multivariate Analysis of Study Subject Characteristics
on Control - Intervention Difference in % Energy from Fat from FFQ at AV-1:

Data as of: January 31, 1999

Study Subject Characteristics		C - I (%)
Age	50-54 vs. 60-69	0.46*
	55-59 vs. 60-69	0.42*
	70-79 vs. 60-69	-1.21**
Ethnicity	Black vs. White	-1.86**
	Hispanic vs. White	-1.86**
	Other Minority vs. White	-1.29**
Education	0-8 Years vs. Post H.S.	0.42
	Some H.S. or Diploma vs. Post H.S.	0.13
Marital Status	Not Married vs. Married	-0.07
Family Income	<20K vs. >75K	-0.64*
	20-35K vs. >75K	-0.19
	35-50K vs. >75K	0.17
	50-75K vs. >75K	-0.13
HRT Randomized	Yes vs. No	0.47*
BMI - Mean(BMI)	BMI - 29.06	-0.02
Hysterectomy	Yes vs. No	-0.02

* 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 4.5 (continued)
Multivariate Analysis of Study Subject Characteristics
on Control - Intervention Difference in % Energy from Fat from FFQ at AV-2:

Data as of: January 31, 1999

Study Subject Characteristics		C - I (%)
Age	50-54 vs. 60-69	-0.39
	55-59 vs. 60-69	0.20
	70-79 vs. 60-69	-1.51**
Ethnicity	Black vs. White	-2.71**
	Hispanic vs. White	-0.03
	Other Minority vs. White	0.08
Education	0-8 Years vs. Post H.S.	-0.72
	Some H.S. or Diploma vs. Post H.S.	-0.13
Marital Status	Not Married vs. Married	-0.59
Family Income	<20K vs. >75K	0.00
	20-35K vs. >75K	0.29
	35-50K vs. >75K	0.71
	50-75K vs. >75K	0.27
HRT Randomized	Yes vs. No	0.18
BMI - Mean(BMI)	BMI - 29.06	-0.06*
Hysterectomy	Yes vs. No	-0.40

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

Table 4.6
Effects of DM Intervention Participation Variables
on Control - Intervention Difference in % Energy from Fat from FFQ at AV-1:

Data as of: January 31, 1999

DM Implementation/Participation	C-I % Energy from Fat[1]	C-I % Energy from Fat[2]	C-I % Energy from Fat[3]
Intervention Group Size	0.01	0.02	0.01
Days from Randomization to Intervention Group/100	-0.59**	-0.62**	-0.61**
# Sessions (out of 1-18) Attended	0.43**		0.25**
# Sessions (out of 1-18) Completed	0.39**		0.09**
Fat Gram Goal	0.01	0.01	0.007
# Early Sessions Completed (1-6)		0.54**	
# Intermediate Sessions Completed (7-12)		0.83**	
# Late Sessions Completed (13-18)		0.81**	
# Sessions (out of 3-18) Providing Fat Scores			0.49**

[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 < .01 from two-sided t-test

Table 4.6 (continued)
Effects of DM Intervention Participation Variables
on Control - Intervention Difference in % Energy from Fat from FFQ at AV-2:

Data as of: January 31, 1999

DM Implementation/Participation	C-I % Energy from Fat[1]	C-I % Energy from Fat[2]	C-I % Energy from Fat[3]	C-I % Energy from Fat[4]
Intervention Group Size	0.00	-0.01	0.00	0.01
Days from Randomization to Intervention Group/100	0.72**	0.45**	0.68**	0.68**
# Sessions (out of 1-18) Attended	0.32**		0.21**	0.22**
# Sessions (out of 1-18) Completed	0.50**		0.29**	0.35**
Fat Gram Goal	-0.10**	0.01	-0.10**	-0.10**
# Maintenance Sessions (out of 1-4) Attended	0.72**		0.67**	0.50**
# Maintenance Sessions (out of 1-4) Completed	0.10		0.10	-0.27
# Early Sessions Completed (1-6)		0.39		
# Intermediate Sessions Completed (7-12)		0.68**		
# Late Sessions Completed (13-18)		1.23**		
# Sessions (out of 3-18) Providing Fat Scores			0.33**	0.25**
# Maintenance Sessions (out of 1-4) Providing Fat Scores				0.61**

[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.

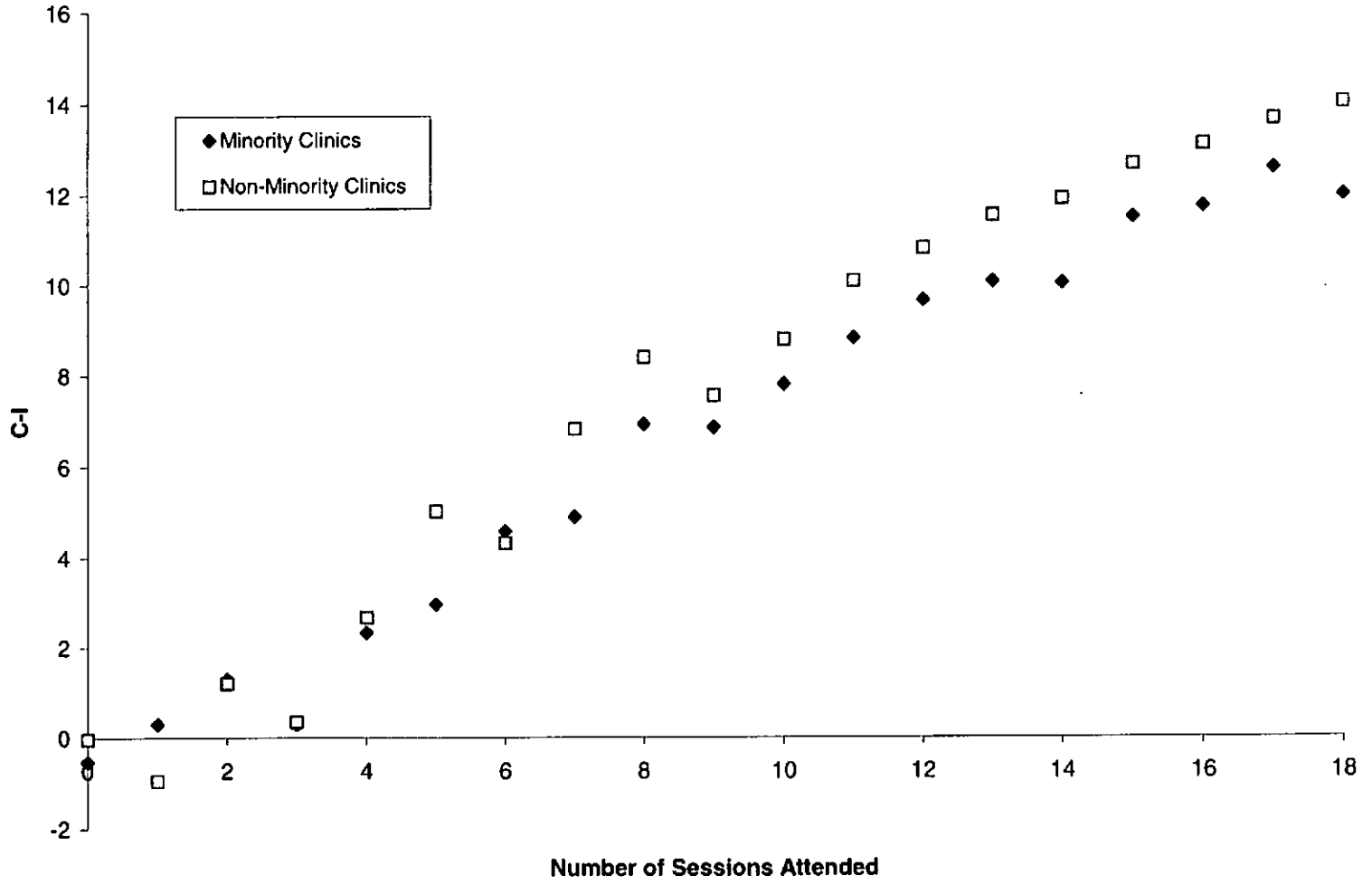
[3] Model adjusted for clinic effects, and includes the following terms: Intervention group size, days from randomization to group assignment, # sessions attended, # sessions completed, fat gram goal, and #sessions fat score provided.

[4] 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 at both year 1 and maintenance sessions.

** Indicates p-value < .01 from two-sided t-test

Figure 4.1
C-I Difference in % Energy from Fat at AV-1 by Participant Session Attendance[1]

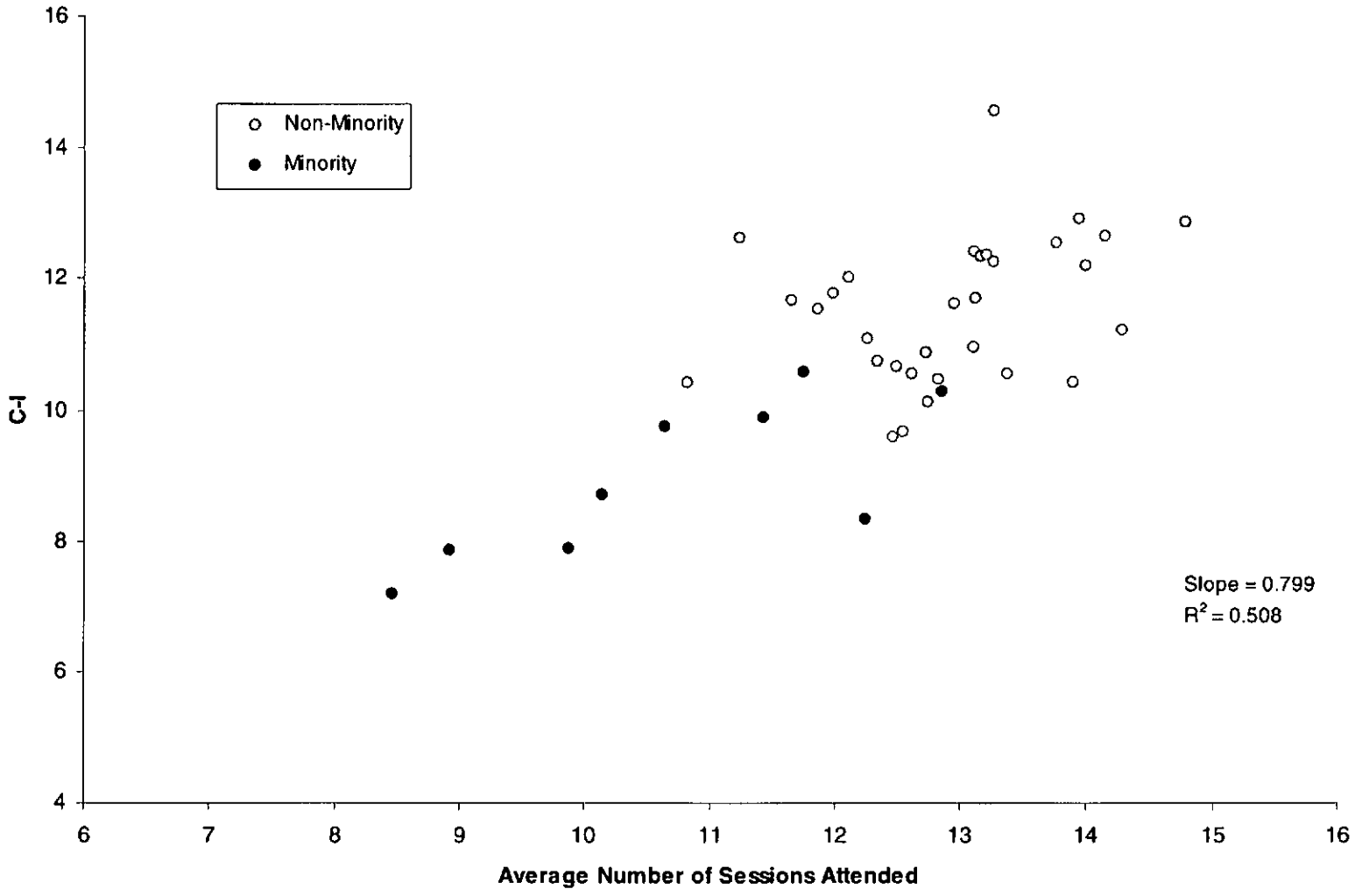
Data as of: January 31, 1999



[1] A clinic is considered to be a minority clinic if minority enrollment >=30%.

Figure 4.2
C-I % Energy from Fat at AV-1 by Average Session Attendance for Each Clinic[1]

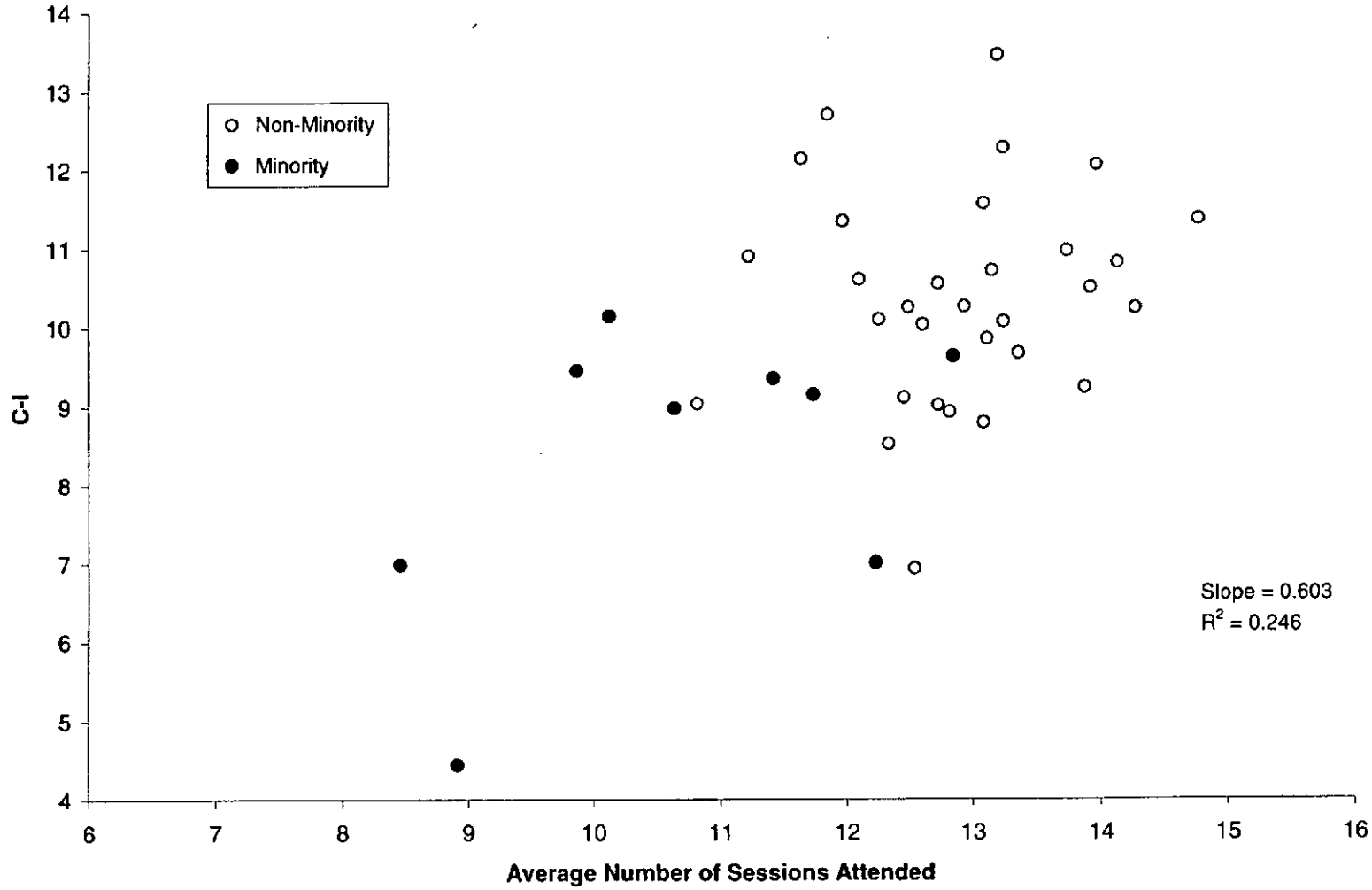
Data as of: January 31, 1999



[1] Note: A Clinic is considered to be a minority clinic if minority enrollment ≥ 30%.

Figure 4.3
C-I % Energy from Fat at AV-2 by Average Session Attendance for Each Clinic[1]

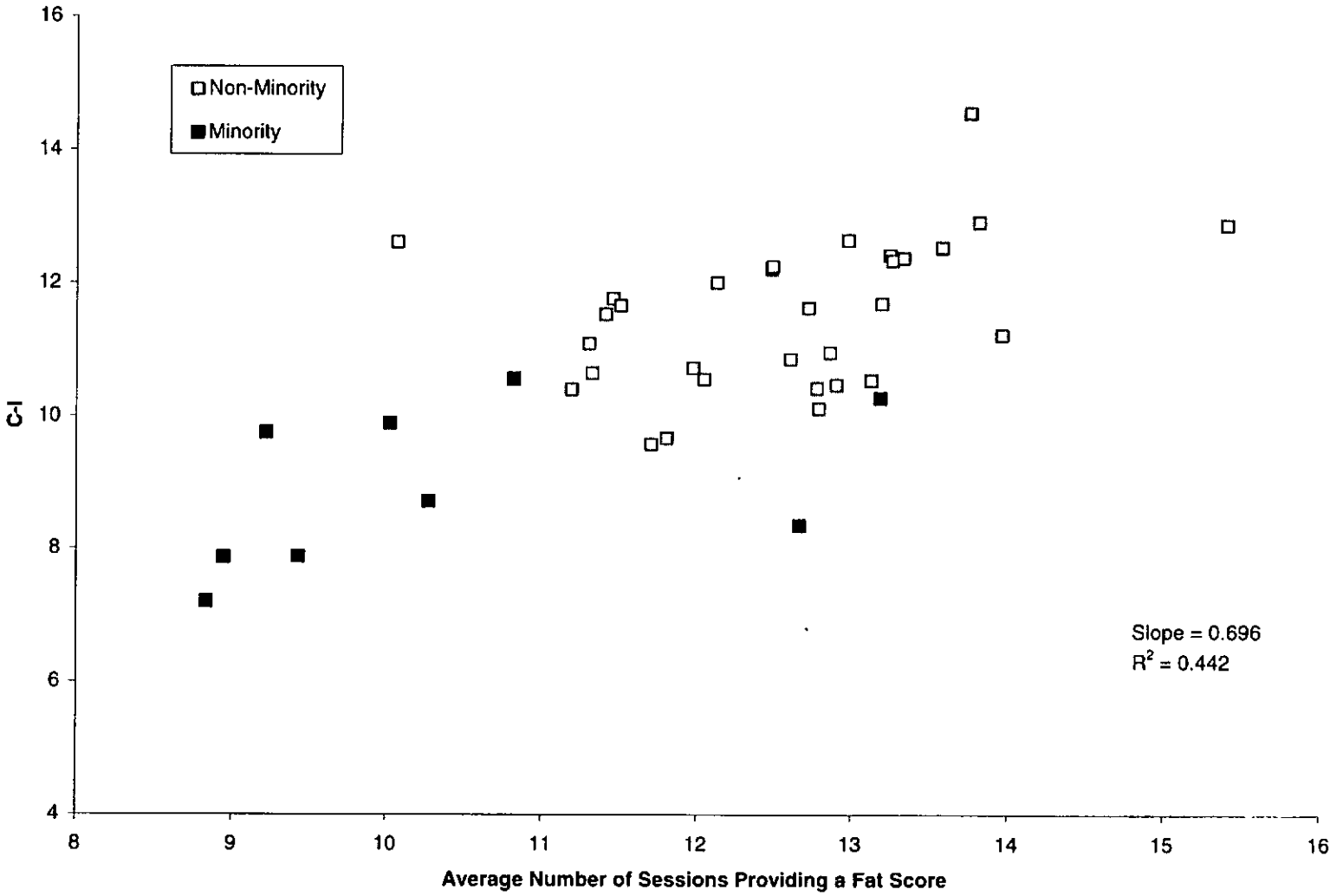
Data as of: January 31, 1999



[1] Note: A Clinic is considered to be a minority clinic if minority enrollment ≥ 30%.

Figure 4.4
C-I % Energy from Fat at AV-1 by Average Number of Sessions Providing a Fat Score for Each Clinic[1]

Data as of: January 31, 1999



[1] Note: A Clinic is considered to be a minority clinic if minority enrollment ≥ 30%.

Figure 4.5
C-I Difference in % Energy from Fat by Visit Number and Year of Randomization

Data as of: January 31, 1999

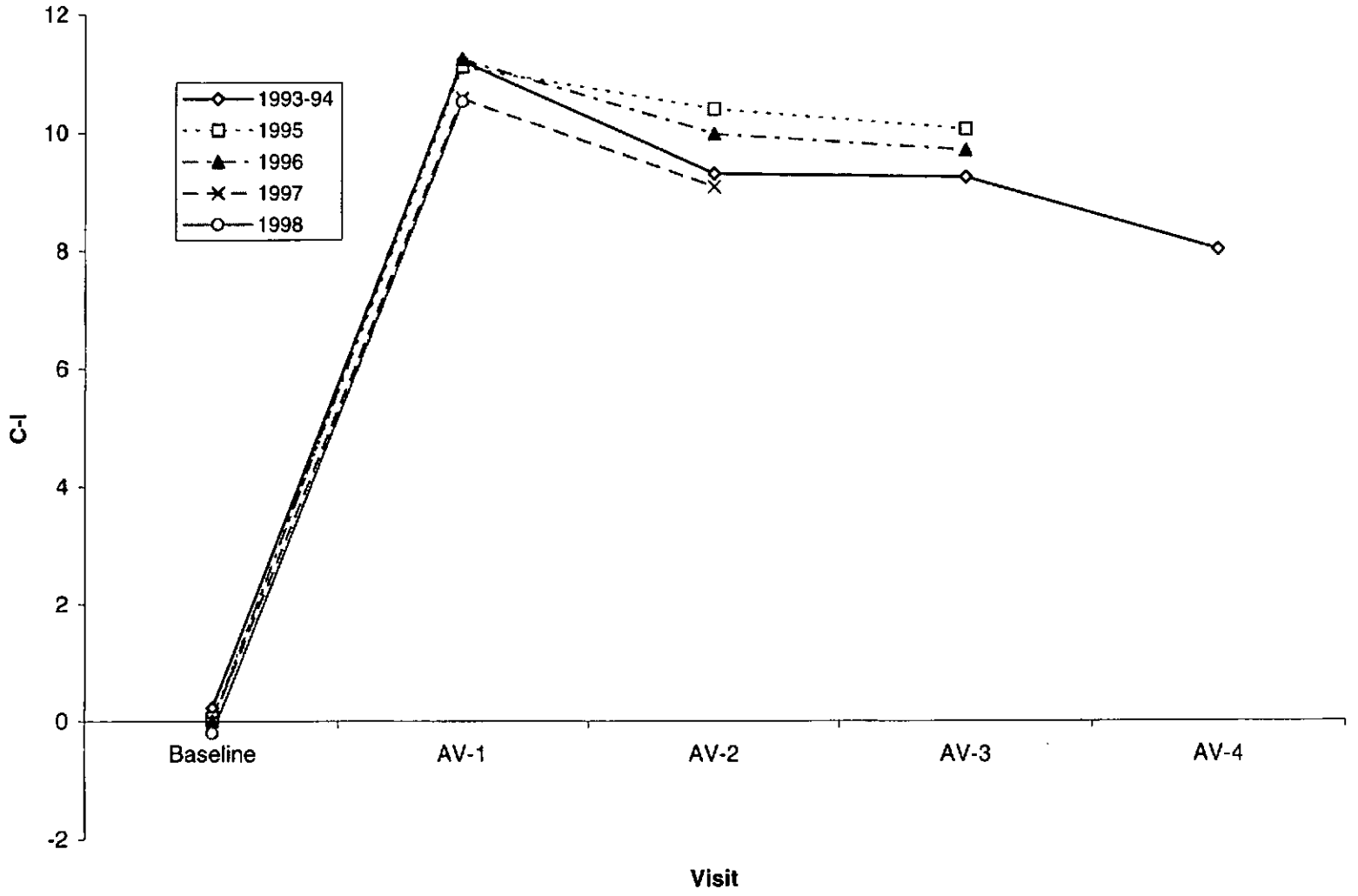


Table 4.7
Session Attendance at AV-1 by Clinic

Data as of: January 31, 1999

Clinic	0 - 11 Sessions N	0 - 11 Sessions %	12 - 18 Sessions N	12 - 18 Sessions %
Atlanta	108	22.2	379	77.8
Birmingham	125	27.7	327	72.3
Bowman	101	24.9	304	75.1
Brigham	108	19.4	448	80.6
Buffalo	71	16.6	357	83.4
Chapel Hill	113	28.0	290	72.0
Chicago	59	13.1	393	86.9
Chicago-Rush	96	34.7	181	65.3
Cincinnati	76	23.0	254	77.0
Columbus	78	18.8	337	81.2
Detroit	76	29.1	185	70.9
Gainesville	120	27.1	323	72.9
GWU-DC	80	20.9	302	79.1
Honolulu	106	29.9	249	70.1
Houston	58	20.6	224	79.4
Iowa City	38	9.6	357	90.4
Irvine	103	30.5	235	69.5
LaJolla	105	19.9	422	80.1
Los Angeles	77	22.0	273	78.0
Madison	83	21.3	307	78.7
Medlantic	163	49.5	166	50.5
Memphis	85	21.7	307	78.3
Miami	139	50.2	138	49.8
Milwaukee	102	26.5	283	73.5
Minneapolis	77	15.4	422	84.6
Nevada	70	18.2	314	81.8
New York City	141	37.0	240	63.0
Newark	137	23.8	438	76.2
Oakland	66	16.7	330	83.3
Pawtucket	160	23.5	521	76.5
Pittsburgh	74	16.7	368	83.3
Portland	60	16.5	303	83.5
San Antonio	121	45.3	146	54.7
Seattle	51	11.4	398	88.6
Stanford	79	17.6	369	82.4
Stonybrook	73	25.5	213	74.5
Torrance	86	30.9	192	69.1
Tucson	110	22.5	378	77.5
UC Davis	108	20.8	411	79.2
Worcester	74	18.0	337	82.0
Total	3757	23.2	12421	76.8

Table 4.8
Adherence to Follow-up Contacts

Data as of: January 31, 1999

Contact	Due N	Conducted N	Conducted %	Conducted in window N	Conducted in window %
Semi-Annual Contact 1	48575	46080	94.9%	34924	71.9%
Intervention	19427	18456	95.0%	14063	72.4%
Control	29148	27624	94.8%	20861	71.6%
Annual Visit 1	44273	42116	95.1%	33858	76.5%
Intervention	17706	16991	96.0%	13804	78.0%
Control	26567	25125	94.6%	20054	75.5%
Semi-Annual Contact 2	37975	34623	91.2%	26399	69.5%
Intervention	15185	13830	91.1%	10504	69.2%
Control	22790	20793	91.2%	15895	69.7%
Annual Visit 2	30373	27999	92.2%	22276	73.3%
Intervention	12162	11215	92.2%	8899	73.2%
Control	18211	16784	92.2%	13377	73.5%
Semi-Annual Contact 3	22325	19834	88.8%	14552	65.2%
Intervention	8944	7910	88.4%	5763	64.4%
Control	13381	11924	89.1%	8789	65.7%
Annual Visit 3	15440	14104	91.3%	11377	73.7%
Intervention	6176	5635	91.2%	4500	72.9%
Control	9264	8469	91.4%	6877	74.2%
Semi-Annual Contact 4	10014	8617	86.0%	6394	63.9%
Intervention	4023	3440	85.5%	2537	63.1%
Control	5991	5177	86.4%	3857	64.4%
Annual Visit 4	6158	5556	90.2%	4682	76.0%
Intervention	2471	2216	89.7%	1852	74.9%
Control	3687	3340	90.6%	2830	76.8%
Semi-Annual Contact 5	2732	2420	88.6%	1868	68.4%
Intervention	1093	966	88.4%	734	67.2%
Control	1639	1454	88.7%	1134	69.2%
Annual Visit 5	106	87	82.1%	78	73.6%
Intervention	42	32	76.2%	27	64.3%
Control	64	55	85.9%	51	79.7%

5. CaD Intervention Status

5.1. Adherence to Supplements

Table 5.1 presents rates of follow-up, stopping intervention and pill collection, and adherence to pill taking by visit schedule for all CaD participants, CaD participants randomized at AV-1 and CaD participants randomized at AV-2, respectively. The adherence pattern among women with pill collections is generally stable over time. The adherence summary for all CaD participants, defined as those women known to be consuming 80% or more of the prescribed dose, has improved since the last report and is now about 53%-59% (adherence summary was 52%-57% in the last progress report). Note that the adherence summary for AV-1 randomized CaD participants is slightly higher (52.5% to 58.6%) than for those participants randomized at AV-2 (51.8% to 54.9%). Adherence to CaD, however, remains low, primarily as 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 30%-35% above the assumed level, a slight improvement since the analysis on the last report when drop-out rates were 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, 1850, 1800 in the intervention arm produces powers within 1%-2% of the protocol-specified values with n=45,000 for all outcomes of interest. The value of 920 mg/day in controls at baseline was determined from the median total calcium intake in the CaD participants at AV-1 who are also DM participants, thus providing FFQ data.

With recruitment ongoing we have conducted power sensitivity analyses using two projected sample sizes (35,000 and 40,000) a range of adherence patterns and revised incidence rates. *Table 5.3* describes the range of adherence patterns we examined. Using the adherence pattern suggested in *Table 5.1*, we assume that a "moderate" adherence pattern may be achievable. *Table 5.4* shows the power for Hip Fractures, Other Fractures and colorectal cancer under two possible sample sizes (40,000 and 35,000) and all other parameters held constant. NB: Power is low for hip fracture and

colorectal cancer in scenarios based on poor adherence. 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 the adherence summary value (1=known to be taking ≥ 80% of pills; 0=otherwise). Reported symptoms of gas or constipation at AV-1 (Form 38) and CaD formulation (chewable or swallowable) were added to the models of adherence. All women who were due for an AV-3 as of January 31, 1999 (and adherent at AV-2) were taking the swallowable formulation so the analysis for that time period was not affected by formulation. *Tables 5.5* through *5.7* present the fitted models. Among women taking the swallowable formulation, the odds for adherence at SAV-2 increased by 50% compared to women taking the chewable formulation. SAV-2 adherence was lower among women reporting moderate to severe symptoms of gas and constipation at AV-1. This effect was not seen in the analyses among women at AV-2 and AV-3 who were adherent at SAV-2 and AV-2, respectively. AV-2 adherence was lower among women reporting mild constipation. These analyses are consistent in indicating that increasing age is associated with better adherence at SAV-2 and AV-2 while DM only participants and racial/ethnic minorities have lower adherence at all time periods. The 4-week call is associated with a statistically significant, higher level of adherence at SAV-2.

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-two percent of the women who have stopped taking their study pills report a reason related to the intervention itself, 23% 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 not liking to take the pills.

5.2. Issues

Previous efforts indicated that the chewable tablet formulation was a significant barrier to adherence. The tablet manufacturer is now providing us with a swallowable pill (OSCal), as an alternative. Dosages of calcium and vitamin D are equal to the chewable tablet.

With the two forms of study pills available (in October 1997), women are given the choice of the chewable or swallowable forms, at randomization and at each follow-up dispensing. Effects of this optional formulation on randomization and adherence rates (*Table 5.5*) have been positive. Clinical Centers have also had some success in starting the swallowable formulation with women who previously dropped intervention before the new formulation became available. Women's preferences for the swallowable formulation have been much higher than anticipated. We are working with the manufacturer to maintain adequate supplies

Clinical Centers have been provided with additional resources (e.g., Web-based government publications) related to management of constipation in older women. PMC site visitors have also provided additional training on how to discuss gastrointestinal symptoms with women before and after randomization to CaD.

Many Clinical Centers have reported that before and after randomization to CaD women were confused about whether or not they can take their own calcium supplements. Study materials (e.g., brochures and information sheets) have been revised or developed to clarify that women can take their own supplements and remain on study pills.

Table 5.1
CaD Adherence Summary
All CaD Participants

Data as of: January 31, 1999

	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	25347	24484	97	20029	79	1775	7	3724	15	21604	85	3255	15	4502	21	13847	64	55
Annual Visit-2	19624	18898	96	15603	80	972	5	1578	9	16175	91	1815	11	2877	18	11483	71	59
Annual Visit -3	10683	10149	95	8366	78	827	8	1150	12	8137	88	879	11	1566	19	5692	70	54
Annual Visit -4	4023	3808	95	3259	81	203	5	334	10	2910	90	292	10	491	17	2127	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 5.1 (continued)
CaD Adherence Summary
Participants Randomized to CaD at Annual Visit 1 (AV-1)

Data as of: January 31, 1999

	Due	Stopped CaD		Missed Pill Collection		Total with Collections		Medication Rate[1] <50%		Medication Rate[1] 50%-80%		Medication Rate[1] 80% +		Adherence Summary[2]
	N	N	%	N	%	N	%	N	%	N	%	N	%	%
Annual Visit-2	19578	972	5.0	1578	8.9	16170	91.1	1814	11.2	2877	17.8	11479	71.0	58.6
Annual Visit -3	9309	631	6.8	923	11.6	7049	88.4	718	10.2	1322	18.8	5009	71.1	53.8
Annual Visit -4	2819	135	4.8	243	10.8	2011	89.2	195	9.7	335	16.7	1481	73.6	52.5

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

Data as of: January 31, 1999

	Due	Stopped CaD		Missed Pill Collection		Total with Collections		Medication Rate[1] <50%		Medication Rate[1] 50%-80%		Medication Rate[1] 80% +		Adherence Summary[2]
	N	N	%	N	%	N	%	N	%	N	%	N	%	%
Annual Visit -3	1316	196	14.9	227	17.3	1085	82.7	160	14.7	243	22.4	682	62.9	51.8
Annual Visit -4	1177	68	5.8	91	9.2	899	90.8	97	10.8	156	17.4	646	71.9	54.9

[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)

Data as of: January 31, 1999

	Total			
	Interval[1]		Cumulative[2]	
Drop-Outs[3]				
AV-2	11.7%	(8.8)	11.7%	(8.8)
AV-3	7.8%	(5.9)	18.5%	(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[2,4]			
Baseline	1920	920	1000
Year 1	1710	930	780
Year 9	1650	950	700
Poor Adherence[3,4]			
Baseline	1920	920	1000
Year 1	1615	930	685
Year 9	1550	950	600

[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. From the data, assume 6% loss to follow-up in both arms.

[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. From the data, assume 6% loss to follow-up in both arms.

[4] For moderate/poor adherence, 50% healthy volunteer effect for year 1, 10% for year 9 were applied to hip fractures. For combined fractures, 30% healthy volunteer effect for year 1, 10% for year 9.

Table 5.4
Sensitivity of CaD Study Power to Adherence and Incidence Rate 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	20	1.61	1.36	62	47	34
		27	1.62	1.31	79	63	46
		33	1.62	1.26	91	77	54
	2004	20	2.84	2.35	90	76	60
		27	2.85	2.25	98	90	76
		33	2.85	2.15	>99	97	88
Combined Fractures							
	2001	19	6.48	5.54	99	97	87
		23	6.50	5.36	>99	>99	96
		28	6.51	5.18	>99	>99	99
	2004	19	10.22	8.62	>99	>99	98
		23	10.24	8.30	>99	>99	>99
		28	10.25	7.98	>99	>99	>99
Colorectal Cancer							
	2001	18	0.90	0.80	25	20	15
		20	0.90	0.79	29	23	17
		22	0.90	0.78	34	27	19
	2004	18	1.48	1.22	74	57	42
		20	1.49	1.20	82	66	49
		22	1.49	1.18	88	74	57

[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 and Incidence Rate 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	20	1.61	1.36	57	42	30
		27	1.62	1.31	74	58	41
		33	1.62	1.26	86	72	54
	2004	20	2.84	2.35	86	70	54
		27	2.85	2.25	96	86	70
		33	2.85	2.15	99	95	84
Combined Fractures							
	2001	19	6.48	5.54	98	94	82
		23	6.50	5.36	>99	99	94
		28	6.51	5.18	>99	>99	98
	2004	19	10.22	8.62	>99	>99	97
		23	10.24	8.30	>99	>99	>99
		28	10.25	7.98	>99	>99	>99
Colorectal Cancer							
	2001	18	0.90	0.80	22	18	13
		20	0.90	0.79	26	21	15
		22	0.90	0.78	30	24	18
	2004	18	1.48	1.22	68	52	38
		20	1.49	1.20	77	60	44
		22	1.49	1.18	84	68	51

[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)[1]

Data as of: January 31, 1999

	CaD (N=25328)		
	Non-Adherent Participants (N=11481)	Adherent[2] Participants (N=13847)	OR
Age:			
50-54[3]	2454	2079	1.00
55-59	3058	3300	1.21**
60-69	4286	6064	1.51**
70-79	1683	2404	1.46**
Ethnicity:			
White	9163	11937	1.00
Black	1300	968	0.68**
Hispanic	619	505	0.66**
Other Minority	377	414	0.88
Education:			
Post H.S.	8842	10414	1.00
Some H.S. / Diploma	2348	3167	1.05
0-8 Years	196	177	0.85
Income:			
<20 K	1872	2231	1.00
20-35K	2667	3482	1.06
35K-50K	2240	2816	1.05
>50K	4094	4632	1.02
Marital Status:			
Married	6993	8763	1.00
Not Married	4427	5037	0.89**
Four Week Phone Call[4]:			
No	1810	1462	1.00
Yes	6684	9483	1.46**
Gas:			
Symptom Did Not Occur	3837	4714	1.00
Mild	5576	7043	1.07*
Moderate to Severe	2068	2090	0.92*
Constipation:			
Symptom Did Not Occur	7502	9443	1.00
Mild	3010	3471	0.94*
Moderate to Severe	969	933	0.83**
Primary CT Randomization:			
DM and HRT	1417	2214	1.00
HRT only	2739	4685	1.03
DM only	7325	6948	0.59**
CaD Formulation:			
Chewable	8969	9394	1.00
Swallowable	2505	4453	1.51**

[1] * P-values <=.05 from Wald Test.

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

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

[3] Underlined levels are reference categories.

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

Table 5.6
Logistic Regression Analyses of CaD Adherence at Annual Visit-2 (AV-2)[1]
for Participants with >80% CaD Adherence at SAV-2

Data as of: January 31, 1999

	CaD (N=10161)		
	Non-Adherent Participants (N=2098)	Adherent[2] Participants (N=8063)	OR
Age:			
50-54[3]	442	1295	1.00
55-59	505	1909	1.30**
60-69	824	3536	1.43**
70-79	327	1323	1.33**
Ethnicity:			
White	1690	7073	1.00
Black	233	502	0.54**
Hispanic	101	258	0.63**
Other Minority	68	220	0.77
Education:			
Post H.S.	1614	6057	1.00
Some H.S. / Diploma	435	1865	1.07
0-8 Years	34	98	0.93
Income:			
<20 K	348	1278	1.00
20-35K	498	2069	1.03
35K-50K	414	1700	1.02
>50K	733	2635	0.92
Marital Status:			
Married	1245	5205	1.00
Not Married	843	2839	0.80**
Gas:			
Symptom Did Not Occur	727	2717	1.00
Mild	1039	4064	1.08
Moderate to Severe	332	1282	1.04
Constipation:			
Symptom Did Not Occur	1370	5456	1.00
Mild	583	2009	0.86**
Moderate to Severe	145	598	1.03
Primary CT Randomization:			
DM and HRT	300	1390	1.00
HRT only	537	2751	1.07
DM only	1261	3922	0.61**
HRT Adherence at AV2:			
No	251	1306	1.00
Yes	586	2835	0.93
CaD Formulation:			
Chewable	1821	6845	1.00
Swallowable	277	1218	1.12

[1] * P-values <=.05 from Wald Test.

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

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

[3] Underlined levels are reference categories.

Table 5.7
Logistic Regression Analyses of CaD Adherence at Annual Visit-3 (AV-3)[1]
for Participants with >80% CaD Adherence at AV-2

Data as of: January 31, 1999

	CaD (N=5070)		
	Non-Adherent Participants (N=1120)	Adherent[2] Participants (N=3950)	OR
Age:			
50-54[3]	223	719	1.00
55-59	298	976	1.03
60-69	435	1677	1.10
70-79	164	578	1.01
Ethnicity:			
White	935	3523	1.00
Black	119	228	0.58**
Hispanic	41	113	0.72
Other Minority	22	83	1.06
Education:			
Post H.S.	854	2961	1.00
Some H.S. / Diploma	237	916	1.05
0-8 Years	19	55	0.89
Income:			
<20 K	183	625	1.00
20-35K	288	1021	1.03
35K-50K	218	833	1.11
>50K	391	1294	1.02
Marital Status:			
Married	691	2602	1.00
Not Married	424	1335	0.86
Gas			
Symptom Did Not Occur	399	1283	1.00
Mild	519	2009	1.17
Moderate to Severe	202	658	0.94
Constipation			
Symptom Did Not Occur	749	2605	1.00
Mild	290	1042	1.02
Moderate to Severe	81	303	1.10
Primary CT Randomization:			
DM and HRT	149	681	1.00
HRT only	264	1248	1.02
DM only	707	2021	0.57**
HRT Adherence at AV2			
No	143	706	1.00
Yes	270	1223	0.91

[1] * P-values <=.05 from Wald Test.

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

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

[3] Underlined levels are reference categories.

Table 5.8
Reasons for Stopping CaD

Data as of: January 31, 1999

Reasons[1]	(N=4008)	
Personal	227	6%
Travel	68	2%
Study Procedures	51	1%
Health	916	23%
Experiencing health problems or symptoms not due to intervention	512	13%
Worried about health effects of medical tests	21	1%
Worried about costs if adverse effects occur	11	(<1%)
Advised not to participate by health care provider	297	7%
Study conflicts with health care needs	212	5%
Expected more care	9	(<1%)
Intervention	1694	42%
Reports health problems or symptoms from WHI Intervention	1137	28%
Problem with Clinic Practitioner or other CC staff	3	(<1%)
Doesn't like taking pills	477	12%
Doesn't like DM requirements	9	(<1%)
Problems with DM group nutritionist or group members	3	(<1%)
Doesn't like DM eating patterns	4	(<1%)
Doesn't like randomized nature of intervention	161	4%
Expected some benefit from intervention	29	1%
Won't participate in safety procedures	17	(<1%)
Other	1284	32%
Not Given	517	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 91.0% of those participants due for the visit overall (range across CCs: 73%-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 92.2% for Year 1 data collection, which includes mailings plus CC follow-up of non-responders, falls short of meeting the 95% goal. For Year 2, the rates are slightly lower, at least in part because CC follow-up of non-responders is not required in even numbered follow-up years. 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[2]		Response to Mailings		Response to CC follow-up		Total Responses	
	# Due[1]	N	%	N	%[3]	N	%[4]	N	%[5]
Year 1	62443	62281	99.7	56207	90.2	1355	22.3	57562	92.2
VCC	29346	29323	99.9	26922	91.8	563	23.4	27485	94.0
NCC	33097	32958	99.6	29285	88.9	792	22.0	30077	90.9
Year 2	37459	36434	97.3	31576	86.7	N/A		31576	84.3
VCC	18344	17791	97.0	15734	88.4	N/A		15734	85.8
NCC	19115	18643	97.5	15842	85.0	N/A		15842	82.9

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

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, for HRT women, 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†	-9.1	-6.7	NA	NA
HDL-C (mg/dl)	5.6	1.2	-1.2	3.9	2.2	4	-1
LDL-C (mg/dl)	-14.5	-16.5	-4.1	-14.6	-11.9	-20	-5
Total cholesterol (mg/dl)	-7.6	-14.0	-4.2	-9.5	-9.8	NA	NA
Triglycerides (mg/dl)	13.7†	11.4†	-3.2†	5.8	0.1	13	5
Glucose (mg/dl)	-2.8	-2.1	-0.5	-2.7	-2.3	NA	NA
Insulin (uIU/ml)	-.24†	-.53†	.53†	-0.8	-0.3	NA	NA

† Calculated on log-transformed values.

Table 7.2 displays the same analytes at *Table 7.1* measured in DM women. For comparison purposes, the Women's Health Trial: Feasibility Study in Minority Populations have reported

[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.

dietary intake and 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. Current WHI results for DM women are shown in the final column.

	WHT:FSMP Results			WHI
	Intervention	Control	C-I	C-I
FFQ % cal from fat				
Baseline	39.7	39.1	-0.6	0.0
12 months	25.7	36.0	10.3	11.0
Total cholesterol (mg/dl)				
Baseline	219	219	0	
Change at 12 months	-8.4	-4.9	-3.5	-6.4

Prospective analyses of OS bloods for these routine measures are being 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 January 31, 1999 the CCC had received serial analysis on 13,825 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 (6 of 91 confirmed MIs).

Table 7.1
Blood Specimen Analysis: HRT Participants

Data as of: January 31, 1999

	Without Uterus			With Uterus		
	n	mean*	std.*	n	mean*	std.*
Micronutrients						
Alpha-Carotene (µg/ml)						
Baseline	541	0.07	0.06	651	0.09	0.07
AV-1	537	0.07	0.04	651	0.09	0.07
AV-1 - Baseline	537	-0.01	0.06	650	0.00	0.04
Alpha-tocopherol (µg/ml)						
Baseline	541	14.9	5.0	651	15.4	5.6
AV-1	537	16.0	5.5	652	15.6	5.3
AV-1 - Baseline	537	1.0	4.3	651	0.2	4.2
Beta-Carotene (µg/ml)						
Baseline	540	0.27	0.16	651	0.34	0.28
AV-1	536	0.25	0.22	652	0.31	0.27
AV-1 - Baseline	536	-0.02	0.23	651	-0.03	0.16
Beta-Cryptoxanthine (µg/ml)						
Baseline	541	0.07	0.04	651	0.09	0.07
AV-1	537	0.07	0.04	651	0.09	0.06
AV-1 - Baseline	537	0.00	0.04	650	0.00	0.05
Gamma-tocopherol (µg/ml)						
Baseline	541	2.45	1.16	651	2.36	1.13
AV-1	537	2.25	1.18	652	1.98	0.98
AV-1 - Baseline	537	-0.21	0.83	651	-0.38	0.79
Lycopene (µg/ml)						
Baseline	541	0.38	0.16	651	0.39	0.16
AV-1	537	0.39	0.14	652	0.40	0.14
AV-1 - Baseline	537	0.01	0.12	651	0.00	0.14
Lutein and Zeaxanthin (µg/ml)						
Baseline	541	0.19	0.06	651	0.21	0.08
AV-1	537	0.20	0.07	652	0.22	0.08
AV-1 - Baseline	537	0.01	0.05	651	0.01	0.05
Retinol (µg/ml)						
Baseline	541	0.59	0.11	651	0.58	0.12
AV-1	537	0.61	0.13	652	0.59	0.12
AV-1 - Baseline	537	0.02	0.09	651	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)
Blood Specimen Analysis: HRT Participants

Data as of: January 31, 1999

	Without Uterus			With Uterus		
	n	mean*	std.*	n	mean*	std.*
Clotting Factor						
Factor VII Activity, Antigen (%)						
Baseline	527	124.0	21.6	634	118.3	22.4
AV-1	519	130.8	26.3	641	124.6	24.9
AV-1 – Baseline	507	7.5	17.4	627	6.3	16.2
Factor VII C (%)						
Baseline	510	129.5	21.4	619	124.2	22.4
AV-1	511	134.1	27.6	634	123.7	24.0
AV-1 – Baseline	485	5.0	21.4	607	-0.9	18.1
Fibrinogen (mg/dl)						
Baseline	527	317.4	52.4	634	307.9	48.5
AV-1	518	309.3	50.1	640	301.1	48.5
AV-1 – Baseline	506	-9.1	45.7	626	-6.7	48.2
Hormones / Other						
Glucose (mg/dl)						
Baseline	539	106.0	28.8	650	100.7	22.9
AV-1	537	103.4	21.7	651	98.4	17.9
AV-1 – Baseline	536	-2.7	19.0	649	-2.3	12.0
Insulin (µIU/ml)						
Baseline	535	12.2	5.9	648	10.9	4.2
AV-1	537	11.5	5.7	649	10.6	4.2
AV-1 – Baseline	532	-0.8	3.2	645	-0.3	2.8

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

Table 7.1 (Continued)
Blood Specimen Analysis: HRT Participants

Data as of: January 31, 1999

	Without Uterus			With Uterus		
	n	mean*	std.*	n	mean*	std.*
Lipoproteins						
HDL-2 (mg/dl)						
Baseline	535	16.2	6.9	638	16.8	6.9
AV-1	530	18.5	7.8	644	18.2	7.3
AV-1 – Baseline	525	2.3	4.1	632	1.2	3.7
HDL-3 (mg/dl)						
Baseline	536	40.4	6.5	638	40.4	6.6
AV-1	532	42.3	6.8	645	41.3	6.1
AV-1 – Baseline	527	1.6	4.7	633	0.8	4.3
HDL-C (mg/dl)						
Baseline	539	56.7	12.0	652	57.3	12.1
AV-1	537	60.7	12.8	651	59.5	11.9
AV-1 – Baseline	536	3.9	7.5	651	2.2	6.1
LDL-C (mg/dl)						
Baseline	534	142.1	27.5	644	140.7	28.5
AV-1	532	127.9	25.5	641	128.7	25.9
AV-1 – Baseline	528	-14.6	25.0	637	-11.9	21.6
Lp(a) (mg/dl)						
Baseline	533	26.2	23.5	644	27.0	24.1
AV-1	530	23.8	22.5	647	24.0	21.8
AV-1 – Baseline	526	-2.6	9.3	640	-2.5	8.7
Total Cholesterol (mg/dl)						
Baseline	540	229.8	29.5	652	227.6	32.9
AV-1	537	220.8	25.2	651	217.8	29.1
AV-1 – Baseline	536	-9.5	26.1	651	-9.8	23.1
Triglyceride (mg/dl)						
Baseline	540	157.1	63.6	652	146.8	65.0
AV-1	537	162.4	61.5	650	146.8	55.3
AV-1 – Baseline	536	5.8	50.5	650	0.1	42.5

* 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: January 31, 1999

	n	mean*	std.*
Micronutrients			
Alpha-Carotene (µg/ml)			
Baseline	1401	0.08	0.06
AV-1	1401	0.09	0.05
AV-1 – Baseline	1399	0.00	0.05
Alpha-tocopherol (µg/ml)			
Baseline	1401	15.4	5.1
AV-1	1401	16.1	5.3
AV-1 – Baseline	1399	0.6	3.9
Beta-Carotene (µg/ml)			
Baseline	1401	0.30	0.22
AV-1	1401	0.30	0.22
AV-1 – Baseline	1399	0.00	0.19
Beta-Cryptoxanthine (µg/ml)			
Baseline	1401	0.08	0.04
AV-1	1400	0.09	0.05
AV-1 – Baseline	1398	0.00	0.04
Gamma-tocopherol (µg/ml)			
Baseline	1401	2.25	1.16
AV-1	1400	1.90	1.09
AV-1 – Baseline	1398	-0.35	0.77
Lycopene (µg/ml)			
Baseline	1401	0.40	0.15
AV-1	1401	0.41	0.16
AV-1 – Baseline	1399	0.00	0.14
Lutein and Zeaxanthin (µg/ml)			
Baseline	1401	0.22	0.09
AV-1	1401	0.22	0.08
AV-1 – Baseline	1399	0.00	0.05
Retinol (µg/ml)			
Baseline	1401	0.60	0.12
AV-1	1401	0.60	0.12
AV-1 – Baseline	1399	0.00	0.08

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

Table 7.2 (Continued)
Blood Specimen Analysis: DM Participants

Data as of: January 31, 1999

	n	mean*	std.*
Clotting Factors			
Factor VII Activity, Antigen (%)			
Baseline	1380	126.6	25.5
AV-1	1369	126.4	26.7
AV-1 - Baseline	1350	-0.2	16.6
Factor VII C (%)			
Baseline	1347	130.4	26.8
AV-1	1342	126.7	25.6
AV-1 - Baseline	1300	-4.4	19.7
Fibrinogen (mg/dl)			
Baseline	1380	300.7	49.7
AV-1	1369	299.8	47.5
AV-1 - Baseline	1350	-0.8	41.6
Hormones/Other			
Glucose (mg/dl)			
Baseline	1401	99.5	21.2
AV-1	1399	98.3	20.3
AV-1 - Baseline	1397	-1.2	16.4
Insulin (μIU/ml)			
Baseline	1395	10.8	4.9
AV-1	1393	10.9	10.9
AV-1 - Baseline	1385	0.1	9.6

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

Table 7.2 (Continued)
Blood Specimen Analysis: DM Participants

Data as of: January 31, 1999

	n	mean*	std.*
Lipoproteins			
HDL-2 (mg/dl)			
Baseline	1376	18.2	7.2
AV-1	1384	18.4	7.2
AV-1 - Baseline	1362	0.3	4.3
HDL-3 (mg/dl)			
Baseline	1378	42.3	7.4
AV-1	1385	41.3	7.0
AV-1 - Baseline	1365	-0.9	4.6
HDL-C (mg/dl)			
Baseline	1397	60.3	13.1
AV-1	1399	59.7	12.5
AV-1 - Baseline	1394	-0.5	6.9
LDL-C (mg/dl)			
Baseline	1380	134.0	29.0
AV-1	1374	127.9	27.5
AV-1 - Baseline	1362	-6.3	18.2
Lp(a) (mg/dl)			
Baseline	1387	26.9	24.9
AV-1	1387	26.7	25.4
AV-1 - Baseline	1374	-0.2	8.4
Total Cholesterol (mg/dl)			
Baseline	1398	225.2	31.7
AV-1	1399	218.9	29.8
AV-1 - Baseline	1395	-6.4	20.8
Triglyceride (mg/dl)			
Baseline	1398	153.3	73.5
AV-1	1399	158.5	81.4
AV-1 - Baseline	1395	4.7	45.5

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

Table 7.3
Bone Mineral Density[1] Analysis: HRT Participants

Data as of: January 31, 1999

	Without Uterus			With Uterus		
	n	mean	std.	n	mean	std.
Whole Body Scan						
Baseline	936	1.01	0.11	1026	0.99	0.10
AV1	801	1.01	0.11	880	1.00	0.10
AV3	377	1.03	0.11	398	1.01	0.10
AV1 % Change from baseline BMD[2]	798	0.41	2.62	878	0.24	2.34
AV3 % Change from baseline BMD[3]	374	1.53	3.25	397	1.73	3.14
Spine Scan						
Baseline	910	0.97	0.16	1004	0.95	0.16
AV1	782	0.99	0.16	857	0.97	0.17
AV3	370	1.00	0.17	391	0.98	0.16
AV1 % Change from baseline BMD	780	1.91	4.59	854	2.04	4.30
AV3 % Change from baseline BMD	368	3.40	6.31	390	4.29	6.07
Hip Scan						
Baseline	933	0.86	0.14	1024	0.84	0.13
AV1	801	0.86	0.14	878	0.84	0.13
AV3	375	0.89	0.15	399	0.87	0.13
AV1 % Change from baseline BMD	798	0.64	3.10	877	0.51	3.02
AV3 % Change from baseline BMD	372	2.08	4.48	398	2.23	4.33

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

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

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

Table 7.4
Bone Mineral Density[1] Analysis: DM Participants

Data as of: January 31, 1999

	n	mean	std.
Whole Body Scan			
Baseline	3619	1.03	0.11
AV1	3251	1.03	0.11
AV3	1781	1.04	0.11
AV1 % Change from baseline BMD[2]	3223	0.17	2.49
AV3 % Change from baseline BMD[3]	1760	1.26	3.20
Spine Scan			
Baseline	3547	0.99	0.17
AV1	3187	1.00	0.17
AV3	1745	1.01	0.17
AV1 % Change from baseline BMD	3164	0.72	3.87
AV3 % Change from baseline BMD	1732	2.15	5.15
Hip Scan			
Baseline	3618	0.87	0.14
AV1	3249	0.87	0.14
AV3	1768	0.88	0.14
AV1 % Change from baseline BMD	3232	-0.05	2.77
AV3 % Change from baseline BMD	1757	1.09	4.12

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

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

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

Table 7.5
Bone Mineral Density[1] Analysis: CaD Participants

Data as of: January 31, 1999

	n	mean	std.
Whole Body Scan			
AV1	2325	1.02	0.11
AV3	1211	1.04	0.11
AV3 % Change from baseline BMD[2]	1180	1.70	2.86
Spine Scan			
AV1	2271	0.99	0.17
AV3	1189	1.01	0.17
AV3 % Change from baseline BMD[2]	1159	1.71	4.29
Hip Scan			
AV1	2319	0.86	0.14
AV3	1201	0.88	0.14
AV3 % Change from baseline BMD[2]	1173	1.62	3.27

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

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

Table 7.6
Bone Mineral Density[1] Analysis: OS Participants

Data as of: January 31, 1999

	n	mean	std.
Whole Body Scan			
Baseline	6404	1.01	0.11
Baseline (for ppts. with an AV3 scan)	2648	1.01	0.10
AV3	2667	1.02	0.11
AV3 % Change from baseline BMD[2]	2648	0.72	3.45
Spine Scan			
Baseline	6306	0.98	0.17
Baseline (for ppts. with an AV3 scan)	2625	0.98	0.17
AV3	2632	0.99	0.18
AV3 % Change from baseline BMD	2625	1.82	5.15
Hip Scan			
Baseline	6408	0.84	0.14
Baseline (for ppts. with an AV3 scan)	2664	0.84	0.14
AV3	2671	0.84	0.14
AV3 % Change from baseline BMD	2664	0.24	4.08

[1] Measured in (g/cm^2).
[2] 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: January 31, 1999

	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]	12940	13	68	13021
Borderline Q-wave change[4]	476	2	6	484
Ischemic ST-T evolution[5]	197	1	6	204
Possible evolving Q-wave MI[6]	185	1	5	191
Evolving Q-wave MI[7]	27[8]	0	6	33
Total	**13825**	**17**	**91**	**13933**
HRT Participants				
No significant Q or ST-T evolution[3]	4550	6	32	4588
Borderline Q-wave change[4]	174	0	2	176
Ischemic ST-T evolution[5]	86	1	3	90
Possible evolving Q-wave MI[6]	77	1	2	80
Evolving Q-wave MI[7]	15	0	3	18
Total	**4902**	**8**	**42**	**4952**
DM Participants				
No significant Q or ST-T evolution[3]	10005	8	48	10061
Borderline Q-wave change[4]	364	2	4	370
Ischemic ST-T evolution[5]	136	1	3	140
Possible evolving Q-wave MI[6]	136	1	4	141
Evolving Q-wave MI[7]	19	0	4	23
Total	**10660**	**12**	**63**	**10735**
CaD Participants				
No significant Q or ST-T evolution[3]	7299	8	26	7333
Borderline Q-wave change[4]	294	1	2	297
Ischemic ST-T evolution[5]	104	1	2	107
Possible evolving Q-wave MI[6]	98	1	2	101
Evolving Q-wave MI[7]	17	0	4	21
Total	**7812**	**11**	**36**	**7859**

[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 for potential cardiovascular, cancer, and fracture outcomes 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. In addition to the cardiovascular, cancer, and fracture outcome data, which are adjudicated, outcomes for selected other diseases, such as diabetes, gallbladder disease, and hysterectomy, are collected as self-reports only.

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. Currently about 84% of the self-reports have been adjudicated. 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 87% of self-reported outcomes in the CT and 81% of the self-reported outcomes in the OS requiring adjudication have been closed, 35% of the outcomes in the CT and 40% of the outcomes in the OS have been closed within 90 days of self-report and 56% (CT) and 62% (OS) within 180 days. (Note: the fact that the percentages for the OS appear better is because most of the outcomes in 1996 and earlier, when outcomes processing was considerably slower, are CT outcomes.)

Since 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 40-45% to 55-60%. 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 3.1% for the CT and 5.7% for the OS. Six months ago about 7% of the forms that are more than a year old had not yet been adjudicated; there has thus been a major improvement in cleaning up old cases!

Figure 8.1-8.4 – Timeliness of Adjudications display Kaplan-Meier curves for the time period from reporting an outcome on *Form 33D* until the adjudication case is closed per year of self-report and, for recent data, per quarter of self-report, separately for the CT and OS. The Kaplan-Meier for self-reports received per year in *Figures 8.1* and *8.3* show that improvements in the processing of outcomes have happened throughout the study. *Figure 8.2* shows the improvement that took place during 1998 in the processing of outcomes for the CT. Comparison of *Figures 8.2* and *8.4* shows that for recent data the outcomes processing for the OS lags behind 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.

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 whose 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 8.3*, 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 outcomes have a 77% agreement

rate between self-reports and locally confirmed outcomes (86% if we exclude angina, which is probably the softest cardiovascular outcome), cancer outcomes have an agreement rate of 84% (95% for the primary cancers), and fracture outcomes have an agreement rate of 80%.

The number of administrative denials is somewhat larger for fractures than for other outcomes categories 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.

There is a considerable backlog of locally confirmed cases that have not yet been centrally adjudicated. This backlog is partly artificial, as it takes about three-four months for a locally confirmed case to finish the central adjudication process. In addition, the cancer coder recently resigned, and CCC staff puts a higher priority on assisting clinics than on central adjudication.

8.4 Outcomes Overview

Tables 8.5-8.9 - Counts (Annualized Percentages) of Participants with Self-Reported Outcomes for the Clinical Trial, Hormone Replacement Therapy Component, Dietary Modification Component, Calcium and Vitamin D Component, and Observational Study, contain counts of the number of self-reports for some of the WHI outcomes that are not locally verified. Note that for many of the confirmed 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 the HRT, DM, and CaD tables, the counts and rates are pooled across all arms.

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 counts for the number of locally verified outcomes for the major WHI outcomes. 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. We estimate that the actual number of cases for most outcomes is currently about 25% larger than what is reported here. When we get further in the study the number of not yet adjudicated cases will decrease as a fraction of the total number of cases.

For most cardiovascular outcomes the CT participants seem to have slightly higher rates than the OS participants, while the OS participants have marginally higher rates for the cancer outcomes, but the difference between the CT and OS rate is typically quite small. It is important

to remember that CT and OS participants were quite different at baseline. For example, many OS participants were screened out of the DM component of the CT because of a low baseline fat intake. The rate of other fractures is considerably higher for the CT, since for the OS currently self-reports of other fractures are only adjudicated at selected bone-density clinics.

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 should diminish 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 30% of those observed in the population.

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: January 31, 1999

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	3776	265	7%	511	14%	2915	77%	85	2%
1996 July - December	1364	311	23%	416	30%	605	44%	32	2%
1997 January-June	2164	765	35%	574	27%	754	35%	71	3%
1997 July-December	2519	982	39%	541	21%	883	35%	113	4%
1998 January	534	210	39%	166	31%	139	26%	19	4%
1998 February	505	228	45%	148	29%	100	20%	29	6%
1998 March	636	262	41%	239	38%	89	14%	46	7%
1998 April	624	283	45%	231	37%	55	9%	55	9%
1998 May	552	262	47%	183	33%	50	9%	57	10%
1998 June	708	443	63%	176	25%	29	4%	60	8%
1998 July	670	411	61%	140	21%	24	4%	95	14%
1998 August	712	421	59%	165	23%			126	18%
1998 September	687	393	57%	135	20%			159	23%
1998 October	771	452	59%	66	9%			253	33%
1998 November	644	338	52%					306	48%
1998 December	569	173	30%					396	70%
1999 January	515	56	11%					459	89%
Total	17950	6255	35%	3691	21%	5643	31%	2361	13%

[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 Clinical Trial Timeliness per Year of Self-Report

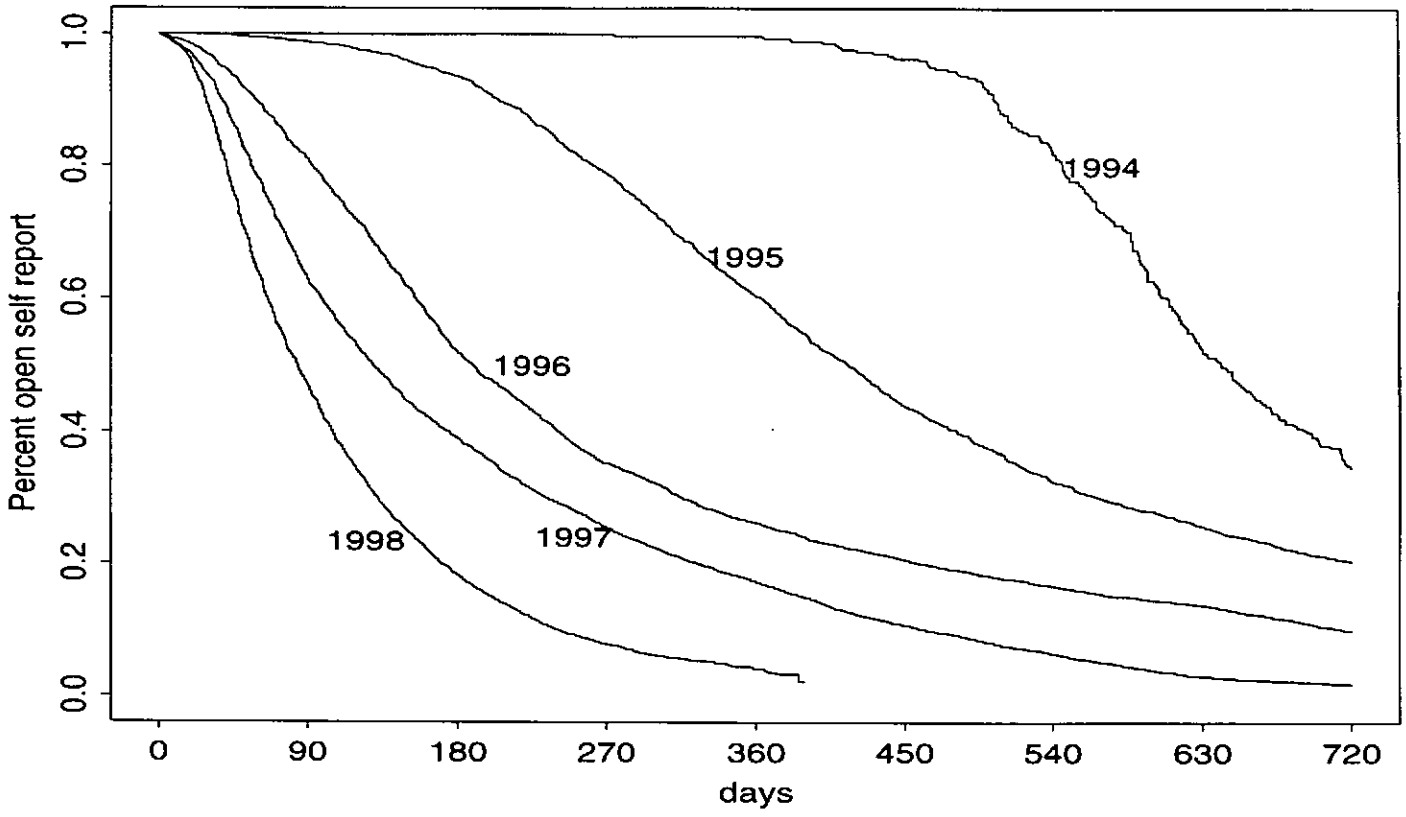


Figure 8.2 Clinical Trial Timeliness per Quarter-Year of Self-Report

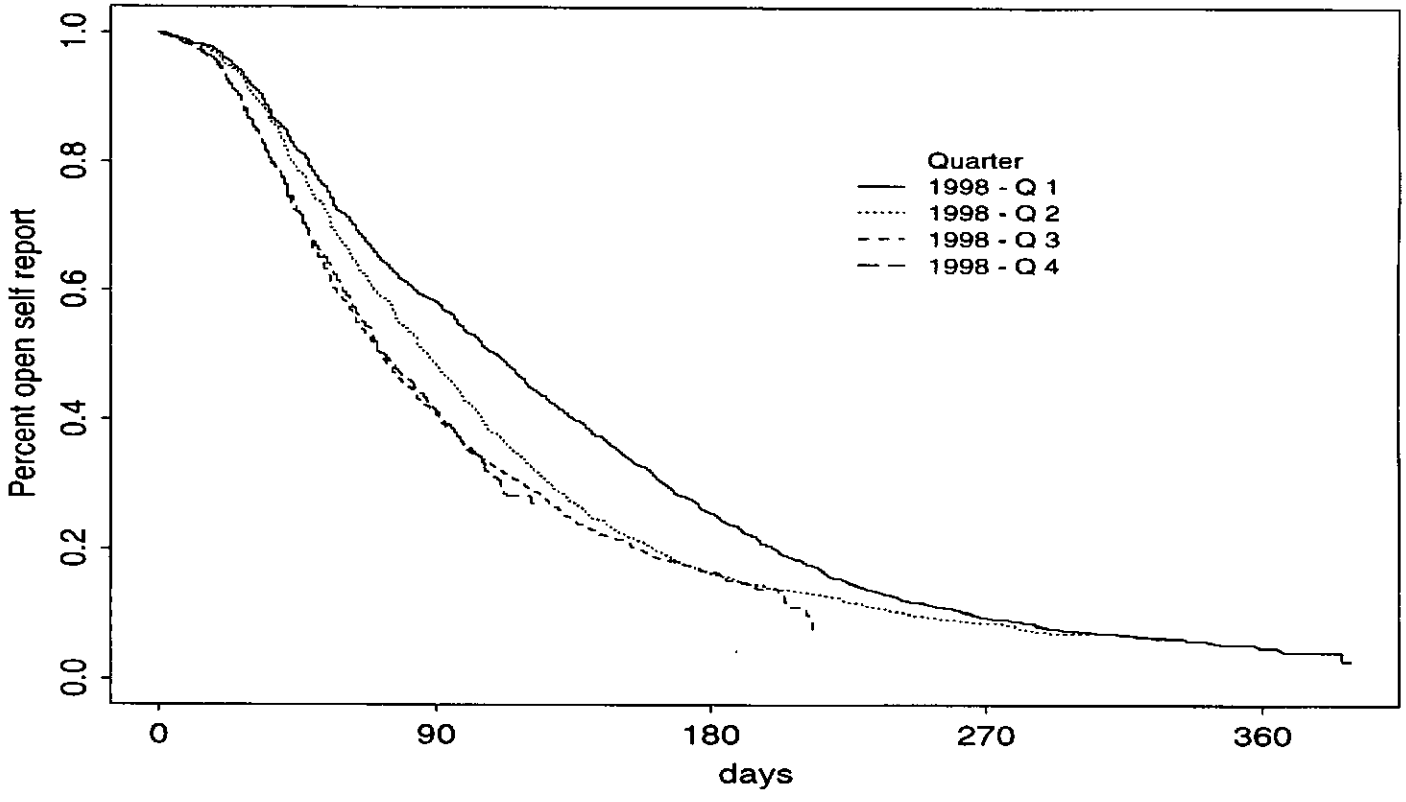


Figure 8.3 Observational Study Timeliness per Year of Self-Report

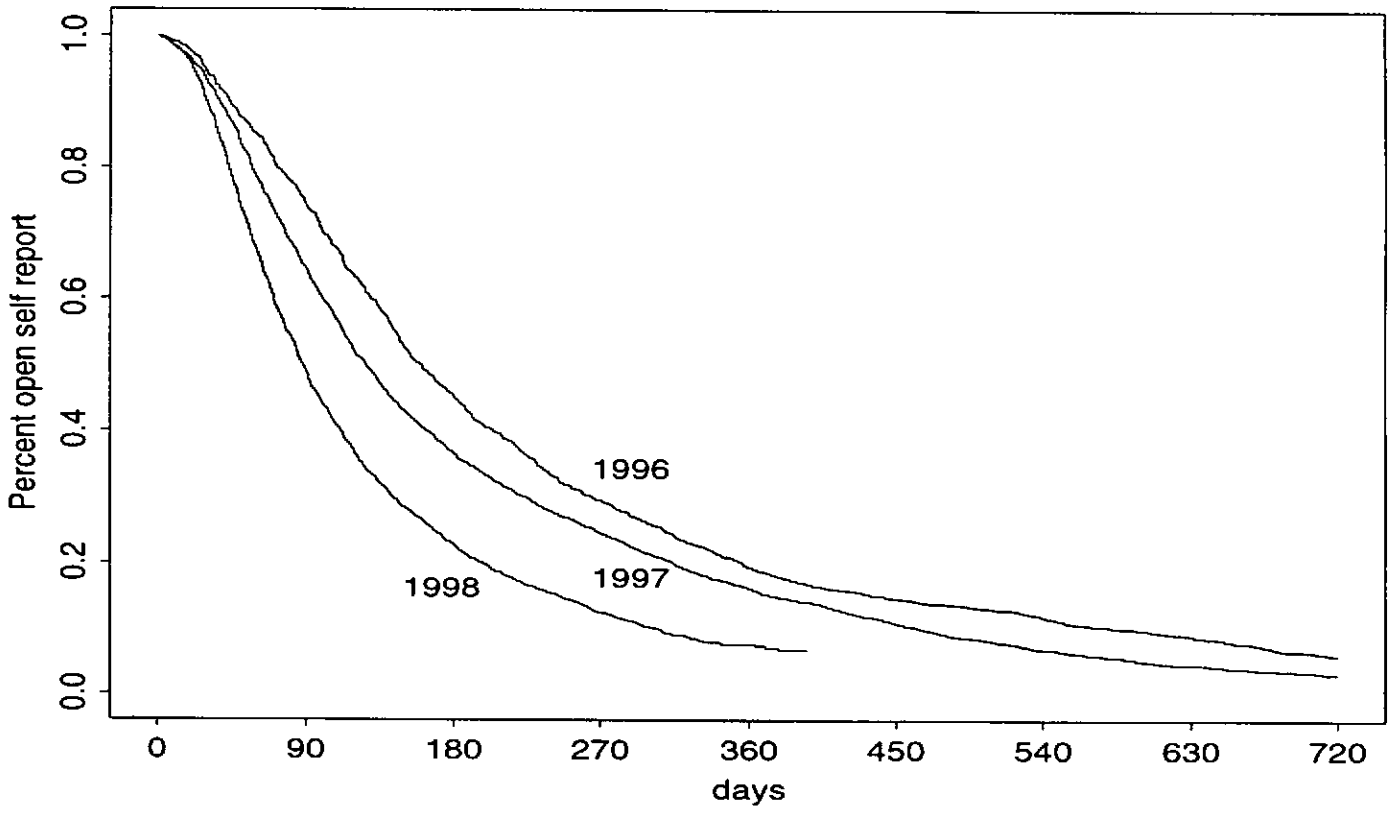


Figure 8.4 Observational Study Timeliness per Quarter-Year of Self-Report

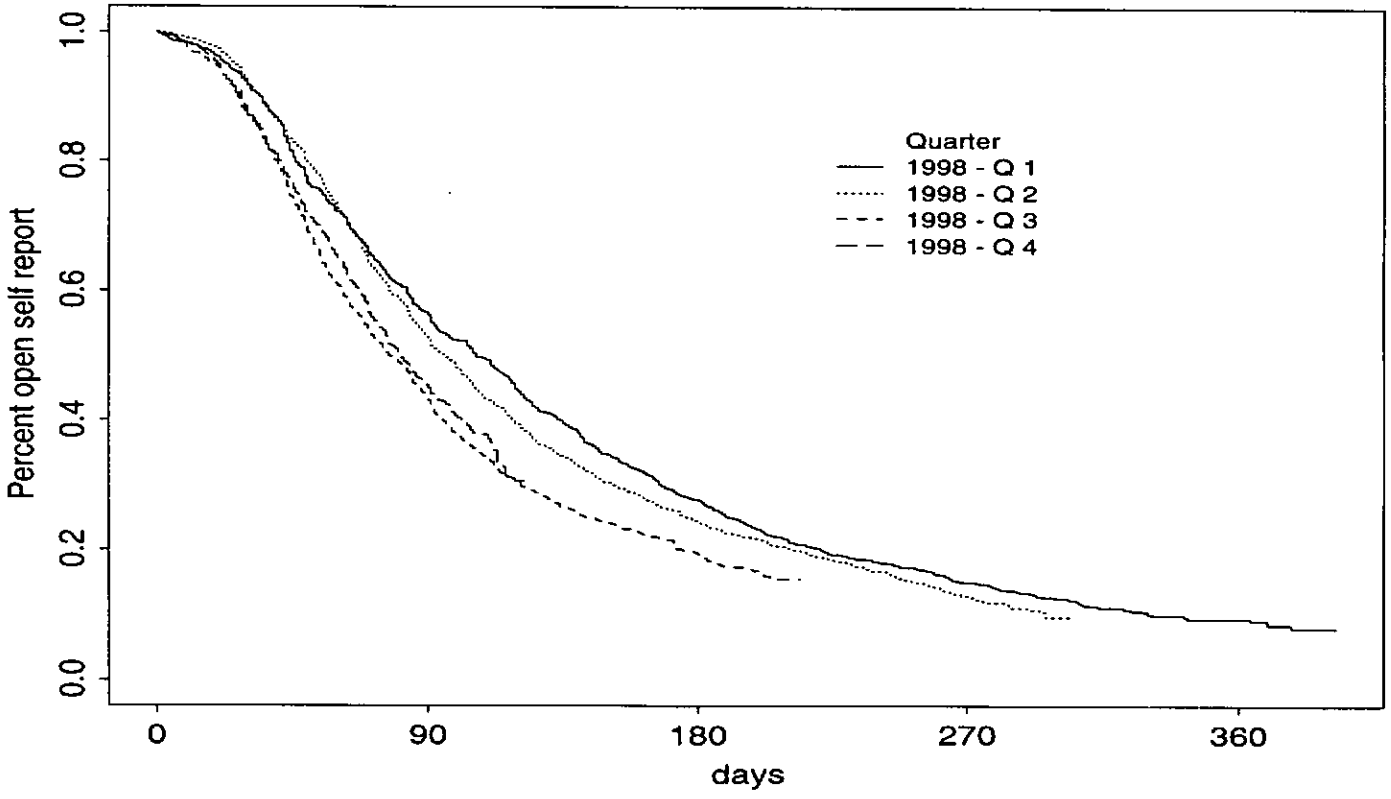


Table 8.2
Timeliness and Completeness of Local Adjudications - OS[1]

Data as of: January 31, 1999

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	234	86	37%	42	18%	102	44%	4	2%
1996 July - December	1298	313	24%	400	31%	550	42%	35	3%
1997 January-June	2140	863	40%	564	26%	624	29%	89	4%
1997 July-December	2276	717	32%	663	29%	694	30%	202	9%
1998 January	408	194	48%	102	25%	80	20%	32	8%
1998 February	365	147	40%	109	30%	68	19%	41	11%
1998 March	444	194	44%	134	30%	72	16%	44	10%
1998 April	508	233	46%	143	28%	79	16%	53	10%
1998 May	514	208	40%	171	33%	48	9%	87	17%
1998 June	569	314	55%	137	24%	35	6%	83	15%
1998 July	615	348	57%	136	22%	16	3%	115	19%
1998 August	660	381	58%	144	22%	0	0%	135	20%
1998 September	599	342	57%	105	18%	0	0%	152	25%
1998 October	682	365	54%	55	8%	0	0%	262	38%
1998 November	558	271	49%	0	0%	0	0%	287	51%
1998 December	597	159	27%	0	0%	0	0%	438	73%
1999 January	454	45	10%	0	0%	0	0%	409	90%
Total	12921	5180	40%	2905	22%	2368	18%	2468	19%

[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—CT and OS

Data as of : January 31, 1999

	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	566	435	77%	299	(69%)	73	(17%)	58	(13%)	5	(1%)
Angina[2]	1489	1161	78%	509	(44%)	158	(14%)	470	(40%)	24	(2%)
Congestive heart failure	360	297	83%	211	(71%)	22	(7%)	59	(20%)	5	(2%)
CABG/PTCA	1103	852	77%	750	(88%)	62	(7%)	33	(4%)	7	(1%)
Carotid artery disease[3]	204	169	83%	131	(78%)	23	(14%)	14	(8%)	1	(1%)
Stroke/TIA[4]	878	678	77%	521	(77%)	36	(5%)	105	(15%)	16	(2%)
PVD	156	119	76%	68	(57%)	19	(16%)	28	(24%)	4	(3%)
DVT[5]	122	103	84%	72	(70%)	12	(12%)	16	(16%)	3	(3%)
PE[5]	51	41	80%	36	(88%)	1	(2%)	4	(10%)	0	(0%)
Cancers											
Breast cancer	1388	1070	77%	972	(91%)	3	(0%)	88	(8%)	7	(1%)
Ovary cancer	125	98	78%	69	(70%)	14	(14%)	14	(14%)	1	(1%)
Endometrial cancer	157	121	77%	91	(75%)	20	(17%)	10	(8%)	0	(0%)
Colorectal	340	265	78%	223	(84%)	15	(6%)	22	(8%)	5	(2%)
Other cancer[6]	1506	1127	75%	774	(69%)	72	(6%)	249	(22%)	32	(3%)
Fractures											
Hip fracture	242	196	81%	156	(80%)	7	(4%)	27	(14%)	6	(3%)
Vertebral fracture	268	216	81%	112	(52%)	11	(5%)	81	(38%)	12	(6%)
Other fracture	2655	2214	83%	1795	(81%)	16	(1%)	337	(15%)	66	(3%)

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

[2] Angina that is self-reported after a confirmed MI, is not adjudicated. In particular, 106 self-reports of angina (102 denied related, 3 denied, 1 administrative denial) are associated with participants who have a confirmed MI

[3] Carotid artery disease that is self-reported after a confirmed Stroke, is not adjudicated. In particular, 3 self-report of Carotid artery disease (3 denied related) is associated with a participant who has a confirmed Stroke.

[4] Stroke and TIA have a combined self-report. Only stroke is monitored. There were 170 participants who reported stroke/TIA for whom only TIA was confirmed

[5] HRT Participants only

[6] Excludes non-melanoma skin cancer

Table 8.4
Agreement of Central Adjudications with Local Adjudications—CT and OS
Data as of: January 31, 1999

	Locally confirmed N	Centrally adjudicated N	%	In agreement N	%[1]
Cardiovascular					
MI	478	229	48%	210	92%
Angina[2]	1029	497	48%	426	86%
Congestive heart failure	444	206	46%	165	80%
CABG/PTCA	834	402	48%	392	98%
DVT[3]	100	48	48%	47	98%
PE[3]	55	23	42%	22	96%
Cancers					
Breast cancer	1008	264	26%	255	97%
Invasive	784	199	25%	189	95%
Non Invasive	235	65	28%	49	75%
Ovary cancer	87	26	30%	24	92%
Endometrial cancer	127	43	34%	41	95%
Colorectal	246	74	30%	71	96%
Fractures					
Hip fracture	190	112	59%	107	96%

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

Table 8.5
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Ethnicity and Age for Clinical Trial

Data as of: January 31, 1999

Outcomes	Total		Ethnicity Minority[1]		White	
No. of participants w/ *Form 33*	66883		12086		54797	
Mean follow-up (months) [2]	25.6		24.0		25.9	
Hospitalizations						
Ever	11276	7.91%	1735	7.19%	9541	8.05%
Two or more	3709	2.60%	548	2.27%	3161	2.67%
Other						
Diabetes (treated)	3102	2.18%	1154	4.78%	1948	1.64%
Gallbladder disease[3]	1681	1.18%	275	1.14%	1406	1.19%
Hysterectomy[4]	643	0.77%	73	0.61%	570	0.80%

Outcome	Age 50-54		55-59		60-69		70-79	
No. of participants w/ *Form 33*	9034		14423		30750		12676	
Mean follow-up (months)[2]	31.6		27.7		23.8		23.2	
Hospitalizations								
Ever	1285	5.41%	2067	6.20%	5171	8.48%	2753	11.23%
Two or more	384	1.62%	624	1.87%	1696	2.78%	1005	4.10%
Other								
Diabetes (treated)	375	1.58%	653	1.96%	1430	2.34%	644	2.63%
Gallbladder disease[3]	265	1.12%	402	1.21%	748	1.23%	266	1.08%
Hysterectomy[4]	111	0.82%	146	0.70%	265	0.75%	121	0.88%

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

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

Table 8.6
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Ethnicity and Age for Hormone Replacement Therapy

Data as of: January 31, 1999

Outcomes	Total		Ethnicity: Minority[1]		White	
No. of participants w/ *Form 33*	26778		5086		21692	
Mean follow-up (months) [2]	24.5		23.4		24.7	
Hospitalizations						
Ever	4428	8.12%	724	7.30%	3704	8.30%
Two or more	1483	2.72%	238	2.40%	1245	2.79%
Other						
Diabetes (treated)	1422	2.61%	542	5.46%	880	1.97%
Gallbladder disease[3]	672	1.23%	115	1.16%	557	1.25%
Hysterectomy[4]	161	0.49%	16	0.33%	145	0.51%

Outcome	Age: 50-54		55-59		60-69		70-79	
No. of participants w/ *Form 33*	3346		5308		12079		6045	
Mean follow-up (months) [2]	29.8		26.2		23.4		22.1	
Hospitalizations								
Ever	441	5.32%	715	6.16%	2036	8.64%	1236	11.12%
Two or more	131	1.58%	222	1.91%	699	2.97%	431	3.88%
Other								
Diabetes (treated)	190	2.29%	305	2.63%	609	2.59%	318	2.86%
Gallbladder disease[3]	98	1.18%	147	1.27%	301	1.28%	126	1.13%
Hysterectomy[4]	18	0.37%	25	0.33%	73	0.51%	45	0.71%

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

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

Table 8.7
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Ethnicity and Age for Dietary Modification

Data as of: January 31, 1999

Outcomes	Total		Ethnicity Minority[1]		White	
No. of participants w/ *Form 33*	48000		8717		39283	
Mean follow-up (months) [2]	26.4		24.4		26.8	
Hospitalizations						
Ever	8226	7.80%	1274	7.20%	6952	7.92%
Two or more	2680	2.54%	392	2.21%	2288	2.61%
Other						
Diabetes (treated)	2152	2.04%	798	4.51%	1354	1.54%
Gallbladder disease[3]	1227	1.16%	198	1.12%	1029	1.17%
Hysterectomy[4]	526	0.88%	60	0.69%	466	0.91%

Outcome	Age 50-54		55-59		60-69		70-79	
No. of participants w/ *Form 33*	6866		10865		22277		7992	
Mean follow-up (months) [2]	32.3		28.4		24.3		24.2	
Hospitalizations								
Ever	1006	5.44%	1605	6.24%	3788	8.41%	1827	11.34%
Two or more	299	1.62%	472	1.83%	1233	2.74%	676	4.20%
Other								
Diabetes (treated)	243	1.31%	464	1.80%	1036	2.30%	409	2.54%
Gallbladder disease[3]	201	1.09%	310	1.20%	544	1.21%	172	1.07%
Hysterectomy[4]	99	0.95%	126	0.80%	212	0.84%	89	1.01%

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

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

Table 8.8
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Ethnicity and Age for Calcium and Vitamin D

Data as of: January 31, 1999

Outcomes	Total		Ethnicity Minority[1]		White	
No. of participants w/ *Form 33*	26919		4323		22596	
Mean follow-up (months) [2]	18.3		16.9		18.6	
Hospitalizations						
Ever	3334	8.13%	462	7.61%	2872	8.22%
Two or more	853	2.08%	122	2.01%	731	2.09%
Other						
Diabetes (treated)	951	2.32%	328	5.40%	623	1.78%
Gallbladder disease[3]	506	1.23%	78	1.28%	428	1.22%
Hysterectomy[4]	187	0.78%	18	0.61%	169	0.80%

Outcome	Age 50-54		55-59		60-69		70-79	
No. of participants w/ *Form 33*	4753		6727		11105		4334	
Mean follow-up (months)[2]	20.0		18.4		18.0		16.9	
Hospitalizations								
Ever	456	5.77%	691	6.70%	1483	8.89%	704	11.51%
Two or more	104	1.31%	156	1.51%	386	2.31%	207	3.38%
Other								
Diabetes (treated)	159	2.01%	223	2.16%	396	2.37%	173	2.83%
Gallbladder disease[3]	87	1.10%	141	1.37%	214	1.28%	64	1.05%
Hysterectomy[4]	37	0.82%	47	0.74%	80	0.82%	23	0.67%

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

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

Table 8.9
Counts (Annualized Percentages) of Participants with Self-Reported Outcomes by Ethnicity and Age for Observational Study

Data as of: January 31, 1999

Outcomes	Total		Ethnicity Minority[1]		White	
No. of participants w/ *Form 33*	71646		10449		61197	
Mean follow-up (months) [2]	24.0		22.7		24.2	
Hospitalizations						
Ever	10339	7.22%	1272	6.42%	9067	7.35%
Two or more	2865	2.00%	358	1.81%	2507	2.03%
Other						
Diabetes (treated)	2678	1.87%	862	4.35%	1816	1.47%
Gallbladder disease[3]	1496	1.04%	204	1.03%	1292	1.05%
Hysterectomy[4]	809	0.96%	112	1.08%	697	0.94%

Outcome	Age 50-54		55-59		60-69		70-79	
No. of participants w/ *Form 33*	10326		14201		30016		17103	
Mean follow-up (months)[2]	25.8		24.8		23.6		22.9	
Hospitalizations								
Ever	1073	4.84%	1546	5.27%	4418	7.49%	3302	10.10%
Two or more	275	1.24%	363	1.24%	1227	2.08%	1000	3.06%
Other								
Diabetes (treated)	278	1.25%	456	1.55%	1205	2.04%	739	2.26%
Gallbladder disease[3]	242	1.09%	299	1.02%	639	1.08%	316	0.97%
Hysterectomy[4]	141	1.06%	146	0.79%	343	1.00%	179	0.97%

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

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

Table 8.10
Locally Verified Outcomes (Annualized Percentages) by Ethnicity for Clinical Trial

Data as of: January 31, 1999

Outcomes	Total		Ethnicity: Minority[1]		White	
No. of participants w/ *Form 33*	66883		12086		54797	
Mean follow-up (months) [2]	25.6		24.0		25.9	
Cardiovascular						
CHD[3]	357	0.25%	44	0.18%	313	0.26%
Coronary death	51	0.04%	7	0.03%	44	0.04%
Total MI	322	0.23%	40	0.17%	282	0.24%
Clinical MI	295	0.21%	33	0.14%	262	0.22%
Silent MI	33	0.02%	7	0.03%	26	0.02%
Angina	555	0.39%	86	0.36%	469	0.40%
CABG/PTCA	470	0.33%	53	0.22%	417	0.35%
Carotid artery disease	107	0.08%	10	0.04%	97	0.08%
Congestive heart failure	216	0.15%	37	0.15%	179	0.15%
Stroke	248	0.17%	41	0.17%	207	0.17%
PVD	62	0.04%	11	0.05%	51	0.04%
DVT	96	0.07%	10	0.04%	86	0.07%
PE	51	0.04%	6	0.02%	45	0.04%
Coronary disease[4]	1021	0.72%	153	0.63%	868	0.73%
DVT/PE	126	0.09%	12	0.05%	114	0.10%
Total CVD	1474	1.03%	213	0.88%	1261	1.06%
Cancer						
Breast cancer[5]	441	0.31%	42	0.17%	399	0.34%
Invasive breast cancer	339	0.24%	30	0.12%	309	0.26%
In situ breast cancer	107	0.08%	12	0.05%	95	0.08%
Ovary cancer	49	0.03%	5	0.02%	44	0.04%
Endometrial Cancer[6]	60	0.07%	8	0.07%	52	0.07%
Colorectal cancer	139	0.10%	20	0.08%	119	0.10%
Other cancer[7,8]	462	0.32%	44	0.18%	418	0.35%
Total cancer	1141	0.80%	118	0.49%	1023	0.86%
Fractures						
Hip fracture	87	0.06%	5	0.02%	82	0.07%
Vertebral fracture	116	0.08%	6	0.02%	110	0.09%
Other fracture[7,9]	1723	1.21%	169	0.70%	1554	1.31%
Total fracture	1888	1.32%	178	0.74%	1710	1.44%
Deaths						
Death other causes-CT	172	0.12%	25	0.10%	147	0.12%
Cardiovascular death	93	0.07%	13	0.05%	80	0.07%
Cancer death	120	0.08%	7	0.03%	113	0.10%
Other death - confirmed[10]	43	0.03%	8	0.03%	35	0.03%
Other death - unconfirmed[11]	203	0.14%	41	0.17%	162	0.14%
Total death	459	0.32%	69	0.29%	390	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] "CHD" includes clinical MI, silent MI, and coronary death.

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

[5] Excludes five 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] Includes adjudicated 'accident/injury' and 'other/unknown' causes of death from Form 124.

[11] Includes deaths which are not yet adjudicated.

Table 8.10
Locally Verified Outcomes (Annualized Percentages) by Age for Clinical Trial

Data as of: January 31, 1999

Outcome	Age 50-54		55-59		60-69		70-79	
No. of participants w/ *Form 33*	9034		14423		30750		12676	
Mean follow-up (months) [1]	31.6		27.7		23.8		23.2	
Cardiovascular								
CHD[2]	28	0.12%	38	0.11%	165	0.27%	126	0.51%
Coronary death	1	0.00%	4	0.01%	20	0.03%	26	0.11%
Total MI	27	0.11%	35	0.11%	153	0.25%	107	0.44%
Clinical MI	23	0.10%	33	0.10%	138	0.23%	101	0.41%
Silent MI	5	0.02%	2	0.01%	17	0.03%	9	0.04%
Angina	34	0.14%	81	0.24%	273	0.45%	167	0.68%
CABG/PTCA	27	0.11%	64	0.19%	227	0.37%	152	0.62%
Carotid artery disease	4	0.02%	14	0.04%	46	0.08%	43	0.18%
Congestive heart failure	10	0.04%	24	0.07%	97	0.16%	85	0.35%
Stroke	11	0.05%	22	0.07%	121	0.20%	94	0.38%
PVD	5	0.02%	9	0.03%	26	0.04%	22	0.09%
DVT	8	0.03%	8	0.02%	44	0.07%	36	0.15%
PE	3	0.01%	4	0.01%	19	0.03%	25	0.10%
Coronary disease[3]	65	0.27%	126	0.38%	488	0.80%	342	1.39%
DVT/PE	8	0.03%	10	0.03%	56	0.09%	52	0.21%
Total CVD	90	0.38%	170	0.51%	703	1.15%	511	2.08%
Cancer								
Breast cancer[4]	46	0.19%	98	0.29%	195	0.32%	102	0.42%
Invasive breast cancer	32	0.13%	77	0.23%	154	0.25%	76	0.31%
In situ breast cancer	15	0.06%	21	0.06%	43	0.07%	28	0.11%
Ovary cancer	8	0.03%	9	0.03%	20	0.03%	12	0.05%
Endometrial Cancer[5]	9	0.07%	11	0.05%	27	0.08%	13	0.10%
Colorectal cancer	7	0.03%	19	0.06%	69	0.11%	44	0.18%
Other cancer[6,7]	48	0.20%	67	0.20%	225	0.37%	122	0.50%
Total cancer	117	0.49%	200	0.60%	531	0.87%	293	1.20%
Fractures								
Hip fracture	8	0.03%	4	0.01%	26	0.04%	49	0.20%
Vertebral fracture	7	0.03%	11	0.03%	52	0.09%	46	0.19%
Other fracture[6,8]	230	0.97%	319	0.96%	808	1.32%	366	1.49%
Total fracture	241	1.01%	331	0.99%	873	1.43%	443	1.81%
Deaths								
Death other causes-CT	12	0.05%	15	0.05%	78	0.13%	67	0.27%
Cardiovascular death	2	0.01%	8	0.02%	42	0.07%	41	0.17%
Cancer death	8	0.03%	16	0.05%	66	0.11%	30	0.12%
Other death - confirmed[9]	8	0.03%	6	0.02%	15	0.02%	14	0.06%
Other death - unconfirmed[10]	15	0.06%	19	0.06%	95	0.16%	74	0.30%
Total death	33	0.14%	49	0.15%	218	0.36%	159	0.65%

[1] 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.*

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

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

[4] Excludes five cases with borderline malignancy.

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

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

[7] Excludes non-melanoma skin cancer

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

[9] Includes adjudicated 'accident/injury' and 'other/unknown' causes of death from Form 124.

[10] Includes deaths which are not yet adjudicated.

Table 8.11

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

Data as of: January 31, 1999

Outcomes	Total		Ethnicity Minority[1]		White	
No. of participants w/ *Form 33*	26778		5086		21692	
Mean follow-up (months) [2]	24.5		23.4		24.7	
Cardiovascular						
CHD[3]	174	0.32%	22	0.22%	152	0.34%
Coronary death	28	0.05%	7	0.07%	21	0.05%
Total MI	156	0.29%	18	0.18%	138	0.31%
Clinical MI	141	0.26%	15	0.15%	126	0.28%
Silent MI	18	0.03%	3	0.03%	15	0.03%
Angina	240	0.44%	34	0.34%	206	0.46%
CABG/PTCA	214	0.39%	24	0.24%	190	0.43%
Carotid artery disease	53	0.10%	2	0.02%	51	0.11%
Congestive heart failure	113	0.21%	24	0.24%	89	0.20%
Stroke	118	0.22%	21	0.21%	97	0.22%
PVD	30	0.05%	6	0.06%	24	0.05%
DVT	90	0.16%	9	0.09%	81	0.18%
PE	45	0.08%	5	0.05%	40	0.09%
Coronary disease[4]	480	0.88%	73	0.74%	407	0.91%
DVT/PE	115	0.21%	11	0.11%	104	0.23%
Total CVD	745	1.37%	106	1.07%	639	1.43%
Cancer						
Breast cancer[5]	139	0.25%	11	0.11%	128	0.29%
Invasive breast cancer	104	0.19%	8	0.08%	96	0.22%
In situ breast cancer	36	0.07%	3	0.03%	33	0.07%
Ovary cancer	10	0.02%	1	0.01%	9	0.02%
Endometrial Cancer[6]	9	0.03%	1	0.02%	8	0.03%
Colorectal cancer	60	0.11%	9	0.09%	51	0.11%
Other cancer[7,8]	191	0.35%	17	0.17%	174	0.39%
Total cancer	407	0.75%	39	0.39%	368	0.82%
Fractures						
Hip fracture	40	0.07%	2	0.02%	38	0.09%
Vertebral fracture	50	0.09%	0	0.00%	50	0.11%
Other fracture[7,9]	744	1.36%	77	0.78%	667	1.49%
Total fracture	820	1.50%	78	0.79%	742	1.66%
Deaths						
Death other causes-HRT[10]	172	0.32%	25	0.25%	147	0.33%
Cardiovascular death	44	0.08%	9	0.09%	35	0.08%
Cancer death	58	0.11%	4	0.04%	54	0.12%
Other death - confirmed[11]	20	0.04%	1	0.01%	19	0.04%
Other death - unconfirmed[12]	84	0.15%	18	0.18%	66	0.15%
Total death	206	0.38%	32	0.32%	174	0.39%

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

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

[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 or colorectal cancer, or cardiovascular disease. Includes deaths which are not yet adjudicated.

[11] Includes adjudicated 'accident/injury' and 'other/unknown' causes of death from Form 124.

[12] Includes deaths which are not yet adjudicated.

Table 8.11
Locally Verified Outcomes (Annualized Percentages) by Age for Hormone Replacement Therapy

Data as of: January 31, 1999

Outcome	Age 50-54		55-59		60-69		70-79	
No. of participants w/ *Form 33*	3346		5308		12079		6045	
Mean follow-up (months) [1]	29.8		26.2		23.4		22.1	
Cardiovascular								
CHD[2]	13	0.16%	17	0.15%	86	0.37%	58	0.52%
Coronary death	1	0.01%	3	0.03%	12	0.05%	12	0.11%
Total MI	12	0.14%	14	0.12%	80	0.34%	50	0.45%
Clinical MI	11	0.13%	13	0.11%	70	0.30%	47	0.42%
Silent MI	2	0.02%	1	0.01%	11	0.05%	4	0.04%
Angina	9	0.11%	33	0.28%	120	0.51%	78	0.70%
CABG/PTCA	10	0.12%	31	0.27%	106	0.45%	67	0.60%
Carotid artery disease	1	0.01%	8	0.07%	23	0.10%	21	0.19%
Congestive heart failure	5	0.06%	14	0.12%	45	0.19%	49	0.44%
Stroke	5	0.06%	9	0.08%	57	0.24%	47	0.42%
PVD	3	0.04%	4	0.03%	15	0.06%	8	0.07%
DVT	7	0.08%	8	0.07%	42	0.18%	33	0.30%
PE	3	0.04%	4	0.03%	16	0.07%	22	0.20%
Coronary disease[3]	25	0.30%	54	0.47%	232	0.98%	169	1.52%
DVT/PE	7	0.08%	10	0.09%	51	0.22%	47	0.42%
Total CVD	40	0.48%	78	0.67%	360	1.53%	267	2.40%
Cancer								
Breast cancer[4]	15	0.18%	26	0.22%	57	0.24%	41	0.37%
Invasive breast cancer	11	0.13%	23	0.20%	41	0.17%	29	0.26%
In situ breast cancer	4	0.05%	3	0.03%	17	0.07%	12	0.11%
Ovary cancer	0	0.00%	0	0.00%	8	0.03%	2	0.02%
Endometrial Cancer[5]	0	0.00%	0	0.00%	4	0.03%	5	0.08%
Colorectal cancer	2	0.02%	5	0.04%	27	0.11%	26	0.23%
Other cancer[6,7]	15	0.18%	22	0.19%	88	0.37%	66	0.59%
Total cancer	32	0.39%	53	0.46%	182	0.77%	140	1.26%
Fractures								
Hip fracture	3	0.04%	0	0.00%	11	0.05%	26	0.23%
Vertebral fracture	3	0.04%	7	0.06%	20	0.08%	20	0.18%
Other fracture[6,8]	95	1.15%	116	1.00%	368	1.56%	165	1.48%
Total fracture	99	1.19%	121	1.04%	398	1.69%	202	1.82%
Deaths								
Death other causes-HRT[9]	12	0.14%	15	0.13%	78	0.33%	67	0.60%
Cardiovascular death	2	0.02%	5	0.04%	18	0.08%	19	0.17%
Cancer death	1	0.01%	5	0.04%	34	0.14%	18	0.16%
Other death - confirmed[10]	4	0.05%	4	0.03%	5	0.02%	7	0.06%
Other death - unconfirmed[11]	6	0.07%	5	0.04%	38	0.16%	35	0.31%
Total death	13	0.16%	19	0.16%	95	0.40%	79	0.71%

[1] 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*.

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

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

[4] Excludes one case with borderline malignancy.

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

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

[7] Excludes non-melanoma skin cancer

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

[9] All deaths except those from breast or colorectal cancer, or cardiovascular disease. Includes deaths which are not yet adjudicated.

[10] Includes adjudicated 'accident/injury' and 'other/unknown' causes of death from Form 124.

[11] Includes deaths which are not yet adjudicated.

Table 8.12
Locally Verified Outcomes (Annualized Percentages) by Ethnicity for Dietary Modification

Data as of: January 31, 1999

Outcomes	Total		Ethnicity: Minority[1]		White	
No. of participants w/ *Form 33*	48000		8717		39283	
Mean follow-up (months) [2]	26.4		24.4		26.8	
Cancer						
Breast cancer[3]	350	0.33%	34	0.19%	316	0.36%
Invasive breast cancer	272	0.26%	24	0.14%	248	0.28%
In situ breast cancer	82	0.08%	10	0.06%	72	0.08%
Ovary cancer	40	0.04%	5	0.03%	35	0.04%
Endometrial Cancer[4]	54	0.09%	7	0.08%	47	0.09%
Colorectal cancer	97	0.09%	14	0.08%	83	0.09%
Other cancer[5,6]	339	0.32%	33	0.19%	306	0.35%
Total cancer	871	0.83%	92	0.52%	779	0.89%
Cardiovascular						
CHD[7]	239	0.23%	28	0.16%	211	0.24%
Coronary death	32	0.03%	1	0.01%	31	0.04%
Total MI	215	0.20%	28	0.16%	187	0.21%
Clinical MI	196	0.19%	22	0.12%	174	0.20%
Silent MI	23	0.02%	6	0.03%	17	0.02%
Angina	381	0.36%	60	0.34%	321	0.37%
CABG/PTCA	308	0.29%	33	0.19%	275	0.31%
Carotid artery disease	67	0.06%	8	0.05%	59	0.07%
Congestive heart failure	135	0.13%	23	0.13%	112	0.13%
Stroke	170	0.16%	27	0.15%	143	0.16%
PVD	41	0.04%	6	0.03%	35	0.04%
DVT	33	0.03%	3	0.02%	30	0.03%
PE	19	0.02%	2	0.01%	17	0.02%
Coronary disease[8]	678	0.64%	99	0.56%	579	0.66%
DVT/PE	46	0.04%	4	0.02%	42	0.05%
Total CVD	950	0.90%	136	0.77%	814	0.93%
Fractures						
Hip fracture	57	0.05%	3	0.02%	54	0.06%
Vertebral fracture	78	0.07%	6	0.03%	72	0.08%
Other fracture[5,9]	1190	1.13%	113	0.64%	1077	1.23%
Total fracture	1298	1.23%	121	0.68%	1177	1.34%
Deaths						
Death other causes-DM[10]	269	0.26%	41	0.23%	228	0.26%
Cardiovascular death	59	0.06%	6	0.03%	53	0.06%
Cancer death	85	0.08%	4	0.02%	81	0.09%
Other death - confirmed[11]	28	0.03%	7	0.04%	21	0.02%
Other death - unconfirmed[12]	138	0.13%	26	0.15%	112	0.13%
Total death	310	0.29%	43	0.24%	267	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] Excludes four cases with borderline malignancy.

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

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

[6] Excludes non-melanoma skin cancer

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

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

[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.

[11] Includes adjudicated 'accident/injury' and 'other/unknown' causes of death from Form 124.

[12] Includes deaths which are not yet adjudicated.

Table 8.12
Locally Verified Outcomes (Annualized Percentages) by Age for Dietary Modification

Data as of: January 31, 1999

Outcome	Age 50-54		55-59		60-69		70-79	
No. of participants w/ *Form 33*	6866		10865		22277		7992	
Mean follow-up (months) [1]	32.3		28.4		24.3		24.2	
Cancer								
Breast cancer[2]	35	0.19%	85	0.33%	160	0.36%	70	0.43%
Invasive breast cancer	24	0.13%	65	0.25%	130	0.29%	53	0.33%
In situ breast cancer	12	0.06%	20	0.08%	31	0.07%	19	0.12%
Ovary cancer	8	0.04%	9	0.03%	13	0.03%	10	0.06%
Endometrial Cancer[3]	9	0.09%	11	0.07%	23	0.09%	11	0.12%
Colorectal cancer	5	0.03%	16	0.06%	51	0.11%	25	0.16%
Other cancer[4,5]	40	0.22%	51	0.20%	173	0.38%	75	0.47%
Total cancer	96	0.52%	168	0.65%	416	0.92%	191	1.19%
Cardiovascular								
CHD[6]	18	0.10%	26	0.10%	113	0.25%	82	0.51%
Coronary death	0	0.00%	3	0.01%	12	0.03%	17	0.11%
Total MI	18	0.10%	24	0.09%	105	0.23%	68	0.42%
Clinical MI	15	0.08%	23	0.09%	94	0.21%	64	0.40%
Silent MI	3	0.02%	1	0.00%	13	0.03%	6	0.04%
Angina	27	0.15%	52	0.20%	196	0.44%	106	0.66%
CABG/PTCA	21	0.11%	38	0.15%	154	0.34%	95	0.59%
Carotid artery disease	4	0.02%	6	0.02%	31	0.07%	26	0.16%
Congestive heart failure	9	0.05%	13	0.05%	66	0.15%	47	0.29%
Stroke	9	0.05%	17	0.07%	89	0.20%	55	0.34%
PVD	2	0.01%	7	0.03%	15	0.03%	17	0.11%
DVT	2	0.01%	3	0.01%	15	0.03%	13	0.08%
PE	0	0.00%	1	0.00%	8	0.02%	10	0.06%
Coronary disease[7]	49	0.26%	82	0.32%	337	0.75%	210	1.30%
DVT/PE	2	0.01%	3	0.01%	21	0.05%	20	0.12%
Total CVD	63	0.34%	110	0.43%	473	1.05%	304	1.89%
Fractures								
Hip fracture	5	0.03%	4	0.02%	18	0.04%	30	0.19%
Vertebral fracture	6	0.03%	7	0.03%	36	0.08%	29	0.18%
Other fracture[4,8]	169	0.91%	238	0.92%	553	1.23%	230	1.43%
Total fracture	178	0.96%	248	0.96%	595	1.32%	277	1.72%
Deaths								
Death other causes-DM[9]	23	0.12%	29	0.11%	132	0.29%	85	0.53%
Cardiovascular death	0	0.00%	5	0.02%	29	0.06%	25	0.16%
Cancer death	7	0.04%	11	0.04%	44	0.10%	23	0.14%
Other death - confirmed[10]	6	0.03%	3	0.01%	11	0.02%	8	0.05%
Other death - unconfirmed[11]	11	0.06%	15	0.06%	66	0.15%	46	0.29%
Total death	24	0.13%	34	0.13%	150	0.33%	102	0.63%

[1] 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.*

[2] Excludes four cases with borderline malignancy.

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

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

[5] Excludes non-melanoma skin cancer

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

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

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

[9] All deaths except those from breast or colorectal cancer, or cardiovascular disease. Includes deaths which are not yet adjudicated.

[10] Includes adjudicated 'accident/injury' and 'other/unknown' causes of death from Form 124.

[11] Includes deaths which are not yet adjudicated.

Table 8.13
Locally Verified Outcomes (Annualized Percentages) by Ethnicity for Calcium and Vitamin D

Data as of: January 31, 1999

Outcomes	Total		Ethnicity: Minority[1]		White	
No. of participants w/ *Form 33*	26919		4323		22596	
Mean follow-up (months) [2]	18.3		16.9		18.6	
Fractures						
Hip fracture	18	0.04%	1	0.02%	17	0.05%
Vertebral fracture	27	0.07%	3	0.05%	24	0.07%
Other fracture[6,3]	476	1.16%	41	0.68%	435	1.24%
Total fracture	511	1.25%	45	0.74%	466	1.33%
Cancer						
Colorectal cancer	43	0.10%	5	0.08%	38	0.11%
Breast cancer[4]	156	0.38%	15	0.25%	141	0.40%
Invasive breast cancer	121	0.29%	12	0.20%	109	0.31%
In situ breast cancer	35	0.09%	3	0.05%	32	0.09%
Ovary cancer	14	0.03%	1	0.02%	13	0.04%
Endometrial Cancer[5]	16	0.07%	1	0.03%	15	0.07%
Other cancer[6,7]	118	0.29%	12	0.20%	106	0.30%
Total cancer	344	0.84%	34	0.56%	310	0.89%
Cardiovascular						
CHD[8]	100	0.24%	8	0.13%	92	0.26%
Coronary death	14	0.03%	2	0.03%	12	0.03%
Total MI	91	0.22%	6	0.10%	85	0.24%
Clinical MI	74	0.18%	3	0.05%	71	0.20%
Silent MI	21	0.05%	3	0.05%	18	0.05%
Angina	137	0.33%	15	0.25%	122	0.35%
CABG/PTCA	113	0.28%	9	0.15%	104	0.30%
Carotid artery disease	24	0.06%	3	0.05%	21	0.06%
Congestive heart failure	65	0.16%	9	0.15%	56	0.16%
Stroke	63	0.15%	5	0.08%	58	0.17%
PVD	14	0.03%	3	0.05%	11	0.03%
DVT	20	0.05%	1	0.02%	19	0.05%
PE	8	0.02%	1	0.02%	7	0.02%
Coronary disease[9]	280	0.68%	32	0.53%	248	0.71%
DVT/PE	27	0.07%	2	0.03%	25	0.07%
Total CVD	385	0.94%	43	0.71%	342	0.98%
Deaths						
Death other cause-CaD[10]	124	0.30%	20	0.33%	104	0.30%
Cardiovascular death	21	0.05%	2	0.03%	19	0.05%
Cancer death	25	0.06%	4	0.07%	21	0.06%
Other death - confirmed[11]	8	0.02%	0	0.00%	8	0.02%
Other death - unconfirmed[12]	75	0.18%	15	0.25%	60	0.17%
Total death	129	0.31%	21	0.35%	108	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] "Other fracture" excludes fractures indicated as pathological.

[4] Excludes three cases with borderline malignancy.

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

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

[7] Excludes non-melanoma skin cancer

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

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

[10] All deaths except those from breast or colorectal cancer, or cardiovascular disease. Includes deaths which are not yet adjudicated.

[11] Includes adjudicated 'accident/injury' and 'other/unknown' causes of death from Form 124.

[12] Includes deaths which are not yet adjudicated.

Table 8.13
Locally Verified Outcomes (Annualized Percentages) by Age for Calcium and Vitamin D

Data as of: January 31, 1999

Outcome	Age 50-54		55-59		60-69		70-79	
No. of participants w/ *Form 33*	4753		6727		11105		4334	
Mean follow-up (months) [1]	20.0		18.4		18.0		16.9	
Fractures								
Hip fracture	3	0.04%	1	0.01%	6	0.04%	8	0.13%
Vertebral fracture	2	0.03%	2	0.02%	11	0.07%	12	0.20%
Other fracture[5,2]	71	0.90%	104	1.01%	212	1.27%	89	1.45%
Total fracture	75	0.95%	107	1.04%	224	1.34%	105	1.72%
Cancer								
Colorectal cancer	4	0.05%	8	0.08%	17	0.10%	14	0.23%
Breast cancer[3]	20	0.25%	43	0.42%	65	0.39%	28	0.46%
Invasive breast cancer	17	0.21%	34	0.33%	51	0.31%	19	0.31%
In situ breast cancer	3	0.04%	9	0.09%	14	0.08%	9	0.15%
Ovary cancer	3	0.04%	2	0.02%	7	0.04%	2	0.03%
Endometrial Cancer[4]	2	0.04%	3	0.05%	10	0.10%	1	0.03%
Other cancer[5,6]	16	0.20%	21	0.20%	57	0.34%	24	0.39%
Total cancer	45	0.57%	76	0.74%	154	0.92%	69	1.13%
Cardiovascular								
CHD[7]	10	0.13%	10	0.10%	49	0.29%	31	0.51%
Coronary death	0	0.00%	0	0.00%	6	0.04%	8	0.13%
Total MI	10	0.13%	10	0.10%	45	0.27%	26	0.42%
Clinical MI	8	0.10%	8	0.08%	34	0.20%	24	0.39%
Silent MI	3	0.04%	2	0.02%	12	0.07%	4	0.07%
Angina	13	0.16%	22	0.21%	61	0.37%	41	0.67%
CABG/PTCA	9	0.11%	15	0.15%	50	0.30%	39	0.64%
Carotid artery disease	1	0.01%	3	0.03%	9	0.05%	11	0.18%
Congestive heart failure	3	0.04%	9	0.09%	29	0.17%	24	0.39%
Stroke	4	0.05%	8	0.08%	30	0.18%	21	0.34%
PVD	1	0.01%	0	0.00%	4	0.02%	9	0.15%
DVT	2	0.03%	2	0.02%	11	0.07%	5	0.08%
PE	0	0.00%	0	0.00%	6	0.04%	2	0.03%
Coronary disease[8]	23	0.29%	37	0.36%	129	0.77%	91	1.49%
DVT/PE	2	0.03%	2	0.02%	17	0.10%	6	0.10%
Total CVD	30	0.38%	48	0.47%	184	1.10%	123	2.01%
Deaths								
Death other causes-CaD[9]	10	0.13%	17	0.16%	50	0.30%	47	0.77%
Cardiovascular death	0	0.00%	1	0.01%	8	0.05%	12	0.20%
Cancer death	0	0.00%	6	0.06%	13	0.08%	6	0.10%
Other death - confirmed[10]	2	0.03%	1	0.01%	2	0.01%	3	0.05%
Other death - unconfirmed[11]	8	0.10%	11	0.11%	30	0.18%	26	0.42%
Total death	10	0.13%	19	0.18%	53	0.32%	47	0.77%

[1] 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*.

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

[3] Excludes three cases with borderline malignancy.

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

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

[6] Excludes non-melanoma skin cancer

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

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

[9] All deaths except those from breast or colorectal cancer, or cardiovascular disease. Includes deaths which are not yet adjudicated.

[10] Includes adjudicated 'accident/injury' and 'other/unknown' causes of death from Form 124.

[11] Includes deaths which are not yet adjudicated.

Table 8.14
Locally Verified Outcomes (Annualized Percentages) by Ethnicity for Observational Study

Data as of: January 31, 1999

Outcomes	Total		Ethnicity: Minority[1]		White	
No. of participants w/ *Form 33*	71646		10449		61197	
Mean follow-up (months) [2]	24.0		22.7		24.2	
Cardiovascular						
CHD[3]	212	0.15%	25	0.13%	187	0.15%
Coronary death	40	0.03%	5	0.03%	35	0.03%
Clinical MI	183	0.13%	22	0.11%	161	0.13%
Angina	506	0.35%	57	0.29%	449	0.36%
CABG/PTCA	364	0.25%	39	0.20%	325	0.26%
Carotid artery disease	89	0.06%	11	0.06%	78	0.06%
Congestive heart failure	228	0.16%	37	0.19%	191	0.15%
Stroke	169	0.12%	31	0.16%	138	0.11%
PVD	67	0.05%	4	0.02%	63	0.05%
DVT	4	0.00%	0	0.00%	4	0.00%
PE	4	0.00%	0	0.00%	4	0.00%
Coronary disease[4]	862	0.60%	103	0.52%	759	0.62%
DVT/PE	7	0.00%	0	0.00%	7	0.01%
Total CVD	1123	0.78%	137	0.69%	986	0.80%
Cancer						
Breast cancer[5]	572	0.40%	63	0.32%	509	0.41%
Invasive breast cancer	458	0.32%	47	0.24%	411	0.33%
In situ breast cancer	115	0.08%	15	0.08%	100	0.08%
Ovary cancer	42	0.03%	2	0.01%	40	0.03%
Endometrial Cancer[6]	67	0.08%	7	0.07%	60	0.08%
Colorectal cancer	114	0.08%	18	0.09%	96	0.08%
Other cancer[7,8]	434	0.30%	30	0.15%	404	0.33%
Total cancer	1213	0.85%	117	0.59%	1096	0.89%
Fractures						
Hip fracture	103	0.07%	3	0.02%	100	0.08%
Vertebral fracture	58	0.04%	1	0.01%	57	0.05%
Other fracture[7,9]	544	0.38%	43	0.22%	501	0.41%
Total fracture	692	0.48%	46	0.23%	646	0.52%
Deaths						
Cardiovascular death	74	0.05%	11	0.06%	63	0.05%
Cancer death	121	0.08%	13	0.07%	108	0.09%
Other death - confirmed[10]	55	0.04%	5	0.03%	50	0.04%
Other death - unconfirmed[11]	280	0.20%	45	0.23%	235	0.19%
Total death	530	0.37%	74	0.37%	456	0.37%

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

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

[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.

[10] Includes adjudicated 'accident/injury' and 'other/unknown' causes of death from Form 124.

[11] Includes deaths which are not yet adjudicated.

Table 8.14
Locally Verified Outcomes (Annualized Percentages) by Age for Observational Study

Data as of: January 31, 1999

Outcome	Age 50-54		55-59		60-69		70-79	
No. of participants w/ *Form 33*	10326		14201		30016		17103	
Mean follow-up (months) [1]	25.8		24.8		23.6		22.9	
Cardiovascular								
CHD[2]	5	0.02%	17	0.06%	76	0.13%	114	0.35%
Coronary death	0	0.00%	2	0.01%	11	0.02%	27	0.08%
Clinical MI	5	0.02%	16	0.05%	68	0.12%	94	0.29%
Angina	27	0.12%	53	0.18%	222	0.38%	204	0.62%
CABG/PTCA	11	0.05%	30	0.10%	170	0.29%	153	0.47%
Carotid artery disease	7	0.03%	7	0.02%	33	0.06%	42	0.13%
Congestive heart failure	6	0.03%	16	0.05%	94	0.16%	112	0.34%
Stroke	3	0.01%	15	0.05%	55	0.09%	96	0.29%
PVD	3	0.01%	3	0.01%	19	0.03%	42	0.13%
DVT	0	0.00%	1	0.00%	2	0.00%	1	0.00%
PE	0	0.00%	1	0.00%	0	0.00%	3	0.01%
Coronary disease[3]	35	0.16%	77	0.26%	367	0.62%	383	1.17%
DVT/PE	0	0.00%	2	0.01%	2	0.00%	3	0.01%
Total CVD	46	0.21%	99	0.34%	455	0.77%	523	1.60%
Cancer								
Breast cancer[4]	74	0.33%	93	0.32%	258	0.44%	147	0.45%
Invasive breast cancer	60	0.27%	74	0.25%	209	0.35%	115	0.35%
In situ breast cancer	15	0.07%	20	0.07%	50	0.08%	30	0.09%
Ovary cancer	4	0.02%	9	0.03%	20	0.03%	9	0.03%
Endometrial Cancer[5]	7	0.05%	9	0.05%	32	0.09%	19	0.10%
Colorectal cancer	7	0.03%	16	0.05%	42	0.07%	49	0.15%
Other cancer[6,7]	36	0.16%	65	0.22%	184	0.31%	149	0.46%
Total cancer	127	0.57%	189	0.64%	530	0.90%	367	1.12%
Fractures								
Hip fracture	2	0.01%	10	0.03%	33	0.06%	58	0.18%
Vertebral fracture	3	0.01%	6	0.02%	23	0.04%	26	0.08%
Other fracture[6,8]	60	0.27%	98	0.33%	234	0.40%	152	0.46%
Total fracture	64	0.29%	112	0.38%	287	0.49%	229	0.70%
Deaths								
Cardiovascular death	2	0.01%	3	0.01%	24	0.04%	45	0.14%
Cancer death	5	0.02%	16	0.05%	50	0.08%	50	0.15%
Other death - confirmed[9]	4	0.02%	6	0.02%	24	0.04%	21	0.06%
Other death - unconfirmed[10]	9	0.04%	30	0.10%	114	0.19%	127	0.39%
Total death	20	0.09%	55	0.19%	212	0.36%	243	0.74%

[1] 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*.

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

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

[4] Excludes three cases with borderline malignancy.

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

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

[7] Excludes non-melanoma skin cancer

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

[9] Includes adjudicated 'accident/injury' and 'other/unknown' causes of death from Form 124.

[10] Includes deaths which are not yet adjudicated.

Table 8.15
Locally Verified Outcomes (Annualized Percentages) for HRT Participants Without and With Uterus

Data as of: January 31, 1999

Outcomes	Without Uterus		With Uterus	
No. of Participants w/ *Form 33*	10479		16299	
Mean follow-up (months)[1]	24.6		24.4	
Cardiovascular				
CHD[2]	69	0.32%	105	0.32%
Coronary death	18	0.08%	10	0.03%
Total MI	57	0.27%	99	0.30%
Clinical MI	51	0.24%	90	0.27%
Silent MI	9	0.04%	9	0.03%
Angina	129	0.60%	111	0.34%
CABG/PTCA	100	0.47%	114	0.34%
Carotid artery disease	24	0.11%	29	0.09%
Congestive heart failure	60	0.28%	53	0.16%
Stroke	62	0.29%	56	0.17%
PVD	16	0.07%	14	0.04%
DVT	23	0.11%	67	0.20%
PE	9	0.04%	36	0.11%
Coronary disease[3]	237	1.10%	243	0.73%
DVT/PE	27	0.13%	88	0.27%
Total CVD	343	1.60%	402	1.21%
Cancer				
Breast cancer[4]	40	0.19%	99	0.30%
Invasive breast cancer	26	0.12%	78	0.24%
In situ breast cancer	14	0.07%	22	0.07%
Ovary cancer	3	0.01%	7	0.02%
Endometrial Cancer	0	0.00%	9	0.03%
Colorectal cancer	32	0.15%	28	0.08%
Other cancer[5,6]	72	0.34%	119	0.36%
Total cancer	147	0.69%	260	0.79%
Fractures				
Hip fracture	17	0.08%	23	0.07%
Vertebral fracture	17	0.08%	33	0.10%
Other fracture[5,7]	281	1.31%	463	1.40%
Total fracture	311	1.45%	509	1.54%
Deaths				
Death other causes-HRT[8]	83	0.39%	89	0.27%
Cardiovascular death	25	0.12%	19	0.06%
Cancer death	23	0.11%	35	0.11%
Other death - confirmed[9]	8	0.04%	12	0.04%
Other death - unconfirmed[10]	47	0.22%	37	0.11%
Total death	103	0.48%	103	0.31%

[1] 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*.

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

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

[4] Excludes one case with borderline malignancy.

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

[6] Excludes non-melanoma skin cancer

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

[8] All deaths except those from breast or colorectal cancer, or cardiovascular disease. Includes deaths which are not yet adjudicated.

[9] Includes adjudicated 'accident/injury' and 'other/unknown' causes of death from Form 124.

[10] Includes deaths which are not yet adjudicated.

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 Performance Summary* for cumulative data through January 31, 1999).

9.2 PMC Committee Activity

In July 1998, the PMC separated its monitoring activities into two separate groups, with one group addressing outcomes and one group addressing adherence/retention and other issues. Membership of the Outcomes PMC includes Anne McTiernan, CCC, chair; David Curb, Honolulu Clinical Center, Marian Limacher, Gainesville Clinical Center; Curt Furberg, CFC; Jacques Rossouw, Project Office; and Bernedine Lund, CCC. Membership of the Adherence/Retention PMC includes: Sally Shumaker, CFC, chair; Shirley Beresford, Seattle Clinical Center; Cheryl Ritenbaugh, Portland Clinical Center; Linda Pottern, Project Office; and Barb Cochrane, Lesley Tinker, Julie Hunt and Bernedine Lund, CCC.

Since September 1, 1998, the Adherence/Retention PMC held one conference call per month, reviewing 4-5 clinical centers on each call. Additional data on each clinical center reviewed on each call included: the newly developed DM Triage System Adherence Levels; comparison of performance to goals as well as to clinical center averages; and task completeness. The committee conducted three Level 4 visits to clinical centers since September 1, and scheduled a fourth Level 4 visit to a clinical center in May 1999. The PMC visits were extended from one to two days, allowing for additional focus on clinical center adherence and retention activities and incorporating an overview of motivational interviewing techniques.

A one-day minority adherence and retention workshop was conducted on November 9, 1998, with two staff members from each clinical center attending. A manual with step-by-step adherence and retention templates was distributed to each clinical center after the workshop. The PMC has proposed a third workshop focusing on challenges related to an aging participant population, and submitted the proposal to the Steering Committee for review.

In the same period, the Outcomes PMC also held one conference call per month, reviewing 4-5 clinical centers on each call. A summary of each clinical center includes 1) recent and cumulative data on collection of required forms, outcomes packet assembly, and local adjudication; 2) a graph showing the timeliness of outcomes processing over time; and 3) a summary of number of staff and local adjudicators.

Table 9.1
CC Performance Summary
Data as of: January 31, 1999

CC Performance Summary
Data as of 1/31/99

Summary - VCC

	Recruitment		HRT Follow-up		DM Follow-up		Retention		HRT Intervention		DM Intervention		CaD Intervention		Outcomes		Central Lab		Data	
	Aug-Oct[1]	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99
Atlanta	77	78	92	89	90	89	8.7	9.0	75	73	10.1	10.0	66	67	33	33	97	97	91	91
Birmingham	104	83	96	95	95	94	7.4	7.7	80	79	7.7	7.7	64	64	22	21	95	96	72	72
Bowman	-	84	93	94	91	91	10.2	10.5	77	75	10.2	9.3	68	70	42	42	97	96	93	93
Brigham	76	88	96	97	94	94	7.3	7.5	82	80	10.4	10.4	69	69	25	26	97	97	77	78
Buffalo	-	100	93	93	94	93	8.8	9.3	76	74	9.7	9.8	71	71	77	77	95	94	97	96
Chicago	-	94	93	93	91	92	9.2	9.7	81	79	10.7	10.7	63	64	29	35	97	96	82	82
Iowa	100	103	99	99	98	98	3.5	3.8	90	89	12.2	12.2	79	79	59	62	95	95	94	94
LaJolla	80	87	90	91	90	90	9.2	9.6	75	73	8.4	9.9	71	72	55	57	96	95	93	93
Memphis	46	88	93	93	90	91	9.5	10.1	81	80	10.7	10.7	61	61	31	29	95	93	71	71
Minneapolis	82	92	90	91	85	86	5.5	5.8	84	83	11.8	11.8	77	77	47	48	99	99	87	87
Newark	114	94	93	91	85	83	6.7	7.2	78	77	10.5	10.6	57	58	50	50	96	98	86	84
Pawtucket	66	88	93	93	92	92	8.4	8.9	82	80	9.8	9.7	69	70	58	55	92	93	81	81
Pittsburgh	-	92	94	95	94	95	6.1	6.5	84	81	11.7	11.7	74	74	46	47	98	99	87	85
Seattle	-	101	92	93	94	95	8.3	8.7	79	77	11.8	11.7	69	69	60	62	96	96	80	80
Tucson	65	101	87	88	92	92	9.6	10.7	72	70	9.6	9.6	58	59	52	52	92	91	91	91
UCDavis	-	112	93	92	91	91	8.2	8.6	83	81	10.0	10.1	69	70	65	69	96	95	78	78

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.

[1] Because the method of calculating CaD Recruitment includes calculations from last year's prior quarter, for this PMC Report only and only for CaD Recruitment, the previous recruitment quarter is Aug-Oct.

Table 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

Summary - NCC

	Recruitment		HRT Followup		DM Followup		Retention		HRT Intervention		DM Intervention		CaD Intervention		Outcomes		Central Labs		Data	
	Aug-Oct[1]	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99
Chapel Hill	67	89	98	97	96	95	4.3	4.6	87	87	9.4	9.3	73	74	45	47	97	97	81	82
Chi-Rush	34	135	95	93	95	93	6.2	7.4	80	80	9.3	9.4	77	78	49	45	95	95	82	83
Cincinnati	76	77	91	91	87	87	7.2	7.3	84	85	9.9	9.6	66	67	47	47	92	92	78	77
Columbus	84	92	98	98	93	94	7.3	7.9	83	82	13.0	12.9	73	74	50	49	95	95	87	87
Detroit	89	79	75	78	72	68	6.8	7.9	79	79	10.1	9.8	63	65	36	34	91	92	79	79
Gainesville	32	88	96	95	96	96	7.4	8.1	86	85	11.2	11.4	74	75	61	61	95	95	97	97
GWU-DC	88	86	94	94	94	94	6.5	6.6	82	82	11.9	12.1	70	70	56	57	94	92	97	97
Honolulu	49	75	91	89	89	90	3.5	4.0	84	85	9.7	9.6	74	75	58	56	98	98	89	89
Houston	59	68	81	81	66	67	5.4	6.0	84	81	10.9	11.0	72	72	38	30	91	92	87	87
Irvine	88	93	84	87	87	86	6.5	6.9	77	77	11.8	11.8	61	62	24	29	97	95	66	67
LA	103	102	92	92	82	81	5.3	5.4	85	85	12.8	11.9	63	64	66	59	96	98	82	83
Madison	48	94	98	97	97	97	6.7	6.7	88	87	11.6	11.6	71	72	85	85	98	97	98	98
Medlantic	86	85	95	95	89	90	5.8	6.8	71	72	6.3	6.1	57	59	26	26	87	86	89	89
Miami	0	77	70	68	58	59	11.2	13.8	74	73	7.9	7.1	64	62	72	53	98	98	86	86
Milwaukee	82	101	97	97	98	97	4.8	5.1	86	86	11.8	12.1	77	77	59	61	94	96	93	93
Nevada	101	95	98	98	99	98	5.2	5.8	84	85	13.7	13.4	74	75	50	45	97	99	97	97
NY City	64	89	88	87	88	87	6.4	6.7	80	79	9.5	9.4	63	64	18	23	94	93	79	79
Oakland	81	87	97	96	96	95	2.8	2.9	91	90	12.3	12.1	80	82	27	27	92	91	86	86
Portland	71	91	93	94	90	92	4.4	5.1	87	87	10.8	10.8	73	75	21	20	92	92	66	66
San Antonio	99	87	82	80	72	75	7.7	8.0	80	80	8.6	8.7	68	69	45	46	95	95	93	92
Stanford	89	96	98	99	97	95	4.8	5.2	86	87	11.0	11.2	73	76	59	63	96	96	83	84
Stony Brook	44	86	99	96	97	97	7.1	7.6	83	83	9.7	9.7	69	69	73	73	94	92	98	98
Torrance	75	84	89	88	85	81	6.5	7.2	82	82	11.7	11.6	70	71	42	45	95	97	82	82
Worcester	62	98	96	98	96	97	6.5	7.0	83	82	9.9	9.9	64	67	49	55	94	93	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.

1 Because the method of calculating CaD Recruitment includes calculations from last year's prior quarter, for this PMC Report only and only for CaD Recruitment,

Table 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

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*			
	Sept-Nov	Dec-Jan	cum., Jan. 99	Sept-Nov	Dec-Jan	cum., Jan. 99	Aug-Oct[5]	Dec-Jan	cum., Jan. 99	Sept-Nov	Dec-Jan	cum., Jan. 99	Sept-Nov	Dec-Jan	cum., Jan. 99	Sept-Nov	Dec-Jan	cum., Jan. 99	Aug-Oct[5]	Dec-Jan	cum., Jan. 99	Rank
Atlanta	-	-	75	-	-	106	81	77	72	-	-	89	-	-	52	-	-	61	81	77	78	16
Birmingham	-	-	101	-	-	100	68	104	71	-	-	91	-	-	65	-	-	52	68	104	83	15
Bowman	-	-	101	-	-	102	-	-	65	-	-	100	-	-	75	-	-	54	-	-	84	14
Brigham	-	-	87	-	-	108	92	76	67	-	-	88	-	-	67	-	-	108	92	76	88	12
Buffalo	-	-	112	-	-	108	597	-	88	-	-	101	-	-	113	-	-	69	597	-	100	5
Chicago	-	-	93	-	-	115	315	-	71	-	-	85	-	-	102	-	-	99	315	-	94	6
Iowa	-	-	138	-	-	95	118	100	91	-	-	94	-	-	117	-	-	60	118	100	103	2
LaJolla	-	-	81	-	-	103	82	80	76	-	-	104	-	-	85	-	-	84	82	80	87	13
Memphis	-	-	100	-	-	96	67	46	79	-	-	91	-	-	93	-	-	63	67	46	88	10
Minneapolis	-	-	109	-	-	100	85	82	78	-	-	98	-	-	95	-	-	62	85	82	92	9
Newark	-	-	103	-	-	114	92	114	78	-	-	102	-	-	96	-	-	67	92	114	94	7
Pawtucket	-	-	91	-	-	108	61	66	75	-	-	92	-	-	80	-	-	73	61	66	88	11
Pittsburgh	-	-	108	-	-	111	166	-	75	-	-	86	-	-	90	-	-	63	166	-	92	8
Seattle	-	-	119	-	-	108	-	-	67	-	-	75	-	-	134	-	-	100	-	-	101	3
Tucson	-	-	99	-	-	107	80	65	70	-	-	99	-	-	135	-	-	119	80	65	101	4
UCDavis	-	-	111	-	-	132	81	-	83	-	-	101	-	-	126	-	-	127	81	-	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.
[5] Because the method of calculating CaD Recruitment includes calculations from last year's prior quarter, for this PMC Report only and only for CaD Recruitment, the previous recruitment quarter is Aug-Oct.

Table 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

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*			
	Sept-Nov	Dec-Jan	cum., Jan. 99	Sept-Nov	Dec-Jan	cum., Jan. 99	Aug-Oct[5]	Dec-Jan	cum., Jan. 99	Sept-Nov	Dec-Jan	cum., Jan. 99	Sept-Nov	Dec-Jan	cum., Jan. 99	Sept-Nov	Dec-Jan	cum., Jan. 99	Aug-Oct[5]	Dec-Jan	cum., Jan. 99	Rank
Chapel Hill	-	-	103	-	-	105	70	67	72	-	-	89	-	-	98	-	-	53	70	67	89	12
Chi-Rush	-	-	177	-	-	177	86	34	86	-	-	91	-	-	122	-	-	101	86	34	135	1
Cincinnati	-	-	71	-	-	78	90	76	89	-	-	100	-	-	71	-	-	57	90	76	77	22
Columbus	-	-	99	-	-	108	78	84	80	-	-	88	-	-	98	-	-	68	78	84	92	9
Detroit	-	-	88	-	-	95	95	89	82	-	-	101	-	-	56	-	-	34	95	89	79	20
Gainesville	-	-	120	-	-	100	38	32	55	-	-	85	-	-	90	-	-	62	38	32	88	13
GWU-DC	-	-	90	-	-	105	92	88	78	-	-	94	-	-	90	-	-	50	92	88	86	17
Honolulu	-	-	68	-	-	104	83	49	69	-	-	104	-	-	54	-	-	52	83	49	75	23
Houston	-	-	76	-	-	85	62	59	65	-	-	91	-	-	43	-	-	41	62	59	68	24
Irvine	-	-	99	-	-	108	80	88	82	-	-	98	-	-	92	-	-	71	80	88	93	8
LA	-	-	100	-	-	119	102	103	86	-	-	102	-	-	116	-	-	92	102	103	102	2
Madison	-	-	108	-	-	102	79	48	87	-	-	92	-	-	96	-	-	65	79	48	94	7
Mediantic	-	-	100	-	-	105	80	86	80	-	-	86	-	-	67	-	-	43	80	86	85	18
Miami	-	-	94	-	-	102	0	0	59	-	-	75	-	-	40	-	-	68	0	0	77	21
Milwaukee	-	-	122	-	-	108	102	82	86	-	-	99	-	-	113	-	-	66	102	82	101	3
Nevada	-	-	107	-	-	101	101	101	88	-	-	101	-	-	97	-	-	65	101	101	95	6
NY City	-	-	100	-	-	98	64	64	68	-	-	104	-	-	101	-	-	73	64	64	89	11
Oakland	-	-	105	-	-	102	75	81	58	-	-	92	-	-	98	-	-	66	75	81	87	14
Portland	-	-	103	-	-	109	80	71	78	-	-	100	-	-	81	-	-	65	80	71	91	10
San Antonio	-	-	117	-	-	89	94	99	92	-	-	83	-	-	56	-	-	44	94	99	87	15
Stanford	-	-	93	-	-	104	70	89	87	-	-	98	-	-	111	-	-	88	70	89	96	5
Stony Brook	-	-	84	-	-	95	64	44	64	-	-	91	-	-	104	-	-	96	64	44	86	16
Torrance	-	-	71	-	-	106	73	75	78	-	-	90	-	-	67	-	-	90	73	75	84	19
Worcester	-	-	100	-	-	113	62	62	75	-	-	101	-	-	116	-	-	88	62	62	98	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.

[5] Because the method of calculating CaD Recruitment includes calculations from last year's prior quarter, for this PMC Report only and only for CaD Recruitment, the previous recruitment q

Table 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

Minority Randomization/Enrollment at Pool 1 Clinics

	% Non-white HRT/DM/OS[1]		
VCCs	cum., Nov. 98	cum., Jan. 99	Rank
Atlanta	24	24	10
Birmingham	34	34	6
LaJolla	25	25	9
Tucson	25	25	8
NCCs			
Chi-Rush	54	54	3
Detroit	29	30	7
Honolulu	76	76	1
Medlantic	58	59	2
Miami	43	43	5
San Antonio	46	48	4

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

Table 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

HRT Follow-up - VCC

	6 Wk[1]	SAV1[1]		AV1[2]		SAV2[2]		AV2[2]		SAV3[2]		AV3[2]		SAV4[2]		AV4[2]		SAV5[2]		Overall[3]		
	Cond	Conducted		Conducted		Conducted		Conducted		Conducted		Conducted		Conducted		Conducted		Conducted				
	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	Rank
Atlanta	97	98	98	98	98	92	92	91	91	89	89	88	88	82	81	91	86		74	92	89	15
Birmingham	95	98	98	98	98	97	97	97	97	96	95	96	95	96	96	93	94	94	86	96	95	4
Bowman	95	97	97	96	96	93	93	95	95	91	92	94	95	92	92	94	94	89	94	93	94	5
Brigham	98	99	99	99	99	98	98	98	97	96	96	96	97	95	95	92	95	92	90	96	97	2
Buffalo	97	97	97	97	97	94	94	93	93	94	93	90	90	91	93	85	86	90	87	93	93	9
Chicago	89	96	96	96	96	94	94	93	93	89	90	94	95	92	93	93	93	90	88	93	93	10
Iowa	100	100	100	100	99	99	99	98	98	98	98	98	98	98	98	98	99	96	96	99	99	1
LaJolla	93	95	95	91	92	90	90	90	90	90	91	92	93	90	90	85	89	83	85	90	91	14
Memphis	93	97	97	97	97	91	91	94	94	92	92	93	93	89	89	93	91	86	90	93	93	8
Minneapolis	100	100	100	100	100	92	92	98	98	71	73	97	98	53	60	99	97	94	93	90	91	13
Newark	92	97	97	95	95	92	92	91	90	89	87	89	90	91	86	93	90	100	94	93	91	12
Pawtucket	97	98	98	97	97	94	94	94	95	92	92	91	92	88	88	88	89	89	90	93	93	6
Pittsburgh	97	99	99	98	98	96	94	97	96	94	94	94	95	93	94	93	90	80	93	94	95	3
Seattle	96	97	97	97	97	96	96	95	95	92	94	92	91	89	91	88	90	82	82	92	93	7
Tucson	86	95	96	93	93	91	91	86	87	88	87	83	84	87	88	80	82	75	88	87	88	16
UCDavis	98	99	99	96	96	94	95	94	94	92	93	92	92	91	91	88	89	82	77	93	92	11

[1] From WHIP1131. Can be run at CC as WHIP0781 or WHIP0786.
[2] From WHIP1141.
[3] Does not include timeliness.
Notes: Conducted = % of visits due for which at least one task has been key-entered.

Table 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

HRT Follow-up - NCC

	6 Wk[1] Cond	SAV1[1] Conducted		AV1[2] Conducted		SAV2[2] Conducted		AV2[2] Conducted		SAV3[2] Conducted		AV3[2] Conducted		SAV4[2] Conducted		Overall[3]		
	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	Rank
Chapel Hill	97	99	99	98	98	97	97	98	97	97	96	97	98		93	98	97	6
Chi-Rush	96	99	99	97	97	96	96	91	92	94	92	90	94		75	95	93	14
Cincinnati	97	99	99	94	92	92	91	83	86	88	87	85	84		95	91	91	16
Columbus	99	99	99	98	98	96	96	96	94	95	94	100	100		100	98	98	3
Detroit	78	89	89	85	86	74	75	68	70	59	60	71	66		100	75	78	23
Gainesville	99	99	99	97	97	96	96	94	94	92	91	94	94	96	91	96	95	10
GWU-DC	97	99	99	98	98	96	95	94	93	92	93	93	94	80	82	94	94	12
Honolulu	93	95	95	95	95	92	92	90	90	84	86	89	90		70	91	89	17
Houston	95	95	95	91	91	85	83	81	81	72	73	69	73	58	57	81	81	21
Irvine	85	94	94	89	89	80	83	84	86	83	83	73	78		100	84	87	20
LA	100	98	98	96	96	95	95	91	90	91	91	76	84		80	92	92	15
Madison	100	100	100	99	99	99	99	98	97	97	98	95	96		88	98	97	5
Mediantic	99	99	99	99	99	95	94	93	93	89	91	92	92		92	95	95	11
Miami	75	88	88	82	82	71	69	68	70	42	48	63	66		44	70	68	24
Milwaukee	100	99	99	98	98	97	97	97	96	98	96	93	90		100	97	97	7
Nevada	98	100	100	99	99	98	98	98	98	97	97	97	96		95	98	98	2
NY City	85	98	98	94	94	90	90	86	87	86	86	79	83		76	88	87	19
Oakland	97	99	99	99	99	97	97	96	96	94	95	95	95		89	97	96	9
Portland	98	98	98	96	97	93	93	92	93	88	90	85	91		91	93	94	13
San Antonio	76	87	87	88	88	78	78	84	84	74	75	84	80		74	82	80	22
Stanford	98	99	99	98	98	98	98	98	98	97	97	100	100		100	98	99	1
Stony Brook	100	100	100	99	99	99	99	99	99	97	96	97	95		80	99	96	8
Torrance	97	94	94	95	95	88	89	88	88	86	85	78	76		80	89	88	18
Worcester	100	100	100	98	98	98	98	96	97	93	95	87	92		100	96	98	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.

Table 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

DM Follow-up - VCC

	SAV1[1] Conducted		AV1[1] Conducted		SAV2[1] Conducted		AV2[1] Conducted		SAV3[1] Conducted		AV3[1] Conducted		SAV4[1] Conducted		AV4[1] Conducted		SAV5[1] Conducted		Overall		
	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	Rank
Atlanta	95	95	96	96	92	91	90	90	88	89	88	88	81	82	86	84	95	89	90	89	14
Birmingham	99	99	99	99	97	97	97	97	96	95	95	95	93	94	94	94	89	81	95	94	4
Bowman	89	89	94	94	88	88	93	93	87	88	93	94	90	91	94	94	89	93	91	91	10
Brigham	99	99	98	98	94	95	96	95	94	94	95	95	91	91	93	93	88	88	94	94	5
Buffalo	97	97	97	97	94	94	94	94	93	93	92	92	93	93	88	87	95	93	94	93	6
Chicago	96	96	94	94	93	93	91	91	90	90	93	93	89	90	91	89	86	92	91	92	8
Iowa	99	99	99	99	99	99	99	99	98	98	98	98	98	98	96	97	98	97	98	98	1
LaJolla	94	94	94	94	92	93	90	91	89	91	89	89	88	88	85	87	87	88	90	90	13
Memphis	93	93	95	96	87	87	93	93	90	90	94	94	89	89	89	89	84	89	90	91	12
Minneapolis	87	87	99	99	91	91	98	98	70	71	98	98	38	44	97	97	85	89	85	86	15
Newark	93	94	92	93	85	86	84	85	79	79	78	77	82	76	79	80	92	81	85	83	16
Pawtucket	97	97	96	96	90	90	95	95	93	93	91	92	88	88	90	92	86	89	92	92	7
Pittsburgh	98	98	98	98	92	92	97	97	93	93	95	95	95	95	94	91	88	94	94	95	3
Seattle	97	97	96	96	95	94	96	96	95	95	97	97	94	95	92	93	87	91	94	95	2
Tucson	96	97	95	95	94	94	92	92	92	92	90	90	90	90	87	86	88	88	92	92	9
UCDavis	96	96	93	96	94	94	95	95	91	91	94	94	89	90	88	90	76	75	91	91	11

[1] From WHIP1140.

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

Table 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

DM Follow-up - NCC

	SAV1[1] Conducted		AV1[1] Conducted		SAV2[1] Conducted		AV2[1] Conducted		SAV3[1] Conducted		AV3[1] Conducted		SAV4[1] Conducted		Overall		
	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	Rank
Chapel Hill	96	96	97	97	95	95	96	96	93	95	95	97		91	96	95	8
Chi-Rush	99	99	97	97	97	97	92	92	91	91	91	94		80	95	93	12
Cincinnati	95	95	95	93	91	91	84	85	85	83	78	82	83	79	87	87	16
Columbus	96	96	97	97	87	90	97	97	86	91	94	95		92	93	94	10
Detroit	90	89	75	75	79	79	66	68	63	62	61	61		42	72	68	22
Gainesville	99	99	96	96	95	95	95	95	95	95	96	96	98	97	96	96	6
GWU-DC	99	99	98	98	96	96	95	95	92	93	92	93	88	82	94	94	11
Honolulu	92	91	95	95	85	85	93	92	82	81	99	97	82	86	89	90	15
Houston	89	88	81	83	75	75	73	73	64	63	61	62	20	27	66	67	23
Irvine	93	93	93	94	85	87	87	88	84	86	79	80		73	87	86	18
LA	88	88	91	91	85	84	81	81	75	76	72	77		71	82	81	19
Madison	100	100	98	98	98	98	98	98	98	98	91	94		95	97	97	3
Medlantic	95	96	96	96	91	91	88	89	85	87	88	90	77	81	89	90	14
Miami	71	71	81	83	56	57	62	65	33	52	47	51		35	58	59	24
Milwaukee	100	99	99	99	98	98	96	96	97	98	97	96		94	98	97	2
Nevada	99	100	99	99	99	99	98	98	98	99	98	97		94	99	98	1
NY City	97	96	94	94	91	89	86	87	79	78	79	83		79	88	87	17
Oakland	97	97	98	98	96	96	96	97	90	89	94	96	100	93	96	95	9
Portland	98	97	97	97	96	96	94	93	89	90	93	91	64	78	90	92	13
San Antonio	85	85	86	87	70	71	81	82	68	69	77	76	38	55	72	75	21
Stanford	99	99	97	98	97	97	97	97	95	95	93	94		88	97	95	7
Stony Brook	99	99	98	98	96	97	98	97	97	96	96	96		94	97	97	4
Torrance	92	92	92	93	88	87	82	81	79	78	74	73		64	85	81	20
Worcester	99	99	98	97	97	97	97	96	95	97	92	93	92	97	96	97	5

[1] From WHIP1140.

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

Table 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

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., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	Rank
Atlanta	26.9	28.5	2.4	2.8	2.5	2.5	2.3	2.5	16.7	16.6	1.3	1.3	-	-	8.7	9.0	10
Birmingham	20.3	21.5	2.5	2.5	6.7	7.3	2.4	2.7	11.0	10.8	1.5	1.5	-	-	7.4	7.7	6
Bowman	27.5	27.8	3.1	3.1	8.9	9.5	3.9	4.0	17.3	17.8	0.4	0.6	-	-	10.2	10.5	15
Brigham	18.5	19.0	1.3	1.4	5.4	6.0	1.1	1.3	17.1	16.9	0.1	0.2	-	-	7.3	7.5	5
Buffalo	30.4	32.2	1.2	1.3	4.8	4.8	2.4	2.4	13.6	14.3	0.3	0.5	-	-	8.8	9.3	11
Chicago	25.4	26.6	2.1	2.5	5.5	6.0	3.0	3.5	18.4	18.3	0.9	1.1	-	-	9.2	9.7	13
Iowa	11.3	12.2	0.8	1.1	1.5	1.8	1.5	1.7	5.3	5.3	0.6	0.7	-	-	3.5	3.8	1
LaJolla	26.9	28.0	4.6	4.6	4.9	5.1	4.2	4.3	12.9	14.2	1.5	1.5	-	-	9.2	9.6	12
Memphis	22.1	23.9	3.0	3.3	8.1	8.5	2.5	2.7	20.0	20.8	1.3	1.4	-	-	9.5	10.1	14
Minneapolis	17.0	17.7	1.2	1.2	3.9	4.3	1.7	1.9	8.6	8.9	0.7	0.8	-	-	5.5	5.8	2
Newark	17.0	18.5	3.3	3.4	1.9	3.2	2.1	2.4	14.9	14.9	1.0	0.9	-	-	6.7	7.2	4
Pawtucket	23.4	24.8	2.9	3.3	5.2	5.5	2.2	2.3	15.7	16.4	1.0	1.0	-	-	8.4	8.9	9
Pittsburgh	18.6	19.6	2.4	2.7	1.5	1.7	1.3	1.4	12.2	12.7	0.3	0.7	-	-	6.1	6.5	3
Seattle	27.2	28.2	2.6	2.7	1.7	1.7	2.2	2.2	15.6	16.6	0.5	0.5	-	-	8.3	8.7	8
Tucson	24.1	26.6	4.7	6.0	4.0	5.1	3.2	3.7	20.6	21.5	1.0	1.3	-	-	9.6	10.7	16
UCDavis	21.6	23.1	3.1	3.1	6.9	7.5	2.8	2.8	13.4	13.6	1.2	1.2	-	-	8.2	8.6	7

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

Table 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

Retention - NCC

	HRT[1]				DM[2]				CaD[3]				OS		Overall		
	% Stopping Intervention		% Stopping Followup		% Stopping Intervention		% Stopping Followup		% Stopping Intervention		% Stopping Followup		% Stopping Followup				
	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	Rank
Chapel Hill	13.2	13.8	0.8	1.1	2.5	2.9	1.5	1.6	6.9	7.3	0.8	0.9	-	-	4.3	4.6	3
Chi-Rush	17.7	22.1	2.8	2.9	3.4	4.2	2.4	2.4	9.7	11.7	0.9	1.1	-	-	6.2	7.4	18
Cincinnati	15.2	15.8	3.7	3.5	7.9	10.1	2.7	2.6	11.7	10.4	2.0	1.6	-	-	7.2	7.3	17
Columbus	19.5	22.0	1.8	2.2	6.8	6.8	2.3	2.4	12.4	13.2	0.7	0.8	-	-	7.3	7.9	21
Detroit	13.3	16.1	4.6	5.7	9.5	11.7	5.0	5.4	6.7	7.0	1.4	1.2	-	-	6.8	7.9	20
Gainesville	20.8	22.5	3.1	3.4	4.5	4.7	2.4	2.8	13.1	14.2	0.4	0.8	-	-	7.4	8.1	23
GWU-DC	20.9	21.8	2.7	2.5	1.3	1.6	2.1	2.1	11.5	11.3	0.6	0.5	-	-	6.5	6.6	10
Honolulu	10.2	10.9	1.7	1.7	1.8	2.7	1.1	1.5	5.3	6.0	0.7	1.0	-	-	3.5	4.0	2
Houston	15.5	17.2	1.3	1.5	5.7	6.0	1.9	2.2	7.3	8.3	0.6	0.8	-	-	5.4	6.0	9
Irvine	22.2	22.9	2.3	2.5	0.9	0.9	1.5	1.6	10.6	11.8	1.4	1.6	-	-	6.5	6.9	14
LA	9.2	9.4	1.8	1.8	4.9	5.1	2.1	2.1	12.4	12.7	1.3	1.2	-	-	5.3	5.4	7
Madison	18.0	18.9	1.7	1.7	5.6	4.4	1.9	1.9	12.0	12.7	0.7	0.7	-	-	6.7	6.7	12
Medlantic	15.8	18.1	2.3	2.3	5.6	9.6	2.3	2.4	7.4	7.4	1.3	1.2	-	-	5.8	6.8	13
Miami	26.5	37.1	5.5	5.7	15.8	17.1	4.1	4.4	12.7	15.8	2.5	2.9	-	-	11.2	13.8	24
Milwaukee	17.1	17.8	0.5	0.9	1.5	1.7	0.7	0.9	8.5	8.9	0.3	0.6	-	-	4.8	5.1	4
Nevada	19.2	20.3	1.4	1.4	0.9	1.6	0.8	1.2	8.4	9.3	0.4	0.8	-	-	5.2	5.8	8
NY City	17.8	19.4	2.5	2.5	2.3	2.3	1.9	1.9	12.8	12.8	1.1	1.1	-	-	6.4	6.7	11
Oakland	8.6	9.2	1.3	1.4	1.6	1.6	1.3	1.4	3.5	3.7	0.2	0.3	-	-	2.8	2.9	1
Portland	11.1	13.3	0.9	1.7	1.3	1.3	1.6	1.7	10.6	12.2	0.6	0.6	-	-	4.4	5.1	5
San Antonio	17.6	18.4	3.1	3.4	9.7	9.9	3.0	3.4	11.1	11.4	1.4	1.5	-	-	7.7	8.0	22
Stanford	14.3	15.6	0.7	1.4	3.1	3.1	0.9	1.2	9.0	9.5	0.5	0.6	-	-	4.8	5.2	6
Stony Brook	22.2	25.1	1.0	1.0	4.7	4.7	1.3	1.4	12.6	12.8	0.7	0.7	-	-	7.1	7.6	19
Torrance	18.5	20.6	2.5	3.1	8.4	9.3	2.0	2.0	7.1	7.3	0.6	0.7	-	-	6.5	7.2	16
Worcester	17.3	19.4	0.8	0.8	4.8	5.4	1.7	1.8	13.5	13.7	0.6	0.7	-	-	6.5	7.0	15

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

Table 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

HRT Intervention - VCC

	AV1						AV2						AV3						AV4								Overall		
	% w/Pill Cnt @ AV1[1]		% ≥ 80% Adherent at AV1[2]		Adhere. Summary at AV1[3]		% w/Pill Cnt @ AV2[1]		% ≥ 80% Adherent at AV2[2]		Adhere. Summary at AV2[3]		% w/Pill Cnt @ AV3[1]		% ≥ 80% Adherent at AV3[2]		Adhere. Summary at AV3[3]		% w/Pill Cnt @ AV4[1]		% ≥ 80% Adherent at AV4[2]		Adhere. Summary at AV4[3]		% Blinded		Weighted Avg.[4]		
	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	Rank
Atlanta	91	91	82	83	73	73	78	79	81	81	58	58	71	72	82	82	51	52	66	72	85	78	80	47	89	89	75	73	15
Birmingham	90	90	87	87	78	77	80	81	85	86	68	68	76	77	86	86	65	65	72	73	88	92	83	66	91	91	80	79	8
Bowman	90	90	79	79	69	69	82	82	86	84	66	65	76	76	83	82	57	58	63	64	84	88	78	52	89	89	77	75	12
Brigham	91	90	88	88	79	79	84	83	89	89	74	72	78	78	88	88	68	68	79	74	91	86	87	63	89	89	82	80	5
Buffalo	89	89	85	85	74	74	77	78	85	85	62	62	73	74	84	83	56	56	60	62	89	89	82	48	84	84	76	74	13
Chicago	90	90	89	89	77	77	81	81	87	87	65	65	75	75	92	93	65	65	70	66	91	94	82	59	89	89	81	79	9
Iowa	95	95	92	92	87	87	93	91	93	92	86	83	89	89	95	94	84	83	81	83	93	96	92	80	87	86	90	89	1
LaJolla	90	90	84	84	68	68	78	79	82	82	57	57	69	71	86	88	55	58	66	66	84	81	76	48	89	89	75	73	14
Memphis	92	92	87	86	77	76	84	84	87	87	69	69	79	80	88	89	65	66	78	78	86	86	81	62	92	92	81	80	6
Minneapolis	94	93	87	87	81	81	86	87	91	91	77	78	79	79	90	89	70	69	75	76	90	92	86	69	92	92	84	83	2
Newark	93	93	86	86	75	75	87	86	79	80	62	62	84	84	75	75	57	57	76	77	89	80	81	59	92	92	78	77	11
Pawtucket	90	90	89	89	78	78	83	83	92	92	72	73	73	73	93	94	64	65	69	66	92	96	85	58	87	86	82	80	7
Pittsburgh	95	95	88	88	82	82	89	89	88	88	77	76	80	81	88	89	68	68	69	70	91	87	89	57	96	95	84	81	3
Seattle	92	92	89	89	79	79	84	83	87	87	69	69	70	70	83	84	53	54	69	66	87	88	83	54	90	90	79	77	10
Tucson	83	84	86	85	67	67	74	76	79	78	51	52	68	68	80	80	45	46	67	68	84	79	76	42	96	96	72	70	16
UCDavis	92	91	90	90	79	79	85	85	89	90	72	73	83	82	88	89	69	69	71	73	90	91	84	62	86	86	83	81	4
*Weights	1		1		1		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 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

HRT Intervention - NCC

	AV1						AV2						AV3								Overall		
	% with Pill Count @ AV1[1]		% ≥ 80% Adherent at AV1[2]		Adherence Summary at AV1[3]		% with Pill Count @ AV2[1]		% ≥ 80% Adherent at AV2[2]		Adherence Summary at AV2[3]		% with Pill Count @ AV3[1]		% ≥ 80% Adherent at AV3[2]		Adherence Summary at AV3[3]		% Blinding[4]		Weighted ave*		
	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	Rank
Chapel Hill	93	93	88	88	79	80	90	90	91	91	81	81	91	87	77	83	69	71	90	89	87	87	3
Chi-Rush	91	90	80	79	70	69	83	83	84	84	64	65	78	76	93	96	65	71	94	94	80	80	19
Cincinnati	92	92	91	92	77	77	87	88	90	90	65	67	78	88	83	78	56	59	89	89	84	85	10
Columbus	92	92	84	84	75	75	81	81	89	87	70	67	72	79	85	79	61	61	94	93	83	82	14
Detroit	92	91	86	86	68	67	91	90	80	83	50	52	80	82	90	93	51	50	92	92	79	79	20
Gainesville	92	92	91	91	81	81	82	82	93	93	72	73	84	81	93	93	74	71	92	92	86	85	9
GWU-DC	90	91	88	87	77	77	79	80	89	88	66	66	68	70	88	87	56	58	84	84	82	82	16
Honolulu	97	97	85	85	78	78	91	91	84	86	69	71	85	87	97	87	74	67	86	86	84	85	7
Houston	95	94	93	93	80	79	82	83	88	89	59	59	82	80	89	90	50	53	94	94	84	81	17
Irvine	88	88	87	86	67	67	76	77	86	82	54	53	67	64	100	96	49	48	94	94	77	77	22
LA	96	96	84	84	77	77	90	90	89	87	72	71	77	83	77	87	42	60	87	86	85	85	11
Madison	93	93	89	89	83	82	87	88	93	92	80	79	80	82	88	90	69	72	89	89	88	87	2
Mediantic	91	91	72	74	65	67	73	75	68	66	46	46	69	65		77	49	47	97	97	71	72	24
Miami	88	86	81	80	58	57	81	79	81	82	45	45	79	73	79	86	40	41	98	97	74	73	23
Milwaukee	94	94	89	90	82	83	85	84	91	92	75	75	79	79	95	92	71	65	87	87	86	86	6
Nevada	92	92	84	84	76	77	86	87	91	90	77	77	83	81	90	86	73	67	86	85	84	85	8
NY City	90	91	84	84	71	71	81	78	87	87	60	59	77	77	85	82	53	53	91	90	80	79	21
Oakland	97	97	93	93	89	89	92	92	93	92	82	82	90	91	92	93	80	82	84	84	91	90	1
Portland	95	94	91	91	83	83	87	86	90	92	72	73	85	83	95	96	71	74	92	92	87	87	5
San Antonio	91	91	90	90	71	71	85	85	82	82	58	58	75	73	88	86	55	50	91	91	80	80	18
Stanford	93	93	92	92	83	83	85	87	91	91	75	77	68	74	100	94	68	69	87	87	86	87	4
Stony Brook	91	90	88	87	78	77	81	81	87	88	70	70	81	77	93	93	73	67	88	88	83	83	12
Torrance	89	90	89	90	75	75	85	85	85	86	63	63	94	95	82	82	58	57	88	87	82	82	15
Worcester	88	88	89	88	77	76	81	81	86	87	68	68	79	73	82	84	58	58	95	94	83	82	13
*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 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

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., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Jan. 99	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Jan. 99	cum., Jan. 99	Average	Rank[11]
Atlanta	69	69	93	92	12	12	85	85	69	69	59	59	2.5	2.5	1.5	1.5	10.3	9.6	10.0	10
Birmingham	67	67	92	92	10	12	85	85	68	67	58	57	2.7	7.3	5.2	4.9	8.4	7.0	7.7	16
Bowman	66	66	84	85	22	22	68	69	70	70	47	48	4.0	9.5	6.0	6.0	8.4	10.2	9.3	15
Brigham	73	73	91	91	17	19	85	84	71	72	60	60	1.3	6.0	4.5	4.3	10.7	10.0	10.4	8
Buffalo	73	73	94	94	4	3	81	81	60	60	48	48	2.4	4.8	2.4	2.4	10.4	9.2	9.8	12
Chicago	77	77	92	92	10	13	91	91	71	71	65	65	3.5	6.0	5.1	5.1	11.2	10.2	10.7	5
Iowa	74	74	99	99	6	5	96	96	78	78	75	75	1.7	1.8	3.0	3.0	12.9	11.4	12.2	1
LaJolla	72	72	87	87	19	21	80	77	65	65	52	50	4.3	5.1	3.4	3.3	12.9	6.9	9.9	11
Memphis	73	73	91	91	21	22	86	86	71	71	61	61	2.7	8.5	5.0	4.9	10.9	10.5	10.7	5
Minneapolis	78	78	92	93	18	20	90	90	70	69	63	62	1.9	4.3	1.4	1.5	12.5	11.0	11.8	2
Newark	68	68	86	86	22	23	76	77	68	67	52	52	2.4	3.2	4.1	4.0	11.1	10.1	10.6	7
Pawtucket	69	69	89	89	16	17	83	85	70	70	58	59	2.3	5.5	2.4	2.3	10.4	8.9	9.7	13
Pittsburgh	74	74	95	95	11	15	86	86	81	81	69	69	1.4	1.7	0.8	0.8	12.9	10.5	11.7	3
Seattle	74	74	92	92	17	18	80	80	77	77	62	62	2.2	1.7	1.3	1.3	12.6	10.8	11.7	3
Tucson	64	64	91	91	16	16	81	81	68	69	56	56	3.7	5.1	4.2	3.7	10.2	9.0	9.6	14
UCDavis	68	68	93	93	15	16	82	82	69	69	57	57	2.8	7.5	2.9	2.9	10.5	9.7	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 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

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		
	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Jan. 99	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Jan. 99	cum., Jan. 99	Average	Rank[11]
Chapel Hill	62	62	88	89	12	15	74	74	65	65	48	48	1.6	2.9	5.9	5.7	9.5	9.1	9.3	21
Chi-Rush	64	64	88	88	17	20	70	70	72	72	50	50	2.4	4.2	10.3	10.2	9.8	9.0	9.4	19
Cincinnati	68	68	91	91	16	16	84	82	61	58	51	47	2.6	10.1	5.0	4.6	10.7	8.5	9.6	17
Columbus	68	69	89	89	10	13	85	85	67	66	57	56	2.4	6.8	2.3	2.3	12.4	13.4	12.9	2
Detroit	62	62	85	84	11	16	74	74	61	60	45	44	5.4	11.7	4.8	4.9	10.5	9.1	9.8	15
Gainesville	67	67	91	91	14	15	82	82	75	74	61	61	2.8	4.7	6.5	6.0	12.1	10.6	11.4	10
GWU-DC	73	73	95	96	9	10	88	88	74	74	65	65	2.1	1.6	3.8	4.2	12.5	11.6	12.1	5
Honolulu	67	66	82	81	21	26	71	69	59	57	41	39	1.5	2.7	9.3	9.9	9.8	9.3	9.6	18
Houston	64	64	92	92	20	24	84	84	67	67	56	56	2.2	6.0	2.4	2.4	11.6	10.3	11.0	12
Irvine	72	72	86	86	25	30	78	78	76	76	60	60	1.6	0.9	2.8	2.6	12.7	10.9	11.8	7
LA	66	66	89	90	23	25	81	82	76	76	61	62	2.1	5.1	4.3	4.9	11.7	12.1	11.9	6
Madison	74	73	97	98	9	10	92	92	63	63	58	58	1.9	4.4	0.8	0.7	12.4	10.7	11.6	8
Mediantic	51	51	74	73	23	27	67	66	63	63	42	41	2.4	9.6	18.4	17.7	7.8	4.4	6.1	24
Miami	53	54	82	85	16	17	73	75	69	68	51	51	4.4	17.1	22.9	21.8	7.2	7.0	7.1	23
Milwaukee	77	77	96	96	12	12	92	92	75	75	68	68	0.9	1.7	6.1	7.3	11.5	12.7	12.1	3
Nevada	72	72	91	91	12	12	90	90	84	84	75	75	1.2	1.6	2.1	2.2	14.5	12.3	13.4	1
NY City	69	69	90	90	20	19	86	86	64	64	55	55	1.9	2.3	6.9	8.4	8.6	10.1	9.4	20
Oakland	79	79	93	92	10	8	84	85	74	74	63	62	1.4	1.6	6.5	6.2	12.2	12.0	12.1	3
Portland	78	77	98	98	1	2	90	90	68	68	61	61	1.7	1.3	2.2	2.1	11.7	9.8	10.8	13
San Antonio	56	56	73	76	36	40	64	67	63	63	40	43	3.4	9.9	15.5	14.7	7.9	9.4	8.7	22
Stanford	74	74	94	94	10	11	86	87	70	70	60	61	1.2	3.1	3.5	3.5	12.3	10.1	11.2	11
Stony Brook	70	68	94	91	10	13	92	88	62	63	57	55	1.4	4.7	11.0	11.0	10.4	9.0	9.7	16
Torrance	64	64	84	86	12	12	73	74	73	73	54	54	2.0	9.3	6.0	5.9	11.8	11.3	11.6	8
Worcester	73	72	89	89	7	8	83	83	71	71	58	58	1.8	5.4	5.7	5.6	11.0	8.8	9.9	14

[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 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

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., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	
Atlanta	92	92	56	57	50	51	85	85	67	67	54	54	75	76	69	70	49	50	76	78	73	73	52	52	66	67	11
Birmingham	86	86	46	48	39	41	87	87	61	61	52	52	83	83	61	61	49	49	83	83	66	64	53	52	64	64	13
Bowman	93	93	59	59	54	54	86	87	72	72	61	62	76	79	70	72	52	56	72	74	72	76	51	55	68	70	6
Brigham	89	90	64	64	57	58	88	87	72	72	59	58	75	76	74	74	55	55	74	72	67	71	49	51	69	69	10
Buffalo	92	92	65	65	58	58	86	87	68	68	57	57	79	79	73	72	54	54	78	80	81	80	61	59	71	71	5
Chicago	75	76	68	68	49	50	77	78	71	72	51	53	74	75	70	71	50	51	63	64	70	73	43	44	63	64	12
Iowa	98	97	70	71	69	69	95	95	74	75	70	70	93	93	74	73	68	67	92	92	77	76	69	69	79	79	1
LaJolla	91	91	67	68	59	61	88	87	72	73	60	61	81	82	70	69	55	55	77	78	76	76	54	57	71	72	4
Memphis	92	91	54	55	47	47	80	81	65	65	50	50	69	70	62	62	41	42	65	66	69	66	42	41	61	61	14
Minneapolis	92	91	75	75	69	68	91	91	77	77	68	68	84	84	78	79	65	66	78	80	85	84	65	65	77	77	2
Newark	78	79	56	57	41	42	87	87	61	60	46	46	75	77	49	49	32	32	68	70	55	56	33	35	57	58	16
Pawtucket	92	93	63	64	56	57	87	86	70	72	58	60	78	80	68	69	51	53	75	75	75	75	52	53	69	70	7
Pittsburgh	92	92	66	68	59	59	93	93	69	70	63	63	87	87	71	70	60	59	84	84	79	79	65	64	74	74	3
Seattle	82	82	66	65	53	52	87	86	73	73	62	61	80	80	69	71	54	55	80	79	68	69	53	53	69	69	9
Tucson	70	70	59	59	39	40	74	76	69	70	47	49	68	69	67	68	42	43	62	62	62	66	35	38	58	59	15
UCDavis	92	92	60	61	55	55	87	87	70	71	59	60	81	82	67	69	52	54	76	76	72	74	51	53	69	70	8

[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 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

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., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	
Chapel Hill	77	79	68	67	51	52	93	95	76	77	67	69	92	89	70	73	60	63	73	74	10
Chi-Rush	98	97	69	68	67	66	90	90	74	74	64	63	90	91	72	80	65	75	77	78	2
Cincinnati	88	87	59	60	50	50	87	87	67	69	51	53	79	79	68	68	45	46	66	67	18
Columbus	93	93	71	73	63	66	86	88	76	78	64	66	71	70	77	80	52	55	73	74	9
Detroit	84	86	60	62	42	45	89	89	70	72	47	50	79	80	60	65	35	39	63	65	19
Gainesville	97	96	67	68	64	64	86	87	74	76	62	65	80	81	74	75	58	60	74	75	8
GWU-DC	91	90	64	65	57	58	84	84	70	70	57	57	83	83	67	68	54	55	70	70	14
Honolulu	87	88	63	64	51	53	91	91	75	75	64	65	97	96	73	73	69	67	74	75	7
Houston	89	89	72	72	54	55	90	91	76	76	57	58	88	88	72	73	47	48	72	72	12
Irvine	41	52	63	60	25	30	86	84	80	80	61	61	86	85	60	60	44	45	61	62	23
LA	76	78	63	64	46	47	79	80	77	75	53	53	78	74	62	66	38	40	63	64	20
Madison	95	95	64	65	61	62	87	88	69	69	60	61	80	83	69	71	53	57	71	72	11
Medlantic	93	94	47	49	44	45	88	89	52	52	44	44	78	78	41	43	30	32	57	59	24
Miami	88	87	49	49	37	36	90	88	61	63	44	45	85	79	77	74	45	42	64	62	22
Milwaukee	94	95	65	66	61	61	91	92	74	73	65	64	90	89	84	81	73	69	77	77	3
Nevada	98	98	62	62	61	61	89	90	77	77	68	68	88	87	65	71	57	62	74	75	5
NY City	89	90	52	55	45	47	78	79	66	67	47	48	75	74	70	69	45	45	63	64	21
Oakland	98	98	77	77	75	75	93	95	76	77	70	73	88	91	79	80	68	73	80	82	1
Portland	92	91	71	71	63	64	85	86	72	73	59	59	82	82	77	82	60	66	73	75	6
San Antonio	93	94	63	63	50	50	83	84	66	66	50	51	89	88	68	69	53	53	68	69	16
Stanford	65	68	79	80	51	54	93	94	81	81	71	72	84	89	72	79	59	69	73	76	4
Stony Brook	96	96	61	61	58	58	85	85	67	67	56	56	77	77	70	70	51	52	69	69	15
Torrance	94	93	62	62	55	55	89	90	61	63	49	52	82	84	80	80	57	58	70	71	13
Worcester	92	93	57	58	52	53	86	87	60	62	50	52	72	75	67	73	43	51	64	67	17

[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 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

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]		
	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	Rank[8]
Atlanta	91	90	91	92	89	89	98	100	85	86	40	42	93	96	78	77			33	33	13
Birmingham	97	96	86	86	97	98	96	100	76	80	41	36	85	88	90	92			22	21	16
Bowman	91	92	94	95	98	98	100	100	87	86	39	39	97	98	55	56			42	42	11
Brigham	96	96	93	93	100	99	100	98	87	91	44	44	86	80	47	42			25	26	15
Buffalo	93	93	93	93	99	100	100	99	96	95	69	69	100	100	89	89			77	77	1
Chicago	91	91	94	94	71	76	94	94	75	75	39	44	98	98	87	88			29	35	12
Iowa	98	98	96	96	98	99	100	99	92	93	62	64	99	97	55	59			59	62	4
LaJolla	91	91	87	89	98	98	100	100	93	92	78	78	70	77	41	41			55	57	5
Memphis	89	89	84	84	94	96	100	86	84	80	48	46	92	96	84	84			31	29	14
Minneapolis	88	88	91	92	91	92	99	99	87	87	56	57	100	100	59	62			47	48	9
Newark	86	86	88	88	91	90	99	99	76	82	58	56	96	95	67	68			50	50	8
Pawtucket	93	94	93	93	98	97	100	100	86	88	66	64	96	97	73	74			58	55	6
Pittsburgh	94	94	81	83	99	99	100	97	91	91	58	57	99	100	95	95			46	47	10
Seattle	94	94	96	96	97	99	99	94	95	91	52	53	100	99	94	93			60	62	3
Tucson	91	91	91	91	98	97	100	99	91	90	54	53	96	97	63	63			52	52	7
UCDavis	93	93	94	94	99	99	100	99	97	95	58	59	100	100	97	97			65	69	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 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

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., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	
Chapel Hill	95	95	91	93	98	100	100	100	73	79	25	28	100	100	93	85			45	47	12
Chi-Rush	97	96	82	83	98	97	99	86	72	69	45	39	96	99	79	75			49	45	16
Cincinnati	86	85	77	83	96	97	98	98	75	78	42	41	96	95	83	86			47	47	13
Columbus	93	94	94	94	98	97	98	100	82	85	43	42	97	94	75	76			50	49	11
Detroit	75	74	85	83	85	85	100	84	38	43	22	21	78	77	71	69			36	34	18
Gainesville	96	96	93	93	98	99	99	96	86	91	50	52	97	97	87	89			61	61	4
GWU-DC	97	96	91	92	94	98	100	99	82	82	41	42	99	97	98	98			56	57	7
Honolulu	89	89	91	91	99	99	97	99	78	86	61	57	99	95	80	78			58	56	8
Houston	78	77	81	81	72	71	98	94	72	82	28	24	96	96	81	83			38	30	19
Irvine	86	87	86	87	95	95	99	100	54	69	16	16	80	68	88	81			24	29	20
LA	87	87	93	93	95	91	99	98	86	93	38	41	99	86	83	74			66	59	6
Madison	98	98	96	97	99	99	98	100	94	97	76	76	99	99	58	60			85	85	1
Mediantic	93	93	78	78	99	100	98	93	64	66	26	26	88	88	67	65			26	26	22
Miami	68	69	73	74	73	82	100	99	26	29	63	28	95	95	65	57			72	53	10
Milwaukee	97	97	95	94	100	100	100	99	93	91	48	49	92	93	99	100			59	61	5
Nevada	98	98	96	97	100	100	99	99	82	87	25	24	89	89	63	59			50	45	17
NY City	91	91	77	77	80	83	99	98	69	74	22	24	79	78	42	42			18	23	23
Oakland	96	96	89	90	99	99	98	99	82	81	16	25	98	99	62	66			27	27	21
Portland	94	94	92	92	93	94	99	99	51	67	23	19	85	87	68	74			21	20	24
San Antonio	79	78	84	84	97	97	99	97	77	80	32	27	90	86	84	84			45	46	14
Stanford	98	98	92	92	99	99	99	99	93	94	39	43	99	98	91	92			59	63	3
Stony Brook	98	97	94	93	99	99	100	99	89	92	55	53	99	100	89	90			73	73	2
Torrance	87	86	85	86	87	93	99	92	71	65	34	30	96	97	72	74			42	45	15
Worcester	97	97	94	95	99	100	100	98	92	93	39	42	99	97	93	93			49	55	9

[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 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

Central Laboratory - VCC

	ECGs		Blood		4DFRs		Summary		
	% grades 1 - 3[1]		% Complete[2]		% < 4 Errors[3]		Average		
	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	Rank
Atlanta	100	100	93	93	99	99	97	97	4
Birmingham	94	95	93	93	99	99	95	96	9
Bowman	96	92	97	97	100	100	97	96	7
Brigham	98	99	95	95	96	96	97	97	5
Buffalo	97	92	93	93	96	96	95	94	13
Chicago	96	94	96	96	99	99	97	96	6
Iowa	88	87	98	98	100	100	95	95	12
LaJolla	95	94	98	98	95	95	96	95	11
Memphis	97	92	90	90	98	98	95	93	14
Minneapolis	99	98	100	100	99	99	99	99	1
Newark	91	98	97	97	99	99	96	98	3
Pawtucket	88	89	92	92	97	97	92	93	15
Pittsburgh	97	99	98	98	99	99	98	99	2
Seattle	98	96	96	96	95	95	96	96	8
Tucson	88	86	95	95	93	93	92	91	16
UCDavis	95	93	98	98	95	95	96	95	10

[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 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

Central Laboratory - NCC

	ECGs		Blood		4DFRs		Summary		
	% grades 1 - 3[1]		% Complete[2]		% < 4 Errors[3]		Average		
	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	cum., Nov. 98	cum., Jan. 99	Rank
Chapel Hill	95	96	95	95	99	99	97	97	7
Chi-Rush	98	96	94	94	94	94	95	95	14
Cincinnati	92	93	87	87	97	97	92	92	18
Columbus	97	97	91	91	98	98	95	95	12
Detroit	89	90	91	91	94	95	91	92	20
Gainesville	98	97	96	95	92	93	95	95	10
GWU-DC	86	79	98	98	99	99	94	92	17
Honolulu	97	97	99	99	99	99	98	98	2
Houston	94	98	80	80	98	99	91	92	19
Irvine	100	96	97	97	95	92	97	95	11
LA	94	98	95	95	100	100	96	98	4
Madison	94	92	99	99	100	100	98	97	6
Medlantic	85	83	92	92	85	83	87	86	24
Miami	100	100	96	96	98	98	98	98	3
Milwaukee	89	94	95	94	99	98	94	96	9
Nevada	93	97	99	99	100	100	97	99	1
NY City	91	87	98	98	93	93	94	93	16
Oakland	85	81	93	93	99	99	92	91	23
Portland	98	96	83	83	96	96	92	92	21
San Antonio	97	95	93	93	96	96	95	95	13
Stanford	93	92	96	96	100	100	96	96	8
Stony Brook	89	81	93	93	100	100	94	92	22
Torrance	88	96	96	96	100	100	95	97	5
Worcester	95	92	94	94	93	94	94	93	15

[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 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

Data Management - VCC

	Timeliness of key-entry[1]		
	cum., Nov. 98	cum., Jan. 99	Rank
Atlanta	91	91	5
Birmingham	72	72	15
Bowman	93	93	3
Brigham	77	78	14
Buffalo	97	96	1
Chicago	82	82	10
Iowa	94	94	2
LaJolla	93	93	4
Memphis	71	71	16
Minneapolis	87	87	7
Newark	86	84	9
Pawtucket	81	81	11
Pittsburgh	87	85	8
Seattle	80	80	12
Tucson	91	91	6
UCDavis	78	78	13

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

Table 9.1 (continued)

CC Performance Summary
Data as of 1/31/99

Data Management - NCC

	Timeliness of key-entry[1]		
	cum., Nov. 98	cum., Jan. 99	Rank
Chapel Hill	81	82	19
Chi-Rush	82	83	17
Cincinnati	78	77	22
Columbus	87	87	11
Detroit	79	79	20
Gainesville	97	97	4
GWU-DC	97	97	5
Honolulu	89	89	8
Houston	87	87	10
Irvine	66	67	23
LA	82	83	16
Madison	98	98	1
Medlantic	89	89	9
Miami	86	86	12
Milwaukee	93	93	6
Nevada	97	97	3
NY City	79	79	21
Oakland	86	86	13
Portland	66	66	24
San Antonio	93	92	7
Stanford	83	84	15
Stony Brook	98	98	2
Torrance	82	82	18
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

Title 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
Estimation of the correlation between nutrient intake measures under restricted sampling	**Wang**, Anderson, Prentice	Gen.	10	

Table 10.1 (continued)

Title of Manuscript	Writing Group	Data Focus	Stage	Publisher
The Women's Health Initiative: Recruitment complete looking back and looking forward (Guest Editorial)	**Rossouw**, Hurd	CT	10	
Factors associated with insurance status among participants in the WHI	**Hsia**, Sofaer, Lillington, Zapaka, Limacher, Kiefe, Sennott-Miller, Mason, Bowen, Kemper	Gen.	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.	9	
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	8	
Correlates of serum lypocene in older women	**Casso**, Agurs-Collins, Haines, Patterson, White	CT	8	
Estimating normal hemogram values for post-menopausal women	**Carleton**, Assaf, Miller	Gen.	8	
Sexual orientation and health: Comparisons in the Women's Health Initative sample	**Valanis**, Whitlock, Charney, Bassford, Bowen, Carter	CT	7	
The health impact of domestic violence in older women	**Mouton**, Rovi, Schulthiess, Payne, Furniss, Lasser	OS	7	
Fat intake in husbands of women in the dietary component of the Women's Health Initiative	**Shikany**	Gen.	7	
Body weight and anthropometric measures of adiposity	**Manson**, Kotchen, Perri, Lewis, Johnson, Freed, Hall, Allen, Foreyt, Tinker, Noonan, Stefanick	Gen.	6	

Table 10.1 (continued)

Title of Manuscript	Writing Group	Data Focus	Stage	Publisher
Patterns of antihypertensive treatment and control among postmenopausal women	**Wassertheil-Smoller**, Manson, Wong, Lasser, Kotchen, Langer, Grimm, Black, Psaty, Anderson	OS	6	
Psychosocial and behavioral correlates of moderate alcohol consumption in women	**Powell**, Hymowitz, Criqui, Ockene, Finnegan, Castro, Trevisan, Curb, Hunt, Noonan	CT	6	
Correlates of serum a- and g-tocopherol in the WHI	**White**, Chen, Wilson, Shikany, Mares-Perlman, Caan, Masaki	CT	6	
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.	6	
Prevalence of pelvic organ prolapse and urinary incontinence in women	**Clark**, Harris, Maddox, McTiernan, Hendrix, Varner, Chang, Barnabei, Francis	CT	6	
Databased tracking and statistical models of the clinical trial recruitment process	**Creech**	CT	6	
Retention of low income and minority women in clinical trials: A focus group study	**Johnson**, Williams, Fouad	CT	6	
Women's Health and the Women's Health Initiative	**Cochrane**, Hunter, Johnson, Matthews, Strickland, Wactawski-Wende, Woods	Gen.	5	
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	

Table 10.1 (continued)

Title of Manuscript	Writing Group	Data Focus	Stage	Publisher
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	
Labeling as a predictor of dietary maintenance	**Hopkins**	CT	5	
Special populations recruitment for the WHI: success and limitations	**Fouad**, Strickland, Wang, Thompson, Talavera, Lakin, Howard, Young, Mouton	Gen.	5	
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.	5	
Sleep complaints: correlates and co-morbidities	**Kripke**, Freeman, Masaki, Brunner, Jackson, Hendrix	CT	5	
Cardiovascular and other physiological correlates of depression	**Wassertheil-Smoller**, Talavera, Campbell, Shumaker, Ockene, Robbins, Dunbar, Greenland, Cochrane	Gen.	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	
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**, Taylor, Glanz, Elam, Klaskala, Powell, Messina	Gen.	4	
Effect of hysterectomy with ovarian preservation on cardiovascular morbidity and mortality	**Brzyski**, Barnabei, Barad, Giudice, Satterfield, Margolis, McNeeley, Taylor	CT	4	
Dietary, physical activity, and exercise patterns among diabetics	**Agurs-Collins**, Adams-Campbell, Hannah, Howard	Gen.	4	
Reliability and physiologic correlates of the physical activity questionnaire in the WHI	**White**, Rodrigues, Wang, Strickland, Siscovick, Rebar, Going, Frid, Cauley, Casso, Stefanick	CT	4	

Table 10.1 (continued)

Title of Manuscript	Writing Group	Data Focus	Stage	Publisher
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	
Hormone replacement therapy effects on the resting ECG	**Greenland**, Schwartz, Limacher, Kadish, Daugherty, Frishman	CT	3	
Prevalence of silent MI	**Sagar**, Kotchen, Hoffman, Wong, Greattinger, Burke Van Voorhees, Oberman, Taylor	CT	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	
Risk of bacterial endocarditis in postmenopausal women undergoing endometrial biopsy	**Limacher**, Barnabei, Smith Bassford, Schatz, Linn, McNeeley	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	
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	
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	
Is a "too low" fat diet a marker of health or disease	**Gilligan**, Van Horn, Stefanick, St. Jeor, Snetselaar, Patterson, Kotchen	CT	3	
Baseline characteristics of the WHI-OS breast cancer survivor cohort	**Paskett**, Sherman, Anderson, Naughton, Hays, McDonald	OS	3	

Table 10.1 (continued)

Title of Manuscript	Writing Group	Data Focus	Stage	Publisher
Insulin resistance and weight change in postmenopausal black and white women	**Howard**, Passaro, Adams-Campbell, Rodrigues, Wagenknecht, Stevens, Safford, Black, Allen	Gen.	3	
Physical activity and CVD in women: the role of moderate vs. vigorous exercise	**Manson**, Mouton, Sheps, Siscovick, Oberman, LaCroix, Greenland, Perri	OS	3	
Physical activity and risk of breast cancer in postmenopausal women: The WHI	**McTiernan**, Coates, Woods, Wilcox, White, Ockene, Kooperberg, Adams-Campbell	Gen.	3	
Incidence and correlates of hip and knee replacement in the WHI	**Wallace**, LaCroix, White, Nevitt, Kaplan, Danchimah, Chang, Sturm	Gen.	3	
Association of yogurt consumption and selected food groups to colorectal cancer among WHI participants in the OS	**Mossavar-Rahmani**, Kristal, Wodarski, Vitolins, Himes, Hebert, Garland, Caan, Parker	OS	3	
Research staff turnover and participant adherence in the WHI	**Jackson**, Chlebowski, Huber, Snetselaar, Milas, Granek, Boe, Meyer	CT	3	
Passive smoke exposure in childhood and adulthood and prevalent coronary heart disease in women enrolled in the WHI	**Wagenknecht**, Ockene, Wong, Frishman, Snetselaar	OS	3	
Adherence to NCEP lifestyle guidelines by hyperlipidemic women in the OS	**Hsia**, Cochrane, Frishman, Howard, Rosal, Snetselaar, Stefanick	OS	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	
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	
Update on the WHI Clinical Trial	**Johnson**	CT	2	
The prevalence of urinary incontinence in WHI women	**Hendrix**	Gen.	2	
Comparison of self-report, discharge diagnosis, and adjudication of cardiovascular events in the WHI	**Heckbert**, Psaty, Safford, McTiernan, Kooperberg, Hsai, Gaziano, Frishman, Curb, Barbour	Gen.	2	
The modifying effect of socio-cultural status on risk factors for Type 2 diabetes in older Mexican American women	**Parra-Medina**	OS	2	

Table 10.1 (continued)

Title of Manuscript	Writing Group	Data Focus	Stage	Publisher
Risk factor clustering in the insulin resistance syndrome and its relationship to cardiovascular disease: comparison of white and black postmenopausal women	**Howard**	OS	2	

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

Table 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?	Funding Dates	Funding Status
1	Arterial Disease Artherosclerosis Prevention Trial (ADAPT)	John Crouse	Greg Burke	Approved	N/A	5 CCs	DM	4000	no	5 year study	dropped
2	Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO	Joel Weissfeld	Lew Kuller	N/A	N/A	1 CC	OS	2200	no	Entire Project	dropped
3	PLCO Offer to WHI-Partners (PLCO-Partners)	Joel Weissfeld	Lew Kuller	N/A	N/A	1 CC	DM Partners	NA	no	N/A	dropped
4	Dietary Modification and Prostate Cancer in WHI Husbands	James Shikany	Al Oberman	Approved	yes	ALL	DM Partners	10922	no	4/1/96 - 3/31/01	dropped
5	Explanations for the Development of Fat Distaste	Pamela Green	Deb Bowen	Approved	N/A	none	DM	160	no	4/1/95 - 9/30/96	dropped
6	Incidence and Impact of Arthritis in Older Women	Susan Hughes	Phil Greenland	Approved	N/A	none	OS	1200	no	1/1/96 - 12/31/01	dropped
7	Effect of HRT on Cardiovascular Morbidity and Mortality in Postmenopausal Women with a low Ankle/Arm BPI	Lewis Kuller	Lew Kuller	Approved	N/A	12, 14, 16, 22, 24, 25, 45	HRT	6500	no	9 year study	dropped
8	Partner's Health Study	Robert Langer	Robert Langer	Approved	N/A	none	WHI Partners	1500	no	7/1/94 - 9/30/95	dropped
9	An investigation of oral hard tissue status in relation to skeletal bone mineral density measures and	Marjorie Jeffcoat	Al Oberman	Approved	N/A	none	OS	650	no	6/1/95 - 5/31/02	funded
10	Urinary Estrogen Metabolites and Breast Cancer Risk	Elaine Meilahn	Lew Kuller	Approved	yes	All	DM	80000	no	7/1/95 - 6/30/00	dropped
11	Validation and Exploration of Sleep and Mood Predictors	Daniel Kripke	Robert Langer	Approved	N/A	none	OS	600	yes	8/1/95 - 7/31/99	funded
12	Empowerment/Nutritional Counseling	Charles Mouton	Norm Lasser	Declined	N/A	1 CC	DM	360	no	7/1/95 - 6/30/99	dropped
13	Prevalence and Correlates of Lumbar Spinal Stenosis	Lewis Kuller	Lew Kuller	Approved	N/A	none	CT	150	no	12 year study	funded
14	High Density Lipoprotein Metabolism	Scott Going, Tamsen Bassford	Tom Moon	Approved	N/A	none	OS	200	no	7/1/94 - 6/30/96	funded
15	The Relationship between Osteopenia and Periodontitis	Jean Wactawski-Wende	Maurizio Trevisan	Approved	yes	none	OS	1300	no	9/16/96 - 9/15/00	funded
16	Lower Extremity Atherosclerotic Disease	Mary McDermott	Phil Greenland	Approved	N/A	7 CCs	OS	5500	no	7/1/95 - 6/30/00	dropped
17	Domestic Violence in Older Women	Charles Mouton	Norm Lasser	Approved	yes	none	OS	1000	no	10/25/94 - 10/24/96	funded
18	WHT:FSMP DM follow-up	Jim Grizzle	Deb Bowen	Approved	yes	12,19,64	WHI women	120	no	11/1/96 - 10/31/00	dropped
19	Coagulation Proteins, Anticardiolipin Antibodies and Stroke in Women	Anthony Orencia	Phil Greenland	Approved	N/A	21,22,60	OS	782	yes	4 year study	dropped
20	Coronary Screening of Postmenopausal Women Using EBCT	Robert Detrano	Rowan Chlebowski	Approved	N/A	63	OS	2666	no	2/1/96 - 1/31/98	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?	Funding Dates	Funding Status
21	Effect of DM, HRT and CaD Admin on Progression of Coronary Atherosclerosis Assessed by EBCT	Robert Detrano	Rowan Chlebowski	Approved	N/A	2 CCs	CT	2666	no	5 year study	dropped
22	Vascular Compliance as a Predictor of Cardiovascular Disease in Postmenopausal Women	Jennifer Robinson	Richard Grimm	Approved	N/A	none	CT	500	no	9 year study	dropped
23	Non-steroidal Anti-inflammatory Drugs and Cancers of the Breast and Colon	Randall Harris	Rebecca Jackson	N/A	N/A	ALL	OS	100000	no	8 year study	dropped
24	Cross-ethnic Comparisons of Skeletal Health of Postmenopausal Women in San Diego County	Diane Schneider	Robert Langer	Approved	yes	none	OS	168	no	1/3/95 - 1/2/97	funded
25	Ankle-Arm Blood Pressure Index Measurement	Kamal Masaki	David Curb	Approved	yes	none	OS	2700	no	2/96 - 1/98	funded
26	HRT and Knee/Hip Osteoarthritis	James Cerhan	Robert Wallace	Approved	yes	ALL	HRT	11374	no	4/1/96 - 3/31/01	dropped
27	Vitamin D, Calcium, and Breast Cancer	Barbara Hulka	David Sheps	Approved	yes	ALL	ALL	2600	yes	12/1/97 - 11/30/02	dropped
28	Perspectives on Aging	S. Wassertheil-Smoller	S. Wassertheil-Smoller	Approved	yes	none	OS	NA	no	5 year follow-up	pending
29	HRT and Cardiovascular Biomarkers Related to Oxidation Status and Platelet Function	Michael Gaziano/JoAnn Manson	JoAnn Manson	Approved	yes	none	HRT	300	no	9/1/95 - 2/29/96	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	yes	6/1/96 - 5/31/00	dropped
31	Eye Care Use	Robert Kleinstein	Al Oberman	Approved	yes	none	OS	300	no	N/A	funded
32	Recruitment Techniques in getting Minority Women to participate in Breast Cancer Clinical Trials	Kathryn Boe	Robert Langer	Approved	N/A	none	NA	400	no	N/A	dropped
33	The Association of HRT with Abdominal and Total Body Fat in Postmenopausal Women	Charlotte Mayo	Al Oberman	Approved	yes	none	OS	690	no	7/31/95 - 3/31/96	funded
34	Ethnic Differences in Hip Bone Geometry by DXA and QCT	Dorothy Nelson	Susan Hendrix	Approved	yes	none	HRT	330	no	12/1/96 - 12/31/02	funded
35	Risk Factors for Fatigue in Women Ages 50 to 75	Arthur Hartz	Jane Kotchen	Approved	yes	21	CT	1200	no	1/1/96 - 6/30/99	dropped
36	Hormone Replacement Therapy and Changes in Mammographic Density	Barbara Hulka	A. McTiernan	Approved	yes	ALL	HRT	NA	no	1/98 - 12/07	funded
37	Lipid Markers of Atherosclerotic Disease in Post Menopausal Women	JoAnn Manson	JoAnn Manson	Declined	N/A	12,15,22	OS	NA	no	N/A	dropped
38	Hemostatic/Thrombotic and Genetic Markers for Coronary Disease in Postmenopausal Women	Paul Ridker	JoAnn Manson	Declined	N/A	12,15,22	OS	NA	no	N/A	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?	Funding Dates	Funding Status
39	The Effects of HRT on the Development and Progression of	Sally Shumaker	Curt Furberg	Approved	yes	all except #18	HRT	4800	no	5/1/96 - 4/30/02	funded
40	Ethnic and age differences in use of Mammography	S. Wassertheil-Smoller	S. Wassertheil-Smoller	Approved	yes	none	All	All	no	N/A	funded
41	Metabolism of Lipoprotein and HRT	Joel Morrisett	John Foreyt	Declined	N/A	none	All	24	yes	10/1/95 - 9/30/00	dropped
42	Impact of Insurance Status on Health Outcomes and Health Services Utilization in the WHI	Judith Hsia/Shoshanna Sofaer	Vallery Miller	Declined	N/A	ALL	OS	All	no	N/A	dropped
43	Decrease of Bone Mass in Older Women	William Goodman	Howard Judd	Declined	N/A	none	CT	362	yes	10/1/95 - 9/30/99	dropped
44	Estrogen and Vaginal pH	Anthony Schaeffer	Philip Greenland	Approved	N/A	none	HRT	100	yes	4/1/96 - 3/31/01	funded
45	Response Set Biases in Dietary Self-Report in the WHI DM	James R. Hebert	James R. Herbert	Approved	yes	14, 16, 21, 30, 48, 49, 50, 53, 65, 67,	DM	1350	no	8/1/96 - 7/31/98	dropped
46	Prostate & Colorectal Cancer in WHI Dietary Arm Husbands	Albert Oberman	Albert Oberman	Approved	yes	All	DM Partners	34200	no	12/1/96 - 11/30/01	dropped
47	Effect of diet intervention on motivation to make other health-	Langer/Lo	Robert Langer	Approved	yes	none	DM	150	no	5/1/96 - 4/30/97	funded
48	Prostate Ca Survey of Spouses of WHI Screened Women	Sylvia Smoller	Sylvia Smoller	Approved	yes	none	All	1607	no	2/1/96 - 6/30/96	funded
49	Applying Creative Self-Monitoring in the WHI	Yasmin Rahmani	Yasmin Rahmani	Declined	N/A	none	DM		no	N/A	dropped
50	Nutrition Practice Guidelines for Maintaining Low-Fat Dietary Change in Post Menopausal Women	Beth Burrows	Ross Prentice	Approved	yes	none	DM	200	no	10/1/96 - 9/30/97	funded
51	Cross-Sectional & Longitudinal Evaluation of Bone Quality	Adrian LeBlanc	John Foreyt	Declined	N/A	none	OS	400	no	N/A	dropped
52	Endogenous Sex Hormones and Breast Cancer in Older Women	Anne McTiernan	A. McTiernan	Approved	yes	All	OS	782	yes	7/1/99 - 6/30/04	pending
53	A Prospective Study of Diet and Hormones in the Development of Prostate Cancer	Geoffrey Kabat	Sylvia Smoller	Declined	N/A	20	OS	17500	yes	4/1/97 - 3/31/01	dropped
54	Women & Minority Recruitment / Retention: A Community-Based Intervention	Mona Fouad	Albert Oberman	Declined	N/A	none	DM	400	no	10/1/96 - 9/30/00	dropped
55	Predictors of Participation Among Latinos in Clinical Trials	Gregory Talavera	Gregory Talavera	Approved	yes	4	All	17270	no	9/1/96 - 8/31/00	dropped
56	Behavioral and psychosocial predictors of dietary change in postmenopausal women	Joan Pleuss	Alice Thomson	Approved	yes	none	DM	260	no	9/1/96 - 8/31/98	funded

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	Specimens?	Funding Dates	Funding Status
57	Hispanic Women's Advocacy and Retention Strategies	Cheryl Ritenbaugh	Cheryl Ritenbaugh	Approved	yes	none	OS	120	no	9/1/96 - 8/31/98	funded
58	Enrollment of Hispanic Women in Prevention Trials	Edward Trapido	Marianna Baum	Approved	yes	none	All	120	no	9/1/96 - 8/31/99	pending
59	Prevalence and Natural History of Autoimmune Thyroid Disease (AITD) in Postmenopausal Women	Margita Zakarija		Declined	N/A	none	OS	2200	yes	10/1/96 - 9/30/95	dropped
60	Fat Intake in Husbands of WHI Dietary Arm Participants	James Shikany	Al Oberman	Approved	yes	none	DM Partners		no	12/1/96	funded
61	Longitudinal Assessment of Memory Functioning in the WHI Clinical Trial	Beth Ober	Mary Haan	Approved	yes		HRT	110	no	6 year study	dropped
62	Prevention of age-related maculopathy in the WHI HRT CT: WHI-	Mary Haan	Mary Haan	Approved	no		HRT	3300	no	9 year study	dropped
63	Development and Evaluation of Eating Style Index	Pam Haines		Approved	yes		OS	800	no	10/1/96 - 6/30/99	funded
64	Examine Mammography Sensitivity in WHI Women	John Foreyt		Declined	N/A		CT	600	no	3 year study	dropped
65	Incidence of Benign breast disease in the DM CT - Pilot	Tom Rohan	A. McTiernan	Approved	yes	all	DM	200	no	4/1/98 - 6/30/99	funded
66	Quantitative, Patient-Specific serially comparable (QPS) mammography	Joel D. Morrisett/Paul E. Sovelius	John Foreyt	Declined	N/A	none	All	5409	yes	4/1/97 - 3/31/02	dropped
67	Prevalence and Natural History of Autoimmune Thyroid Disease is Postmenopausal Women	Marjita Zakarija	Marianna Baum	Approved	N/A	51	OS Blood Comp	1040	yes	7/97 - 3/31/05	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	no	1/1/97 - 12/31/05	funded
69	Birth Place and CVD Risk in Women	Judy Wylie-Rosett		Approved	N/A	none	OS		no	N/A	dropped
70	The Prevalence & Prognostic Importance of Myocardial Ischemia During Daily Life, & its Relationship to	David Sheps	David Sheffield	Approved	yes	10	OS	3200	no	9/1/97 - 8/31/00	funded
71	Assessing Stages of Change in Postmenopausal Women Enrolled in the Dietary Modification Arm if the	Amy Brewer	Applegate	Declined	N/A	5	DM	250	no	7/1/97 - 6/30/05	dropped
72	Ethnicity, Body Composition, Bone Density and Breast Cancer	Zhao Chen	Cheryl Ritenbaugh	Approved	yes	none	OS	800	no	9/1/97 - 8/30/02	funded
73	Psychosocial and Cultural Determinants of NIDDM in Latinas	Deborah Parra-Medina	Robert Langer	Approved	yes	3	OS	228	yes	5/1/97 - 4/30/98	funded
74	The Effectiveness of Individual Versus Group Behavioral Strategies to Increase Participants Adherence	Lois Wodarski	Maurizio Trevisan	Approved	yes	none	DM	50	no	7/1/97 - 9/30/97	funded
75	Adherence to Dietary Modification in the WHI	Milagros C. Rosal	Judith Ochene	Approved	N/A	6	DM	480	no	9/1/97 - 8/30/02	funded

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?	Funding Dates	Funding Status
76	Tailored Messages to Enhance Adherence of Older Women to Dietary Programs for Breast Cancer	Rowan Chlebowski	Linda Lillington	Approved	yes	none	DM	28	no	9/1/97 - 8/13/98	funded
77	HRT Decision Project	David Kerner	Robert	Declined	N/A	none	OS	160	no	N/A	dropped
78	Community Strategy to Retain Women Enrolled in Research	Mona Fouad		Approved	N/A	none	CT	40	no	7/1/97 - 9/30/97	funded
79	How a Low Fat Diet Is Related to Adiposity and Body Fat Distribution: Cross-sectional and longitudinal	Judith Wylie-Rosett	Sylvia Smoller	Declined	N/A	none	OS	300	no	N/A	dropped
80	Combine Effect of HRT and Heritable Prothrombotic Mutations on the Risk of Deep Venous Thrombosis (DVT) and Pulmonary Embolus (PE)	Bruct Psaty	Bruce Psaty	Approved	no	none	HRT	1000	yes	4/1/97 - 3/31/99	dropped
81	Abnormal Androgeneic Hair Growth in Postmenopausal Women	Ruth Freeman	Sylvia Smoller	Declined	N/A	none	All	500	no	N/A	dropped
82	Extension of Bone Mineral Density Assessment in WHI Native American Women	Zhao Chen	Cheryl Ritenbaugh	Approved	yes	none	OS	200	no	7/1/97 - 6/30/01	funded
83	Thrombotic, Inflammatory, and Genetic Markers for Coronary Heart Disease in Postmenopausal Women: A WHI Umbrella Study	Paul Ridker	JoAnn Manson	Approved	yes	none	OS	1300	yes	7/1/99 - 6/30/03	pending
84	Apolipoprotein E genotype, ERT use, and fat-soluble vitamin intake: Effects on Cognitive Function In Older	Julie E. Dunn	Philip Greenland	Approved	yes	none	DM+OS	260	yes	11/98 - 12/03	funded
85	Brain Imaging with (F-18)-Fluorometatyrosine in Post-Menopausal Women on or off Hormonal Replacement Therapy - A Pilot Study to Determine the	Thomas E. Nordahl		Declined					no	N/A	dropped
86	Sensitivity of Form 39 to Impaired Executive Control Function (ECF) as measured by the CLOX: an Executive Clock-Drawing Task	M.J. Polk	Robert Schenken			none	HRT	50	no	N/A	funded
87	The Effect of Dietary Change on Blood Flavonoid and F2-Isoprostane	Michael Simon	Susan Hendrix	Declined	no	none	DM	236	yes	12/1/98 - 11/30/00	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	no	12	DM	30	yes	N/A	dropped

Table 10.2 (continued)

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89	Effect of HRT on plasma homocysteine concentration	Selhub and Manson	JoAnn Manson	Declined	no	none	HRT	700	yes	7/98 - 6/03	dropped
90	Biochemical and genetic determinants of fracture in	Cummings and Jamal	Charles Kooperberg	Approved	yes	none	OS	910	yes	6 or 7/99 sub	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	no		CT		no	N/A	dropped
92	Fasting glucose in baseline plasma from all CT participants	Barbara Howard					CT		no	N/A	pending
93	The Epidemiology of Venous Disease	Michael Criqui		Approved	no		OS	725	no	3/11/98 - 6/30/99	funded
94	The Effect of Lowfat Dietary Modification on Markers of Bone Turnover and Bone Mineral Density	Rebecca Jackson		Declined	N/A		DM	80	no	N/A	dropped
95	Work organization, psychological distress, and health among minority older women	Beatriz Rodriguez		Approved	N/A	none	OS	500	no	7/23/97 - 7/22/98	funded
96	Longitudinal Insulin Sensitivity and Postmenopausal HRT	Daryl Cottrell		Declined	N/A	none	OS	75	no	N/A	pending
97	Modeling serum markers for cost-effective ovarian cancer screening	Garnet Anderson		Approved	yes	all	OS	720	yes	4/1/00 - 3/31/04	pending
98	Bone mineral density as a predictor for periodontitis	Jean Wactawski-Wende		Approved	N/A	none	OS	1000	yes	5/1/99 - 4/30/02	pending
99	GENNID Study	Rowan Chlebowski		Approved	yes	none	ALL	40	yes	12/1/98 - 3/31/00	funded
100	Genetic, Biochemical and Behavioral Determinants of Obesity	Jennifer Hays	Jennifer Hays	Approved	yes		OS	775	yes	4/1/99 - 3/31/01	pending
101	Women's Health Oral History Project	Catherine (Kit) Allen	Catherine Allen	Approved	yes	none	DM+HRT+OS	50	no	1/99 - 12/00	funded
102	Quality of Life Improvements and Willingness to Pay: An Investigation of Selective Estrogen Receptor	Mona Fouad	Albert Oberman		yes	none	OS	120	no	10/98 - 9/98	funded
103	Effects of Hormone Replacement Therapy on Cognitive Aging: Women's Health Initiative Study of Cognitive Aging (WHISCA)	Sally Shumaker		Approved			HRT	1800	no	4/1/99 - 3/31/05	pending
104	Tamoxifen Prevention: Is it acceptable to women at risk?	John Robbins	John Robbins			none	OS	150	no	7/1/99 - 6/30/01	pending

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	Specimens?	Funding Dates	Funding Status
105	Xanthophyll Pigments in the Diet, Blood and Ocular Macula and Relationship to Age-Related Eye Disease in the Women's Health	Julie Mares-Perlman	Catherine Allen			4 others to participate, IDs unknown	OS Blood Comp	2880	yes	4/1/00 - 3/31/04	pending
106	Gene-Diet Interactions in Human Breast Cancer Risk	Jennifer Hu	Electra Paskett			none	OS Blood Comp	800	yes	6/1/99 - 5/31/03	pending
107	Hashimoto's Thyroiditis in Postmenopausal Women	Margita Zakarija				51	OS Blood Comp	2900	yes	4/1/00 - 3/31/05	pending
108	Gene-environment effects and colorectal cancer	Rowan Chlebowski/Henry Lin	Rowan Chlebowski			all	OS Blood Comp	2000	yes	4/1/00 - 3/31/05	pending
109	Serum xenoestrogens and the risk of breast cancer	Vanessa Barnabei	Jane Kotchen			none	OS Blood Comp		yes	12/99 - 12/01	pending
110	Sex steroid hormones and risk of coronary heart disease: A nested case control study	Kathryn Rexrode/JoAnn Manson	JoAnn Manson			33	OS Blood Comp	700	yes	4/1/00 - 3/31/03	pending
111	Role of Inflammation in Acute Myocardial Infarction in Women	David Brown	S. Wassertheil-Smoller			all	OS Blood Comp	750	yes	2/1/00 - 1/31/02	pending
112	Motivators and Barriers to Exercise in Older Women	Mary Haan/Carol Parise	Mary Haan			none	OS	1100	no	9/1/99 - 9/30/00	pending
113	Some Aspects of Mediterranean Diet In Relation to Risk of Chronic Diseases among Postmenopausal Women	Iman Hakim	Tamsen Bassford			none	OS	1000	yes	8/1/99 - 7/31/02	pending