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# The Women's Health Initiative Observational Study: Baseline Characteristics of Participants and Reliability of Baseline Measures

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## INTRODUCTION

The Women's Health Initiative (WHI) Observational Study (OS) was established to explore the predictors and natural history of important causes of morbidity and mortality in postmenopausal women, and to serve as a secular control for the WHI Clinical Trial (CT). It enrolled 93,676 ethnically diverse women born in four different decades, from those who came of age in the depression-era, to the first members of the baby boom. Accordingly, this cohort reflects a wide range of socio-cultural influences on opportunities and health behaviors.

OS participants will contribute longitudinal data on health status, risk exposures and disease events. The follow-up interval will be slightly shorter than that in the clinical trial, approximately 7 years. All OS women had a physical examination at baseline and 3 years. Additional data are obtained with annual mailed questionnaires. These forms explore risk exposures, health behaviors, and the prevalence of less common diseases to provide a comprehensive view of both classical and novel risk factors, as well as secular trends in the predictors of healthy aging and disease events. Because of its size, the OS will permit exploration of factors associated with less common diseases.

This article describes the demographic, reproductive, dietary, and health characteristics of the OS women by ethnicity and age. In addition, we present information on the reliability of many of the baseline measures assessed in a subset of participants who were selected for the Measurement Precision Study (OS-MPS).

## METHODS

Study participants were enrolled at 40 centers throughout the United States between October 1, 1993 and December 31, 1998. Potential subjects were excluded if they did not plan to reside in the area for at least 3 years, had medical conditions predictive of survival less than 3 years, or had complicating conditions such as alcoholism, drug dependency or dementia. All participants provided informed consent using materials approved by institutional review boards at each center. Details of the scientific rationale, eligibility requirements and other aspects of the design of the WHI have been published (1).

Participants entered the OS by expressing interest in either the diet modification (DM) or postmenopausal hormone therapy (PHT) components of the clinical trial, but proving ineligible or unwilling to participate in the clinical trial, or by responding to a direct invitation to be screened for the OS. Thus, the specific exclusions for the DM and PHT components influenced the characteristics of women in the OS. Those exclusions are outlined in Hays' article in this issue.

### Data Collection and Definition of Variables

Demographic and risk exposure data, as well as data regarding family and medical history, were obtained by self-report using standardized questionnaires. Certified staff took physical measurements, including blood pressure, height and weight, and blood samples at the clinic visit. Most blood is reserved for nested case-control studies, but levels of certain nutrients and cardiovascular risk markers, assayed in a subsample, are reported here. A standardized written protocol, centralized training of local clinic staff, local quality assurance activities, and periodic quality assurance visits by the

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Clinical Coordinating Center were used to maintain uniform data collection procedures at all study sites. Additional details can be found in the appendix to Anderson's article.

### Statistical Analyses

Distributions of categorical variables were calculated in strata defined by age and ethnicity, and the chi-square statistic was used to assess group differences. For continuous variables, means and standard deviations were calculated for these same strata, and analysis of variance (ANOVA) was used to assess the significance of differences between age and ethnic categories, with and without adjustment for effect modifiers.

Since the sample size was very large, tests for statistical significance were highly significant ($p < 0.001$) for nearly all comparisons. Accordingly, the level of statistical significance is not shown in the tables. Age-adjustment was applied to all variables but only meaningfully affected the fractions living alone, widowed, and with hysterectomy. Given the limited utility of age-adjustment with so few factors affected, unadjusted rates are reported in all tables. All contrasts noted in the results were statistically significant with or without adjustment; the items highlighted were chosen based on either the magnitude of differences or "ad hoc" hypotheses.

### Reliability Subsample

The test-retest reliability of selected measures was assessed in a subset of OS women who participated in the Measurement Precision Study. The self-administered baseline questionnaires and the blood draw were repeated approximately 3 months after baseline. Physical measures and interviewer-administered questionnaires were not included. The Food Frequency Questionnaire (FFQ) was not repeated because it was assessed in a separate study (2).

A predefined number of women who enrolled in the OS between October 1996 and June 1997 were randomly selected each month and invited to join the OS-MPS at the time of their entry into the WHI. Sampling was stratified by center, age, and race/ethnicity and continued until 1000 women agreed to participate. To reduce burden, each participant repeated four of the original eight questionnaires based on a random assignment of clinics into two groups. Thus, the reliability of each variable was tested in approximately half of the women participating in the OS-MPS.

Overall, 2045 women were selected, 1092 completed the repeat questionnaires, and 872 had the repeat fasting blood draw. The average time between measures was 3 months (range: 8–15 weeks). The response rate was greater than the apparent 53% because some women who enrolled did not participate 3 months later as their clinic had reached its quota.

Kappa statistics were calculated for dichotomous or nominal categorical variables, weighted kappa was used for ordered categorical variables, and the intra-class correlation coefficient (ICC) was used for continuous measures (the blood measures) (3). The distributions of the blood analytes were generally positively skewed; however, the ICCs with and without log transformation were almost identical, so the untransformed values are given. These statistics are reported in Tables 1, 2, and 4 alongside the primary study data for the items assessed.

## RESULTS

93,726 women enrolled in the OS between September 1, 1994 and December 31, 1998. Of these, 31 provided insufficient baseline data to be included in these analyses, and 19 duplicate enrollments were found across multiple sites. After removing these, the remaining 93,676 women form the final analytic OS cohort, of which 78,013 (83.3%) were White, 7,639 (8.2%) Black, 3,623 (3.9%) Hispanic, 2,671 (2.9%) Asian/Pacific Islander, 422 (0.57%) American Indian, and 1308 (1.4%) of unknown race/ethnicity. The age distribution was 31.7%, 44.0% and 24.3%, respectively, for groups 50 to 59, 60 to 69, and 70 to 79 years old. Comparisons between OS and CT participants can be made by contrasting the tables presented in similar formats in this and preceding articles as well as in the appendix to Hays' article.

### Age Contrasts

Educational attainment, occupational level, and total family income declined with age (Table 1). Twenty-five percent of the women aged 70 to 79 years had total family income less than $20,000 compared with 10% of women aged 50 to 59 years. Conversely, over half the women aged 50 to 59 years reported family incomes greater than $50,000 compared with about 25% of women aged 70 to 79 years.

Current smoking was inversely associated with age, declining by 2% for each decade from a maximum of 8% in women 50 to 59 years old. Women 70 to 79 years old were the least likely to have ever smoked. Current alcohol use decreased with age, and older women were more likely to be past drinkers. The frequency of moderate or greater physical activity decreased with age. Conversely, the youngest age group reported more hours sedentary. Body Mass Index (BMI) was lowest in women 70 to 79 years old, but waist/hip ratio increased slightly with age.

All participants were postmenopausal so childbearing was complete. Nonetheless, women in the oldest two age groups reported more pregnancies and live births than women aged 50 to 59 years (Table 2). Yet, a greater

**TABLE 1.** Baseline demographic and general health characteristics of WHI Observational Study participants by age

| | Age at screening (y) | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 50–59 (N = 29,705) | | | 60–69 (N = 41,197) | | | 70–79 (N = 22,774) | | | Total (N = 93,676) | | | Reliability (N = 564) |
| Characteristic | N | % | Mean ± SD | N | % | Mean ± SD | N | % | Mean ± SD | N | % | Mean ± SD | κ |
| Race/Ethnicity | | | | | | | | | | | | | 0.99 |
| American Indian | 178 | 0.6 | | 161 | 0.4 | | 83 | 0.4 | | 422 | 0.5 | | |
| Asian/Pacific Islander | 861 | 2.9 | | 1102 | 2.7 | | 708 | 3.1 | | 2671 | 2.9 | | |
| Black | 2978 | 10.0 | | 3256 | 7.9 | | 1405 | 6.2 | | 7639 | 8.2 | | |
| Hispanic | 1761 | 5.9 | | 1399 | 3.4 | | 463 | 2.0 | | 3623 | 3.9 | | |
| White | 23,565 | 79.3 | | 34,677 | 84.2 | | 19,771 | 86.8 | | 78,013 | 83.3 | | |
| Unknown | 362 | 1.2 | | 602 | 1.5 | | 344 | 1.5 | | 1308 | 1.4 | | |
| Education | | | | | | | | | | | | | 0.87[a] |
| 0–8 years | 433 | 1.5 | | 612 | 1.5 | | 515 | 2.3 | | 1560 | 1.7 | | |
| Some high school | 676 | 2.3 | | 1572 | 3.8 | | 1040 | 4.6 | | 3288 | 3.5 | | |
| High school diploma/GED | 3715 | 12.6 | | 7343 | 18.0 | | 4063 | 18.0 | | 15,121 | 16.3 | | |
| School after high school | 10,422 | 35.4 | | 14,793 | 36.2 | | 8718 | 38.6 | | 33,933 | 36.5 | | |
| College degree or higher | 14,173 | 48.2 | | 16,560 | 40.5 | | 8269 | 36.6 | | 39,002 | 42.0 | | |
| Family income | | | | | | | | | | | | | 0.81[a] |
| <$10,000 | 991 | 3.5 | | 1648 | 4.3 | | 1277 | 6.2 | | 3916 | 4.5 | | |
| $10,000–$19,999 | 1744 | 6.2 | | 4460 | 11.7 | | 3896 | 18.8 | | 10,100 | 11.6 | | |
| $20,000–$34,999 | 4266 | 15.2 | | 9640 | 25.3 | | 6320 | 30.5 | | 20,226 | 23.3 | | |
| $35,000–$49,999 | 5143 | 18.4 | | 8167 | 21.5 | | 4119 | 19.9 | | 17,429 | 20.1 | | |
| $50,000–$74,999 | 6951 | 24.8 | | 7551 | 19.8 | | 2984 | 14.4 | | 17,486 | 20.2 | | |
| $75,000 + | 8880 | 31.7 | | 6603 | 17.3 | | 2125 | 10.3 | | 17,608 | 20.3 | | |
| Occupation | | | | | | | | | | | | | 0.64 |
| Managerial/Professional | 13,945 | 49.1 | | 16,540 | 42.1 | | 8137 | 37.8 | | 38,622 | 43.3 | | |
| Technical/Sales/Administrative | 7951 | 28.0 | | 11,512 | 29.3 | | 6017 | 28.0 | | 25,480 | 28.6 | | |
| Service/Labor | 4537 | 16.0 | | 6813 | 17.3 | | 4120 | 19.2 | | 15,470 | 17.3 | | |
| Homemaker only | 1964 | 6.9 | | 4457 | 11.3 | | 3237 | 15.0 | | 9658 | 10.8 | | |
| Body mass index (BMI), kg/m$^2$ | 29,353 | | 27.5 ± 6.3 | 40,696 | | 27.4 ± 5.8 | 22,519 | | 26.7 ± 5.3 | 92,568 | | 27.3 ± 5.9 | |
| Height (cm) | 29,491 | | 163.1 ± 6.8 | 40,846 | | 161.7 ± 6.6 | 22,583 | | 159.7 ± 6.5 | 92,920 | | 161.7 ± 6.8 | |
| Weight (kg) | 29,536 | | 73.4 ± 18.0 | 40,988 | | 72.2 ± 16.7 | 22,680 | | 68.6 ± 15.1 | 93,204 | | 71.7 ± 16.9 | |
| Waist/hip ratio (WHR) | 29,555 | | 0.8 ± 0.1 | 40,960 | | 0.8 ± 0.1 | 22,652 | | 0.8 ± 0.1 | 93,167 | | 0.8 ± 0.1 | |
| Waist (cm) | 29,588 | | 84.2 ± 14.4 | 41,017 | | 85.4 ± 13.7 | 22,674 | | 84.6 ± 12.5 | 93,279 | | 84.8 ± 13.7 | |
| Marital status | | | | | | | | | | | | | 0.95 |
| Never married | 1618 | 5.5 | | 1764 | 4.3 | | 1008 | 4.5 | | 4390 | 4.7 | | |
| Divorced/Separated | 6048 | 20.5 | | 6234 | 15.2 | | 2445 | 10.8 | | 14,727 | 15.8 | | |
| Widowed | 1676 | 5.7 | | 6795 | 16.6 | | 7819 | 34.5 | | 16,290 | 17.5 | | |
| Presently married/Living as married | 20,218 | 68.4 | | 26,212 | 63.9 | | 11,375 | 50.2 | | 57,805 | 62.0 | | |
| Living alone | | | | | | | | | | | | | 0.89 |
| No | 24,010 | 81.4 | | 30,463 | 74.5 | | 13,837 | 61.3 | | 68,310 | 73.5 | | |
| Yes | 5476 | 18.6 | | 10,409 | 25.5 | | 8718 | 38.7 | | 24,603 | 26.5 | | |
| U.S. region | | | | | | | | | | | | | |
| Northeast | 6309 | 21.2 | | 10,007 | 24.3 | | 4957 | 21.8 | | 21,273 | 22.7 | | |
| South | 8919 | 30.0 | | 10,380 | 25.2 | | 5163 | 22.7 | | 24,459 | 26.1 | | |
| Midwest | 6457 | 21.7 | | 9436 | 22.9 | | 4714 | 20.7 | | 20,607 | 22.0 | | |
| West | 8023 | 27.0 | | 11,374 | 27.6 | | 7940 | 34.9 | | 27,337 | 29.2 | | |

(*continued*)

**TABLE 1.** *Continued*

| Characteristic | Age at screening (y) 50–59 (N = 29,705) N | % | Mean ± SD | 60–69 (N = 41,197) N | % | Mean ± SD | 70–79 (N = 22,774) N | % | Mean ± SD | Total (N = 93,676) N | % | Mean ± SD | Reliability (N = 564) κ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Years lived in current state | | | | | | | | | | | | | 0.73[a] |
| <5 | 1297 | 4.4 | | 1439 | 3.5 | | 586 | 2.6 | | 3322 | 3.6 | | |
| 5–9 | 1447 | 4.9 | | 1401 | 3.4 | | 736 | 3.3 | | 3584 | 3.9 | | |
| 10–19 | 3298 | 11.2 | | 2749 | 6.7 | | 1393 | 6.2 | | 7440 | 8.0 | | |
| 20+ | 23,468 | 79.5 | | 35,330 | 86.3 | | 19,882 | 88.0 | | 78,680 | 84.6 | | |
| Born in the U.S. | | | | | | | | | | | | | 1.00 |
| No | 2422 | 8.2 | | 2876 | 7.0 | | 1504 | 6.6 | | 6802 | 7.3 | | |
| Yes | 27,098 | 91.8 | | 38,053 | 93.0 | | 21,130 | 93.4 | | 86,281 | 92.7 | | |
| U.S. region of birth | | | | | | | | | | | | | 0.99 |
| Not born in U.S. | 2422 | 8.3 | | 2876 | 7.1 | | 1504 | 6.7 | | 6802 | 7.4 | | |
| Northeast | 7769 | 26.5 | | 11,807 | 29.0 | | 6187 | 27.5 | | 25,763 | 27.9 | | |
| Midwest | 7970 | 27.2 | | 12,144 | 29.9 | | 6963 | 30.9 | | 27,077 | 29.3 | | |
| South | 7156 | 24.4 | | 8683 | 21.3 | | 4479 | 19.9 | | 20,318 | 22.0 | | |
| West | 3972 | 13.6 | | 5160 | 12.7 | | 3366 | 15.0 | | 12,498 | 13.5 | | |
| Smoking | | | | | | | | | | | | | 0.94 |
| Never smoked | 14,427 | 49.1 | | 20,246 | 49.8 | | 12,350 | 55.4 | | 47,023 | 50.9 | | |
| Past smoker | 12,570 | 42.8 | | 17,884 | 44.0 | | 9060 | 40.6 | | 39,514 | 42.8 | | |
| Current smoker | 2386 | 8.1 | | 2503 | 6.2 | | 902 | 4.0 | | 5791 | 6.3 | | |
| Years as a child lived with smoker | | | | | | | | | | | | | 0.83[a] |
| Never lived with a smoker | 8375 | 28.7 | | 14,528 | 36.1 | | 10,234 | 46.4 | | 33,137 | 36.2 | | |
| <1 | 269 | 0.9 | | 350 | 0.9 | | 200 | 0.9 | | 819 | 0.9 | | |
| 1–4 | 895 | 3.1 | | 1138 | 2.8 | | 569 | 2.6 | | 2602 | 2.8 | | |
| 5–9 | 1891 | 6.5 | | 2241 | 5.6 | | 1114 | 5.0 | | 5246 | 5.7 | | |
| 10–18 | 17,704 | 60.8 | | 21,979 | 54.6 | | 9953 | 45.1 | | 49,636 | 54.3 | | |
| Years as adult lived with smoker | | | | | | | | | | | | | 0.73[a] |
| Never lived with a smoker | 8573 | 29.2 | | 10,114 | 24.8 | | 5675 | 25.3 | | 24,362 | 26.3 | | |
| <1 | 793 | 2.7 | | 775 | 1.9 | | 444 | 2.0 | | 2012 | 2.2 | | |
| 1–4 | 3801 | 12.9 | | 3707 | 9.1 | | 1647 | 7.3 | | 9155 | 9.9 | | |
| 5–9 | 3404 | 11.6 | | 3550 | 8.7 | | 1619 | 7.2 | | 8573 | 9.3 | | |
| 10–19 | 5145 | 17.5 | | 6588 | 16.2 | | 2917 | 13.0 | | 14,650 | 15.8 | | |
| 20–29 | 3868 | 13.2 | | 6526 | 16.0 | | 3494 | 15.6 | | 13,888 | 15.0 | | |
| 30–39 | 2804 | 9.5 | | 4949 | 12.2 | | 3015 | 13.4 | | 10,768 | 11.6 | | |
| 40+ | 1015 | 3.5 | | 4498 | 11.0 | | 3620 | 16.1 | | 9133 | 9.9 | | |
| Years worked with smoker | | | | | | | | | | | | | 0.63[a] |
| Never worked with a smoker | 7040 | 24.0 | | 10,034 | 24.7 | | 6269 | 27.9 | | 23,343 | 25.3 | | |
| <1 | 1223 | 4.2 | | 1396 | 3.4 | | 758 | 3.4 | | 3377 | 3.7 | | |
| 1–4 | 5509 | 18.8 | | 6039 | 14.9 | | 2969 | 13.2 | | 14,517 | 15.7 | | |
| 5–9 | 5314 | 18.1 | | 6134 | 15.1 | | 2856 | 12.7 | | 14,304 | 15.5 | | |
| 10–19 | 5653 | 19.3 | | 7870 | 19.4 | | 3885 | 17.3 | | 17,408 | 18.8 | | |
| 20–29 | 3241 | 11.0 | | 5403 | 13.3 | | 3078 | 13.7 | | 11,722 | 12.7 | | |
| 30–39 | 1129 | 3.8 | | 2555 | 6.3 | | 1557 | 6.9 | | 5241 | 5.7 | | |
| 40+ | 243 | 0.8 | | 1225 | 3.0 | | 1058 | 4.7 | | 2526 | 2.7 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Alcohol intake | | | | | | | | | |
| Never drinker | 2736 | 9.3 | 4566 | 11.2 | 3175 | 14.1 | 10,477 | 11.3 | |
| Past drinker | 5303 | 17.9 | 7534 | 18.4 | 4718 | 20.9 | 17,555 | 18.9 | |
| <1 drink per mo | 3869 | 13.1 | 4567 | 11.2 | 2297 | 10.2 | 10,733 | 11.5 | |
| <1 drink per wk | 6143 | 20.8 | 8216 | 20.1 | 4369 | 19.4 | 18,728 | 20.1 | |
| 1–<7 drinks per wk | 8059 | 27.3 | 10,541 | 25.8 | 5242 | 23.2 | 23,842 | 25.6 | |
| 7 + drinks per wk | 3448 | 11.7 | 5487 | 13.4 | 2774 | 12.3 | 11,709 | 12.6 | |
| Physical activity | | | | | | | | | 0.67[a] |
| No activity | 4213 | 14.3 | 5343 | 13.1 | 3081 | 13.7 | 12,637 | 13.6 | |
| Some activity | 10,432 | 35.5 | 15,560 | 38.2 | 9656 | 42.9 | 35,648 | 38.5 | |
| 2–<4 episodes per wk of moderate + activity | 5304 | 18.1 | 7686 | 18.9 | 4103 | 18.2 | 17,093 | 18.5 | |
| 4 + episodes per wk of moderate + activity | 9425 | 32.1 | 12,144 | 29.8 | 5682 | 25.2 | 27,251 | 29.4 | |
| Total expenditure/wk from physical activity (METs) | | | | | | | | | 0.77[a] |
| 0–1.5 | 5904 | 2.01 | 7602 | 18.7 | 4382 | 19.5 | 17,888 | 19.3 | |
| >1.5–8 | 7215 | 24.6 | 10,089 | 24.8 | 6026 | 26.8 | 23,330 | 25.2 | |
| >8–19 | 8400 | 28.6 | 12,119 | 29.8 | 6686 | 29.7 | 27,205 | 29.4 | |
| >19 | 7855 | 26.7 | 10,923 | 26.8 | 5428 | 24.1 | 24,206 | 26.1 | |
| Hours/day spent sitting, sleeping or lying down | | | | | | | | | 0.60[a] |
| 4–12.5 | 6364 | 21.7 | 9569 | 23.5 | 5586 | 24.9 | 21,519 | 23.2 | |
| 13–14.5 | 4408 | 15.0 | 7564 | 18.6 | 4355 | 19.4 | 16,327 | 17.6 | |
| 15–16.5 | 4837 | 16.5 | 7955 | 19.5 | 4608 | 20.5 | 17,400 | 18.8 | |
| 17+ | 13,776 | 46.9 | 15,686 | 38.5 | 7926 | 35.3 | 37,388 | 40.4 | |
| Any supplement use | | | | | | | | | |
| No | 9287 | 31.3 | 10,745 | 26.1 | 5535 | 24.3 | 25,567 | 27.3 | |
| Yes | 20,418 | 68.7 | 30,452 | 73.9 | 17,239 | 75.7 | 68,109 | 72.7 | |
| Multivitamin use (with or without minerals) | | | | | | | | | |
| No | 18,261 | 61.5 | 23,682 | 57.5 | 12,897 | 56.6 | 54,840 | 58.5 | |
| Yes | 11,444 | 38.5 | 17,515 | 42.5 | 9877 | 43.4 | 38,836 | 41.5 | |
| Vitamin C as single supplement | | | | | | | | | |
| No | 21,975 | 74.0 | 28,825 | 70.0 | 15,794 | 69.4 | 66,594 | 71.1 | |
| Yes | 7730 | 26.0 | 12,372 | 30.0 | 6980 | 30.6 | 27,082 | 28.9 | |
| Vitamin E as single supplement | | | | | | | | | |
| No | 20,859 | 70.2 | 26,835 | 65.1 | 14,638 | 64.3 | 62,332 | 66.5 | |
| Yes | 8846 | 29.8 | 14,362 | 34.9 | 8136 | 35.7 | 31,344 | 33.5 | |
| Calcium as single supp (including antacids) | | | | | | | | | |
| No | 21,894 | 73.7 | 29,194 | 70.9 | 15,902 | 69.8 | 66,990 | 71.5 | |
| Yes | 7811 | 26.3 | 12,003 | 29.1 | 6872 | 30.2 | 26,686 | 28.5 | |
| Single supplement (not vitamin C, E, or calcium) | | | | | | | | | |
| No | 17,926 | 60.3 | 23,709 | 57.6 | 13,063 | 57.4 | 54,898 | 58.4 | |
| Yes | 11,779 | 39.7 | 17,488 | 42.4 | 9711 | 42.6 | 38,978 | 41.6 | |

[a]Weighted kappa.

**Table 2.** Baseline reproductive and medical history status of WHI Observational Study participants by age

| | Age at screening (y) | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 50–59 (N = 29,705) | | | 60–69 (N = 41,197) | | | 70–79 (N = 22,774) | | | Total (N = 93,676) | | | Reliability (N = 564) |
| Reproductive and Medical History | N | % | Mean ± SD | N | % | Mean ± SD | N | % | Mean ± SD | N | % | Mean ± SD | κ |
| Hysterectomy[b] | | | | | | | | | | | | | 0.95 |
| No | 18,047 | 60.8 | | 23,694 | 57.6 | | 12,702 | 55.8 | | 54,443 | 58.2 | | |
| Yes | 11,628 | 39.2 | | 17,463 | 42.4 | | 10,056 | 44.2 | | 39,147 | 41.8 | | |
| Age at hysterectomy (y) | | | | | | | | | | | | | 0.92[a] |
| Not hysterectomized | 18,047 | 60.9 | | 23,694 | 57.7 | | 12,702 | 55.9 | | 54,443 | 58.3 | | |
| <40 | 4918 | 16.6 | | 5367 | 13.1 | | 2174 | 9.6 | | 12,459 | 13.3 | | |
| 40–49 | 5090 | 17.2 | | 7677 | 18.7 | | 4025 | 17.7 | | 16,792 | 18.0 | | |
| 50–54 | 1297 | 4.4 | | 2167 | 5.3 | | 1635 | 7.2 | | 5099 | 5.5 | | |
| 55+ | 285 | 1.0 | | 2191 | 5.3 | | 2175 | 9.6 | | 4651 | 5.0 | | |
| Ever pregnant | | | | | | | | | | | | | 0.98 |
| No | 3272 | 11.0 | | 3660 | 8.9 | | 2425 | 10.7 | | 9357 | 10.0 | | |
| Yes | 26,348 | 89.0 | | 37,404 | 91.1 | | 20,252 | 89.3 | | 84,004 | 90.0 | | |
| Age at first birth (y)[c] | | | | | | | | | | | | | 0.86[a] |
| Never had term pregnancy | 1134 | 4.7 | | 859 | 2.6 | | 544 | 3.1 | | 2537 | 3.4 | | |
| <20 | 4301 | 17.9 | | 4758 | 14.3 | | 1458 | 8.4 | | 10,517 | 14.1 | | |
| 20–29 | 16,664 | 69.2 | | 24,962 | 74.9 | | 12,887 | 74.2 | | 54,513 | 72.9 | | |
| 30+ | 1969 | 8.2 | | 2763 | 8.3 | | 2473 | 14.2 | | 7205 | 9.6 | | |
| Number of pregnancies | | | | | | | | | | | | | 0.97[a] |
| Never pregnant | 3272 | 11.1 | | 3660 | 8.9 | | 2425 | 10.7 | | 9357 | 10.0 | | |
| 1 | 2632 | 8.9 | | 2449 | 6.0 | | 1699 | 7.5 | | 6780 | 7.3 | | |
| 2–4 | 18,845 | 63.7 | | 23,844 | 58.2 | | 13,090 | 57.9 | | 55,779 | 59.9 | | |
| 5+ | 4819 | 16.3 | | 11,021 | 26.9 | | 5411 | 23.9 | | 21,251 | 22.8 | | |
| Number of live births | | | | | | | | | | | | | 0.98[b] |
| Never pregnant | 3272 | 11.1 | | 3660 | 8.9 | | 2425 | 10.7 | | 9357 | 10.1 | | |
| None | 1186 | 4.0 | | 920 | 2.2 | | 591 | 2.6 | | 2697 | 2.9 | | |
| 1 | 3405 | 11.5 | | 3208 | 7.8 | | 2166 | 9.6 | | 8779 | 9.4 | | |
| 2–4 | 19,581 | 66.4 | | 26,776 | 65.5 | | 14,317 | 63.4 | | 60,674 | 65.2 | | |
| 5+ | 2066 | 7.0 | | 6340 | 15.5 | | 3094 | 13.7 | | 11,500 | 12.4 | | |
| Any induced abortions[c] | | | | | | | | | | | | | 0.71 |
| Pregnant, never had an abortion | 21,658 | 86.5 | | 32,289 | 92.9 | | 17,520 | 94.0 | | 71,467 | 91.1 | | |
| One or more abortions | 3385 | 13.5 | | 2464 | 7.1 | | 1116 | 6.0 | | 6965 | 8.9 | | |
| Number of months breastfed | | | | | | | | | | | | | 0.89[a] |
| Never breastfed | 15,316 | 52.1 | | 19,949 | 49.2 | | 10,178 | 45.8 | | 45,443 | 49.3 | | |
| 1–6 | 6892 | 23.4 | | 10,707 | 26.4 | | 6269 | 28.2 | | 23,868 | 25.9 | | |
| 7–12 | 3313 | 11.3 | | 4322 | 10.7 | | 2613 | 11.7 | | 10,248 | 11.1 | | |
| 13–23 | 2396 | 8.1 | | 3448 | 8.5 | | 1918 | 8.6 | | 7762 | 8.4 | | |
| 24+ | 1487 | 5.1 | | 2152 | 5.3 | | 1261 | 5.7 | | 4900 | 5.3 | | |
| Age at tubal ligation (y) | | | | | | | | | | | | | 0.94 |
| Never had tubal ligation | 20,509 | 69.5 | | 35,522 | 86.9 | | 21,259 | 94.3 | | 77,290 | 83.2 | | |
| <30 | 1154 | 3.9 | | 844 | 2.1 | | 324 | 1.4 | | 2322 | 2.5 | | |
| 30–34 | 2964 | 10.0 | | 1058 | 2.6 | | 395 | 1.8 | | 4417 | 4.8 | | |
| 35–39 | 3298 | 11.2 | | 1679 | 4.1 | | 358 | 1.6 | | 5335 | 5.7 | | |
| 40–44 | 1343 | 4.6 | | 1380 | 3.4 | | 155 | 0.7 | | 2878 | 3.1 | | |
| 45+ | 246 | 0.8 | | 404 | 1.0 | | 54 | 0.2 | | 704 | 0.8 | | |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Age last had any menstrual bleeding (y) | | | | | | | | | | | | 0.83[a] |
| <40 | 4207 | 15.8 | | 4725 | 12.4 | | 1904 | 9.0 | | 10,836 | 12.6 | |
| 40–44 | 3329 | 12.5 | | 5448 | 14.3 | | 2867 | 13.6 | | 11,644 | 13.6 | |
| 45–49 | 6120 | 23.0 | | 7724 | 20.3 | | 4572 | 21.7 | | 18,416 | 21.5 | |
| 50–54 | 10,080 | 37.9 | | 12,384 | 32.5 | | 7670 | 36.4 | | 30,134 | 35.1 | |
| 55–59 | 2894 | 10.9 | | 5137 | 13.5 | | 2678 | 12.7 | | 10,709 | 12.5 | |
| 60+ | | | | 2668 | 7.0 | | 1355 | 6.4 | | 4023 | 4.7 | |
| Current health care provider | | | | | | | | | | | | 0.59 |
| No | 2002 | 6.8 | | 1994 | 4.9 | | 798 | 3.5 | | 4794 | 5.2 | |
| Yes | 27,414 | 93.2 | | 38,812 | 95.1 | | 21,731 | 96.5 | | 87,957 | 94.8 | |
| Mammogram in last 2 y | | | | | | | | | | | | |
| No | 3936 | 13.6 | | 5217 | 13.0 | | 3557 | 16.2 | | 12,710 | 14.0 | |
| Yes | 24,979 | 86.4 | | 34,828 | 87.0 | | 18,355 | 83.8 | | 78,162 | 86.0 | |
| Pap smear in last 3 y | | | | | | | | | | | | |
| No | 1109 | 6.6 | | 1857 | 8.5 | | 1624 | 14.2 | | 4590 | 9.2 | |
| Yes | 15,625 | 93.4 | | 19,982 | 91.5 | | 9785 | 85.8 | | 45,392 | 90.8 | |
| History of PHT use[d] | | | | | | | | | | | | |
| Never | 9854 | 33.2 | | 16,906 | 41.1 | | 11,057 | 48.7 | | 37,817 | 40.4 | |
| Past | 2965 | 10.0 | | 5674 | 13.8 | | 4493 | 19.8 | | 13,132 | 14.0 | |
| Current | 16,846 | 56.8 | | 18,565 | 45.1 | | 7168 | 31.6 | | 42,579 | 45.5 | |
| Total PHT duration (y) | | | | | | | | | | | | |
| Non-user | 9854 | 33.2 | | 16,906 | 41.0 | | 11,057 | 48.6 | | 37,817 | 40.4 | |
| <5 | 10,071 | 33.9 | | 6969 | 16.9 | | 3791 | 16.6 | | 20,831 | 22.2 | |
| 5–<10 | 5830 | 19.6 | | 5262 | 12.8 | | 1552 | 6.8 | | 12,644 | 13.5 | |
| 10–<15 | 2482 | 8.4 | | 5358 | 13.0 | | 1447 | 6.4 | | 9287 | 9.9 | |
| 15+ | 1467 | 4.9 | | 6701 | 16.3 | | 4927 | 21.6 | | 13,095 | 14.0 | |
| History of E-alone use[d] | | | | | | | | | | | | |
| Never | 19,266 | 64.9 | | 25,635 | 62.3 | | 13,443 | 59.2 | | 58,344 | 62.4 | |
| Past | 2046 | 6.9 | | 4735 | 11.5 | | 4304 | 18.9 | | 11,085 | 11.8 | |
| Current | 8356 | 28.2 | | 10,787 | 26.2 | | 4979 | 21.9 | | 24,122 | 25.8 | |
| Total E-alone duration (y) | | | | | | | | | | | | |
| Non-user | 19,266 | 64.9 | | 25,635 | 62.2 | | 13,443 | 59.0 | | 58,344 | 62.3 | |
| <5 | 4768 | 16.1 | | 4798 | 11.6 | | 3098 | 13.6 | | 12,664 | 13.5 | |
| 5–<10 | 2948 | 9.9 | | 2821 | 6.8 | | 1220 | 5.4 | | 6989 | 7.5 | |
| 10–<15 | 1511 | 5.1 | | 2785 | 6.8 | | 1050 | 4.6 | | 5346 | 5.7 | |
| 15+ | 1212 | 4.1 | | 5157 | 12.5 | | 3963 | 17.4 | | 10,332 | 11.0 | |
| History of E+P use[d] | | | | | | | | | | | | |
| Never | 18,443 | 62.1 | | 29,519 | 71.7 | | 19,128 | 84.0 | | 67,090 | 71.7 | |
| Past | 2544 | 8.6 | | 3708 | 9.0 | | 1380 | 6.1 | | 7632 | 8.2 | |
| Current | 8705 | 29.3 | | 7950 | 19.3 | | 2252 | 9.9 | | 18,907 | 20.2 | |
| Total E+P duration (y) | | | | | | | | | | | | |
| Non-user | 18,443 | 62.1 | | 29,519 | 71.7 | | 19,128 | 84.0 | | 67,090 | 71.6 | |
| <5 | 7162 | 24.1 | | 4628 | 11.2 | | 1580 | 6.9 | | 13,370 | 14.3 | |
| 5–<10 | 3098 | 10.4 | | 3404 | 8.3 | | 695 | 3.1 | | 7197 | 7.7 | |
| 10–<15 | 842 | 2.8 | | 2537 | 6.2 | | 630 | 2.8 | | 4009 | 4.3 | |
| 15+ | 159 | 0.5 | | 1109 | 2.7 | | 741 | 3.3 | | 2009 | 2.1 | |
| Systolic blood pressure (mm Hg) | 29,665 | | 120.7 ± 16.1 | 41,146 | | 127.7 ± 17.4 | 22,740 | | 133.8 ± 18.6 | 93,551 | | 127.0 ± 18.0 |
| ≤120 | 16,191 | 54.6 | | 15,290 | 37.2 | | 5706 | 25.1 | | 37,187 | 39.8 | |
| >120–140 | 10,297 | 34.7 | | 17,328 | 42.1 | | 9764 | 42.9 | | 37,389 | 40.0 | |
| >140 | 3177 | 10.7 | | 8528 | 20.7 | | 7270 | 32.0 | | 18,975 | 20.3 | |

(*continued*)

**Table 2.** *Continued*

| Reproductive and Medical History | Age at screening (y) 50–59 (N = 29,705) N | % | Mean ± SD | 60–69 (N = 41,197) N | % | Mean ± SD | 70–79 (N = 22,774) N | % | Mean ± SD | Total (N = 93,676) N | % | Mean ± SD | Reliability (N = 564) κ |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Diastolic blood pressure (mm Hg) | 29,665 | | 75.4 ± 9.2 | 41,137 | | 75.0 ± 9.3 | 22,729 | | 73.4 ± 9.6 | 93,531 | | 74.7 ± 9.4 | |
| <90 | 27,600 | 93.0 | | 38,448 | 93.5 | | 21,501 | 94.6 | | 87,549 | 93.6 | | |
| ≥90 | 2065 | 7.0 | | 2689 | 6.5 | | 1228 | 5.4 | | 5982 | 6.4 | | |
| History of hypertension | | | | | | | | | | | | | 0.86 |
| Never hypertensive | 22,029 | 75.3 | | 26,195 | 64.8 | | 12,975 | 58.1 | | 61,199 | 66.5 | | |
| Untreated hypertensive | 2192 | 7.5 | | 3268 | 8.1 | | 1858 | 8.3 | | 7318 | 8.0 | | |
| Treated hypertensive | 5035 | 17.2 | | 10,948 | 27.1 | | 7481 | 33.5 | | 23,464 | 25.5 | | |
| Treated diabetes (pills or shots) | | | | | | | | | | | | | 0.86 |
| No | 28,743 | 96.8 | | 39,287 | 95.5 | | 21,624 | 95.1 | | 89,654 | 95.8 | | |
| Yes | 938 | 3.2 | | 1855 | 4.5 | | 1109 | 4.9 | | 3902 | 4.2 | | |
| Treated hypercholesterolemia (pills) | | | | | | | | | | | | | 0.82 |
| No | 26,289 | 90.6 | | 33,499 | 83.2 | | 18,047 | 80.8 | | 77,835 | 85.0 | | |
| Yes | 2732 | 9.4 | | 6761 | 16.8 | | 4281 | 19.2 | | 13,774 | 15.0 | | |
| Depression (shortened CES-D/DIS≥0.06) | | | | | | | | | | | | | 0.49 |
| No | 24,836 | 85.5 | | 35,950 | 89.6 | | 19,972 | 91.0 | | 80,758 | 88.6 | | |
| Yes | 4204 | 14.5 | | 4177 | 10.4 | | 1987 | 9.0 | | 10,368 | 11.4 | | |
| Benign breast disease | | | | | | | | | | | | | 0.77 |
| No | 22,185 | 79.4 | | 29,225 | 76.6 | | 15,899 | 76.7 | | 67,309 | 77.5 | | |
| Yes, 1 biopsy | 4071 | 14.6 | | 6100 | 16.0 | | 3332 | 16.1 | | 13,503 | 15.6 | | |
| Yes, 2+ biopsies | 1673 | 6.0 | | 2841 | 7.4 | | 1487 | 7.2 | | 6001 | 6.9 | | |
| History of MI | | | | | | | | | | | | | 0.93 |
| No | 29,363 | 98.9 | | 40,148 | 97.5 | | 21,772 | 95.7 | | 91,283 | 97.5 | | |
| Yes | 319 | 1.1 | | 1013 | 2.5 | | 974 | 4.3 | | 2306 | 2.5 | | |
| History of stroke | | | | | | | | | | | | | 0.58 |
| No | 29,459 | 99.2 | | 40,567 | 98.5 | | 22,180 | 97.5 | | 92,206 | 98.5 | | |
| Yes | 235 | 0.8 | | 602 | 1.5 | | 578 | 2.5 | | 1415 | 1.5 | | |
| History of CHF | | | | | | | | | | | | | 0.44 |
| No | 29,559 | 99.5 | | 40,792 | 99.0 | | 22,427 | 98.5 | | 92,778 | 99.0 | | |
| Yes | 145 | 0.5 | | 401 | 1.0 | | 346 | 1.5 | | 892 | 1.0 | | |
| History of angina | | | | | | | | | | | | | 0.82 |
| No | 28,876 | 97.5 | | 39,072 | 95.3 | | 20,915 | 92.5 | | 88,863 | 95.3 | | |
| Yes | 729 | 2.5 | | 1935 | 4.7 | | 1708 | 7.5 | | 4372 | 4.7 | | |
| History of carotid endarterectomy/angioplasty | | | | | | | | | | | | | 0.67 |
| No | 29,333 | 99.9 | | 40,406 | 99.7 | | 22,087 | 99.2 | | 91,826 | 99.6 | | |
| Yes | 35 | 0.1 | | 138 | 0.3 | | 171 | 0.8 | | 344 | 0.4 | | |
| History of DVT | | | | | | | | | | | | | 0.58 |
| No | 28,844 | 97.2 | | 39,450 | 95.8 | | 21,727 | 95.5 | | 90,021 | 96.2 | | |
| Yes | 841 | 2.8 | | 1710 | 4.2 | | 1021 | 4.5 | | 3572 | 3.8 | | |
| History of PE | | | | | | | | | | | | | 0.89 |
| No | 29,473 | 99.3 | | 40,708 | 98.9 | | 22,479 | 98.8 | | 92,660 | 99.0 | | |
| Yes | 214 | 0.7 | | 469 | 1.1 | | 276 | 1.2 | | 959 | 1.0 | | |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| History of peripheral arterial disease PAD | | | | | | | | | 0.72 |
| No | 29,380 | 99.2 | 40,352 | 98.4 | 22,008 | 97.4 | 91,740 | 98.4 | |
| Yes | 231 | 0.8 | 643 | 1.6 | 593 | 2.6 | 1467 | 1.6 | |
| History of CABG/PTCA | | | | | | | | | 0.90 |
| No | 29,149 | 99.3 | 39,744 | 98.0 | 21,500 | 96.6 | 90,393 | 98.1 | |
| Yes | 217 | 0.7 | 799 | 2.0 | 757 | 3.4 | 1773 | 1.9 | |
| History of polyp removal | | | | | | | | | 0.88 |
| No | 27,252 | 94.1 | 35,693 | 89.4 | 18,781 | 85.6 | 81,726 | 90.0 | |
| Yes | 1709 | 5.9 | 4241 | 10.6 | 3160 | 14.4 | 9110 | 10.0 | |
| History of fracture at age 55+[e] | | | | | | | | | 0.65 |
| No | 16,176 | 94.8 | 34,368 | 84.8 | 16,882 | 75.4 | 67,426 | 84.3 | |
| Yes | 893 | 5.2 | 6148 | 15.2 | 5500 | 24.6 | 12,541 | 15.7 | |
| History of hip fracture at age 55+ | | | | | | | | | 0.67 |
| No | 29,242 | 100.0 | 40,309 | 99.5 | 22,061 | 98.6 | 91,612 | 99.4 | |
| Yes | 10 | 0.0 | 207 | 0.5 | 321 | 1.4 | 538 | 0.6 | |
| Number of falls in last 12 mo | | | | | | | | | 0.45[a] |
| None | 19,756 | 67.3 | 27,791 | 68.3 | 15,063 | 67.0 | 62,610 | 67.7 | |
| 1 | 5746 | 19.6 | 8063 | 19.8 | 4585 | 20.4 | 18,394 | 19.9 | |
| 2 | 2439 | 8.3 | 3219 | 7.9 | 1921 | 8.6 | 7579 | 8.2 | |
| 3+ | 1407 | 4.8 | 1607 | 4.0 | 897 | 4.0 | 3911 | 4.2 | |
| History of cancer[f] | | | | | | | | | 0.77 |
| No | 26,552 | 89.9 | 35,604 | 87.1 | 18,697 | 83.0 | 80,853 | 87.0 | |
| Yes | 2984 | 10.1 | 5270 | 12.9 | 3821 | 17.0 | 12,075 | 13.0 | |
| History of breast cancer | | | | | | | | | 0.89 |
| No | 28,436 | 95.8 | 38,925 | 94.6 | 21,171 | 93.1 | 88,532 | 94.6 | |
| Yes | 1233 | 4.2 | 2222 | 5.4 | 1566 | 6.9 | 5021 | 5.4 | |
| History of colorectal cancer | | | | | | | | | 1.00 |
| No | 29,504 | 99.6 | 40,733 | 99.1 | 22,325 | 98.3 | 92,562 | 99.1 | |
| Yes | 107 | 0.4 | 367 | 0.9 | 386 | 1.7 | 860 | 0.9 | |
| History of endometrial cancer | | | | | | | | | 0.82 |
| No | 29,260 | 98.6 | 40,450 | 98.3 | 22,120 | 97.3 | 91,830 | 98.2 | |
| Yes | 409 | 1.4 | 699 | 1.7 | 613 | 2.7 | 1721 | 1.8 | |
| History of melanoma | | | | | | | | | 0.76 |
| No | 29,258 | 98.8 | 40,332 | 98.2 | 22,116 | 97.5 | 91,706 | 98.2 | |
| Yes | 363 | 1.2 | 729 | 1.8 | 567 | 2.5 | 1659 | 1.8 | |
| History of cervical cancer | | | | | | | | | 1.00 |
| No | 29,071 | 98.6 | 40,310 | 98.7 | 22,178 | 98.8 | 91,559 | 98.7 | |
| Yes | 418 | 1.4 | 514 | 1.3 | 273 | 1.2 | 1205 | 1.3 | |
| History of osteoporosis | | | | | | | | | 0.77 |
| No | 27,973 | 95.5 | 36,860 | 90.7 | 19,325 | 85.8 | 84,158 | 91.0 | |
| Yes | 1325 | 4.5 | 3770 | 9.3 | 3187 | 14.2 | 8282 | 9.0 | |
| History of arthritis | | | | | | | | | 0.81 |
| No arthritis | 18,670 | 63.6 | 20,011 | 49.4 | 9006 | 40.5 | 47,687 | 51.8 | |
| Rheumatoid arthritis | 1253 | 4.3 | 2243 | 5.5 | 1479 | 6.6 | 4975 | 5.4 | |
| Other arthritis | 9425 | 32.1 | 18,221 | 45.0 | 11,767 | 52.9 | 39,413 | 42.8 | |

(*continued*)

**Table 2.** *Continued*

| | Age at screening (y) | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 50–59 (N = 29,705) | | | 60–69 (N = 41,197) | | | 70–79 (N = 22,774) | | | Total (N = 93,676) | | | Reliability (N = 564) |
| Reproductive and Medical History | N | % | Mean ± SD | N | % | Mean ± SD | N | % | Mean ± SD | N | % | Mean ± SD | κ |
| Family history of myocardial infarction | | | | | | | | | | | | | 0.83 |
| No | 14,655 | 51.7 | | 17,863 | 45.7 | | 9570 | 45.0 | | 42,088 | 47.5 | | |
| Yes | 13,698 | 48.3 | | 21,196 | 54.3 | | 11,675 | 55.0 | | 46,569 | 52.5 | | |
| Family history of stroke | | | | | | | | | | | | | 0.84 |
| No | 18,905 | 66.9 | | 23,218 | 59.9 | | 12,278 | 57.5 | | 54,401 | 61.6 | | |
| Yes | 9333 | 33.1 | | 15,565 | 40.1 | | 9061 | 42.5 | | 33,959 | 38.4 | | |
| Family history of breast cancer | | | | | | | | | | | | | 0.92 |
| No | 23,088 | 81.8 | | 31,306 | 80.4 | | 16,948 | 79.5 | | 71,342 | 80.6 | | |
| Yes | 5148 | 18.2 | | 7622 | 19.6 | | 4360 | 20.5 | | 17,130 | 19.4 | | |
| Family history of colorectal caner | | | | | | | | | | | | | 0.85 |
| No | 23,564 | 86.2 | | 31,195 | 82.8 | | 16,402 | 80.1 | | 71,161 | 83.2 | | |
| Yes | 3782 | 13.8 | | 6458 | 17.2 | | 4079 | 19.9 | | 14,319 | 16.8 | | |
| Parent broke bone after age 40 | | | | | | | | | | | | | 0.88 |
| No | 16,480 | 59.9 | | 22,545 | 59.2 | | 13,148 | 62.8 | | 52,173 | 60.3 | | |
| Yes | 11,031 | 40.1 | | 15,516 | 40.8 | | 7793 | 37.2 | | 34,340 | 39.7 | | |
| Family history of adult diabetes | | | | | | | | | | | | | 0.88 |
| No | 18,954 | 66.8 | | 25,848 | 66.1 | | 14,671 | 68.6 | | 59,473 | 66.9 | | |
| Yes | 9416 | 33.2 | | 13,262 | 33.9 | | 6725 | 31.4 | | 29,403 | 33.1 | | |

MI, myocardial infarction; CHF, congestive heart failure; DVT, deep vein thrombosis; PE, pulmonaryembolism.
[a]Weighted kappa.
[b]Hysterectomy at randomization.
[c]Applies only to participants who have ever been pregnant.
[d]Based on estrogen and progesterone pills and patches only (creams and shots excluded). Episodes less than 3 months are excluded.
[e]Applies only to participants age 55 and older.
[f]Excluding non-melanoma skin cancer.

fraction of women 70 to 79 years old had their first child after age 30 than women in the younger age cohorts.

The prevalence of diabetes, hypertension, prior myocardial infarction, stroke, cancer, fracture, and hysterectomy increased with age. Access to a health care provider increased, but the frequency of mammography and Pap smears declined with age. Women 50 to 59 years old were the most likely to be depressed, with a prevalence about 50% greater than women aged 70 to 79 years.

Total energy intake declined, while the use of supplements and servings of fruits and vegetables increased with age (Table 3). There were no other important age-related differences in dietary factors. The small sample size for blood analytes precludes meaningful comparisons by age group (Table 4).

### Racial/Ethnic Contrasts

The distributions of variables by ethnicity are shown in the appendix to Hays' article. The average age ranged from 60.6 years for Hispanic women to 63.9 years for White women. Hispanic women reported the lowest educational attainment, the lowest frequency of managerial/professional occupation, and the highest frequency of homemaker as sole occupation. Hispanics and American Indians had similar distributions of income, with nearly 40% reporting a family income below $20,000. In contrast, White women were 1.9 times more likely than American Indian and Hispanic, and 1.6 times more likely than Black women, to report family income above $50,000.

While few women in any of the ethnic groups had never married, Black women were less likely to be married currently than women of the other races/ethnicities. Previously married Black and Hispanic women were more likely to be divorced than widowed, while White and Asian women were slightly more likely to be widowed than divorced. Black women had the highest rates of living alone, divorce, and widowhood. Asian/Pacific Islander women were the least likely to live alone.

More Asian/Pacific Islanders reported never having been smokers than women of other races, while Black and American Indian women reported being current smokers more often than the other groups. White women reported a greater prevalence of alcoholic beverage use, and more frequent drinking than the other groups. White women engaged in substantially more moderate or strenuous activity than women in the other groups.

Black women had the highest prevalence of hysterectomy (54.8%). Black and American Indian women reported similar high rates of hysterectomy before the age of 40 (24.8% and 25.4%, respectively). Black and Hispanic women had substantially higher rates of tubal ligation (21.6% and 23.6%) than women of other races. The percentage of women ever breastfeeding was highest among Asian/Pacific Islanders (62.2%), and lowest among Blacks (47.7%). Benign breast disease was most common in Whites (23.0%) and least frequent in Hispanics (17.5%).

Over 60% of White and Asian/Pacific Islander participants were current or past users of postmenopausal hormones. Duration of use was greatest in Whites and Asian/

**Table 3.** Dietary intake of WHI Observational Study participants by age, from a Food Frequency Questionnaire

| | Age at screening (y) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 50–59 (N = 28,487) | | 60–69 (N = 39,640) | | 70–79 (N = 21,789) | | Total (N = 89,916) | |
| Nutrient[a] | N | Mean ± SD | N | Mean ± SD | N | Mean ± SD | N | Mean ± SD |
| Energy (kcal) | 28,487 | 1498 ± 563 | 39,640 | 1460 ± 531 | 21,789 | 1413 ± 512 | 89,916 | 1460 ± 537 |
| Total fat (g) | 28,487 | 50 ± 26 | 39,640 | 49 ± 25 | 21,789 | 48 ± 24 | 89,916 | 49 ± 25 |
| % Energy from fat | 28,487 | 30 ± 8 | 39,640 | 30 ± 8 | 21,789 | 30 ± 8 | 89,916 | 30 ± 8 |
| Total carbohydrate (g) | 28,487 | 189 ± 74 | 39,640 | 184 ± 69 | 21,789 | 180 ± 67 | 89,916 | 184 ± 70 |
| Protein (g) | 28,487 | 62 ± 26 | 39,640 | 61 ± 24 | 21,789 | 59 ± 24 | 89,916 | 61 ± 25 |
| Total SFA (g) | 28,487 | 17 ± 9 | 39,640 | 16 ± 9 | 21,789 | 16 ± 8 | 89,916 | 16 ± 9 |
| % Energy from SFA | 28,487 | 10 ± 3 | 39,640 | 10 ± 3 | 21,789 | 10 ± 3 | 89,916 | 10 ± 3 |
| Total trans fatty acid (g) | 28,487 | 2.9 ± 1.4 | 39,640 | 2.9 ± 1.4 | 21,789 | 2.9 ± 1.3 | 89,916 | 2.9 ± 1.4 |
| Dietary fiber (g) | 28,487 | 16 ± 6 | 39,640 | 16 ± 6 | 21,789 | 16 ± 6 | 89,916 | 16 ± 6 |
| Cholesterol (mg) | 28,487 | 173 ± 101 | 39,640 | 170 ± 98 | 21,789 | 161 ± 93 | 89,916 | 168 ± 98 |
| Vitamin D (mcg) | 28,487 | 4.1 ± 2.0 | 39,640 | 4.3 ± 2.1 | 21,789 | 4.4 ± 2.2 | 89,916 | 4.3 ± 2.1 |
| Total alpha-toc eq (mg) | 28,487 | 7.4 ± 3.0 | 39,640 | 7.5 ± 3.0 | 21,789 | 7.5 ± 3.0 | 89,916 | 7.5 ± 3.0 |
| Vitamin C (mg) | 28,487 | 94 ± 54 | 39,640 | 99 ± 54 | 21,789 | 104 ± 55 | 89,916 | 99 ± 54 |
| Folacin (mcg) | 28,487 | 228 ± 98 | 39,640 | 236 ± 97 | 21,789 | 238 ± 98 | 89,916 | 234 ± 98 |
| Calcium (mg) | 28,487 | 680 ± 372 | 39,640 | 675 ± 362 | 21,789 | 668 ± 363 | 89,916 | 675 ± 366 |
| Total calcium (mg) | 28,487 | 978 ± 611 | 39,640 | 1012 ± 618 | 21,789 | 1002 ± 611 | 89,916 | 999 ± 614 |
| Fruits and vegetables (servings/day) | 28,487 | 3.7 ± 1.6 | 39,640 | 3.9 ± 1.6 | 21,789 | 4.2 ± 1.7 | 89,916 | 3.9 ± 1.7 |
| Grains (servings/day) | 28,480 | 4.3 ± 1.8 | 39,633 | 4.0 ± 1.7 | 21,788 | 3.7 ± 1.5 | 89,901 | 4.0 ± 1.7 |

[a]Means and standard deviations were computed on the log scale and back-transformed values are reported.

**Table 4.** Baseline blood analytes from a random sample of WHI Observational Study participants by age

| | Age at screening (y) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | 50–59 (N = 325) | | 60–69 (N = 453) | | 70–79 (N = 284) | | Total (N = 1062) | | Reliability (N = 564) |
| Blood Analyte[a,b] | N | Mean ± SD | N | Mean ± SD | N | Mean ± SD | N | Mean ± SD | ICC[c] |
| Total cholesterol (mg/dl) | 325 | 210 ± 35.6 | 453 | 217.1 ± 34.9 | 284 | 220.3 ± 36.9 | 1062 | 215.4 ± 35.8 | 0.82 |
| LDL-C (mg/dl) | 316 | 115.8 ± 34 | 444 | 120.8 ± 33.6 | 282 | 125.3 ± 35.4 | 1042 | 120.4 ± 34.3 | 0.83 |
| HDL-C (mg/dl) | 324 | 60.2 ± 17.2 | 453 | 62.9 ± 16.4 | 284 | 60.6 ± 16.1 | 1061 | 61.4 ± 16.5 | 0.89 |
| HDL-2 (mg/dl) | 313 | 18.5 ± 8.7 | 447 | 20.5 ± 9.3 | 273 | 19.9 ± 9.2 | 1033 | 19.7 ± 9.1 | 0.88 |
| HDL-3 (mg/dl) | 313 | 40.6 ± 9.7 | 447 | 41.5 ± 8.8 | 273 | 40.3 ± 8.7 | 1033 | 40.8 ± 9 | 0.86 |
| Triglyceride (mg/dl) | 325 | 130.5 ± 65.9 | 453 | 131.3 ± 60.8 | 284 | 136.1 ± 58.8 | 1062 | 132.1 ± 61.6 | 0.80 |
| Lp(a) (mg/dl) | 322 | 16.6 ± 18 | 453 | 17.7 ± 19.7 | 284 | 15.1 ± 16.6 | 1059 | 16.6 ± 18.2 | 0.95 |
| Retinol (μg/ml) | 325 | 0.6 ± 0.14 | 452 | 0.61 ± 0.14 | 284 | 0.61 ± 0.16 | 1061 | 0.61 ± 0.15 | 0.81 |
| Alpha-carotene (μg/ml) | 325 | 0.07 ± 0.07 | 452 | 0.08 ± 0.06 | 284 | 0.08 ± 0.06 | 1061 | 0.08 ± 0.06 | 0.73 |
| Beta-carotene (μg/ml) | 325 | 0.22 ± 0.2 | 452 | 0.26 ± 0.2 | 284 | 0.29 ± 0.25 | 1061 | 0.26 ± 0.22 | 0.84 |
| Beta-cryptoxanthine (μg/ml) | 325 | 0.07 ± 0.05 | 452 | 0.08 ± 0.05 | 284 | 0.09 ± 0.06 | 1061 | 0.08 ± 0.06 | 0.62 |
| Lycopene (μg/ml) | 325 | 0.4 ± 0.22 | 452 | 0.36 ± 0.2 | 284 | 0.33 ± 0.21 | 1061 | 0.36 ± 0.21 | 0.65 |
| Lutein and zeaxanthin (μg/ml) | 325 | 0.19 ± 0.09 | 452 | 0.21 ± 0.1 | 284 | 0.22 ± 0.1 | 1061 | 0.21 ± 0.1 | 0.83 |
| Alpha-tocopherol (μg/ml) | 325 | 15.1 ± 5.7 | 452 | 17.2 ± 6.8 | 284 | 18.6 ± 7.4 | 1061 | 16.9 ± 6.7 | 0.81 |
| Gamma-tocopherol (μg/ml) | 325 | 1.4 ± 1.2 | 452 | 1.2 ± 0.9 | 284 | 1.2 ± 1 | 1061 | 1.3 ± 1 | 0.85 |
| Factor VII activity, antigen (%) | 309 | 126.2 ± 32.2 | 447 | 124.4 ± 29.7 | 273 | 121.1 ± 29.3 | 1029 | 123.7 ± 30.2 | 0.86 |
| Factor VIIC (%) | 299 | 121.5 ± 32 | 434 | 124.4 ± 29.1 | 268 | 122 ± 28.8 | 1001 | 122.6 ± 29.8 | 0.83 |
| Fibrinogen (mg/dl) | 309 | 286.7 ± 57.8 | 445 | 292.4 ± 55.5 | 274 | 298.5 ± 58.1 | 1028 | 292.1 ± 56.7 | 0.67 |
| Glucose (mg/dl) | 322 | 94.4 ± 19.2 | 452 | 93 ± 14.1 | 281 | 96.6 ± 18.8 | 1055 | 94.3 ± 17 | 0.83 |
| Insulin (μIU/ml) | 309 | 8.9 ± 4.6 | 428 | 8.5 ± 4 | 270 | 9.1 ± 4.6 | 1007 | 8.8 ± 4.3 | 0.71 |

[a]Means and standard deviations were computed on the log scale and back-transformed values are reported.
[b]Means and standard deviations are weighted by the overall CT & OS ethnic distribution.
[c]Intra-class correlation coefficient.

Pacific Islanders. Self-reported fracture at age 55 or older was twice as common in White (14.7%) compared with Black women (6.8%), with women of other races falling in between these rates. Hispanic women had the lowest rates of identifying a regular health care provider. Hispanic and American Indian women had the lowest rates of mammography within the past 2 years, or a PAP smear within the past 3 years, the highest prevalence of depression (23%), double the rate in Whites, and triple the rate in Asian/Pacific Islanders.

Systolic and diastolic blood pressures were greatest in Black women. The prevalence of treated hypertension in Blacks was 1.6 to 2.2 times greater than that of the other groups. American Indians were the most likely to have untreated hypertension. Black and American Indian women were more likely to have experienced a stroke or myocardial infarction. BMI was the lowest in Asian/Pacific Islanders and highest in Blacks; the mean BMI in all groups except Asian/Pacific Islanders was at least in the overweight range. The prevalence of diabetes was five times greater in American Indian, almost four times greater in Black and more than two times greater in Hispanic, than in White women.

Although White and American Indian women reported a previous diagnosis of cancer more often than women in the other ethnic groups, they did not have a striking excess of any specific type except melanoma. Black women had the highest rates of prior breast and colon cancers, while Asian/Pacific Islanders were the least likely to have had breast cancer.

Black women reported a relatively low total energy intake, but a high percent of energy from fat. White women reported low cholesterol consumption, and the highest consumption of energy, protein, carbohydrates, fiber, calcium, vitamin D, and fruit and vegetable servings.

### Measurement Precision Study

Reliability statistics are shown in the final columns of Tables 1, 2, and 4. There were no major differences by age or ethnicity (data not shown). Most demographic factors, reproductive variables, and family medical history were reliably reported, with kappa or weighted kappa above 0.8. Occupation, years lived in the current state of residence, passive smoking exposure, physical activity and induced abortion had reliability coefficients in the 0.6 to 0.8 range. Most of the self-reported medical conditions yielded kappa above 0.75, however self-report for some medical conditions was not reliable at this level. These conditions included stroke, congestive heart failure, carotid endarterectomy/angioplasty, peripheral arterial disease, deep venous thrombosis, depression, and bone fracture at or after age 55. Reported number of falls in the last 12 months also had low reproducibility (kappa = 0.45), but part of this poor reliability is probably due to the shift in the 1-year reference period

between the first and second administration of the questionnaire.

Most blood analytes were reliable with ICCs above 0.8. Blood measures with less reliable ICCs (between 0.6 and 0.8), included insulin, fibrinogen and several of the serum carotenoids. Limited dietary sources of some of the carotenoids (e.g., lycopene) may make their serum levels more variable over time than for other nutrients.

### Representative Relative Risks Demonstrable in Prospective Analyses

Applying conventional statistical assumptions of $\alpha = 0.05$ and $\beta = 0.80$, analyses in the entire OS population should allow demonstration of exposure:disease associations with a relative risk (RR) of 1.4 after 3 years, and well-below 1.25 after 6 years of follow-up for an exposure present in at least 10% of the population, e.g., hyperlipidemia, and a disease with an annual incidence of 5 per 1000, such as coronary heart disease (CHD) in women aged 70 to 74 years. An equivalent RR could be demonstrated after 3 years for an exposure present in at least 30% of the population, e.g. hypertension. For a less common disease with an annual incidence of 1 per 1000, e.g., breast cancer at ages 65 to 79 or CHD at ages 55 to 59, the detectable relative risks after 3, 6, and 9 years of follow-up for an exposure found in at least 30% of the population, e.g., high fat diet, are 1.5, 1.4 and 1.25, respectively.

At the other end of the spectrum, for analyses restricted to a sub-population of 6,000 participants, e.g., ethnic subgroups, demonstrable RRs at 3, 6, and 9 years for a risk factor with 10% exposure and a disease with 5/1000 annual incidence, are 2.75, 1.9, and 1.75, respectively. These estimates improve to 1.9, 1.65, and 1.4 if the exposure is present in 30% of the population. For a disease with 1/1000 annual incidence and a risk factor with 10% exposure, a RR of 3.2 is detectable at 9 years. If the exposure is present in 30% of the population, the detectable RR is 2.8 at 6 years and 2.5 after 9 years.

## DISCUSSION

The fraction of the US population comprised of ethnic minorities decreases with age and this is reflected in the composition of the WHI OS cohort. According to US Census data for women aged 50 to 59, 60 to 69, and 70 to 79 years, the fraction of Blacks declines from 11% to 10% to 8%, and the fraction of Hispanics from 7% to 6% to 4%, while the fraction of Whites increases from 78% to 81% to 85% (4). The trends in the OS are similar but the minority fractions are slightly lower in each decade. Overall, 81% of US women aged 50 to 79 years were White, and the fraction in the OS is similar at 83%. While the cohort overall is somewhat better educated than same aged women in the US, OS volunteers are less different from the US population in general than participants in other recent studies of postmenopausal women (5,6).

Women enrolled in the OS have some traits that result from the clinical trial exclusions. Although its benefit remains to be proven, postmenopausal hormone use was popular as a preventive intervention for coronary disease when women were recruited to the WHI, and few women who were taking hormones were willing to participate in a randomized trial of this treatment. Thus, more OS women were on hormones at baseline than clinical trial participants. Other studies have found that women who elected to take hormones generally had more favorable risk factor profiles and healthier lifestyles than women who did not, even before they began using hormones (7–9).

Similarly, potential participants were excluded from the dietary modification trial if their diets were already low in fat. If they did not join the PHT trial, women excluded from the DM trial for this reason were offered participation in the OS. Eating a low fat diet is a common healthy behavior that may overlap with other healthy life style traits. Thus, because of the selection process for both the dietary and hormone trials, the OS would be expected to have more women with healthy life styles than the clinical trial and this is indeed the case.

Consistent with other US population data (10), total family income declined with increasing age. Some of this effect may be attributable to the parallel increase in widowhood and living alone. It is also possible that there is a cohort effect due to inflation, since wages were lower when the oldest participant's households were employed, which could influence the current value of savings. In census data from 1990 that were unselected for gender, the prevalence of total family income <$15,000 rose steeply from 5% to 37% as householder age went from between 45 and 54 years to between 65 and 74 years. Corresponding rates for income >$50,000 were 40% and 13% (10).

The trends in parity by age may be attributable to the social and economic trends during the reproductive years for these women. The oldest participants were in their childbearing years during World War II and the post-war baby boom, while the younger participants came of age when women were increasingly involved in the workplace. Oral contraceptives became available near the end of the reproductive years for the oldest women, but were an option throughout the reproductive years for the youngest.

As expected, the prevalence of hypertension increased with age in parallel with the age-related increases in systolic blood pressure. Yet, OS women may be healthier than the population from which they were drawn. For example, among NHANES-III women aged 50 to 79 years, 48%

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were hypertensive, 7% reported a history of physician-diagnosed heart attack, and 5% reported a physician-diagnosed stroke (11). Equivalent rates in the OS were 34%, 3%, and 2%. Thus, the prevalence of coronary disease and stroke was only about half that expected using NHANES-III estimates. The fraction of current smokers in the OS, at 6%, is one-third the 18% rate in NHANES-III. This may be related to a healthy volunteer effect.

The frequency of engaging in some form of exercise did not decline by age in the OS sample. Similar findings have been reported for women aged 50 to 79 years in the NHANES-III population (12). However, BMI declined and waist/hip ratio increased with age. It is not clear whether these differences are meaningful in terms of body-weight–associated disease risks. They may also represent changes in body habitus resulting from age-related changes in height and girth, including those related to osteoporosis. A similar trend for declining BMI with age has been reported in NHANES-III (13).

Yet, despite their generally healthy risk factor profiles and lower self-reported prevalence of cardiovascular disease, cancer prevalence in the OS group was higher than population estimates. Compared with the NHANES-III cohort, slightly greater proportions of the OS cohort reported having had a cancer other than skin cancer. Similarly, estimated prevalence rates of invasive cancer computed from the Connecticut SEER registry (personal communication), weighted to the age distribution of the OS women, are 30% to 70% lower for breast, colorectal, and endometrial cancer, and two to three times lower for melanoma or cervical cancer. The excess rates in the OS may be explained by the likelihood that cancer survivors were motivated to join the WHI but were excluded from the clinical trial. The three-fold excess of melanoma and cervical cancer reported by WHI women may reflect in-situ disease that would not appear in SEER, or confusion of non-melanoma skin cancers with melanoma and cervical dysplasia with cancer in self-report. Conversely, the rates of melanoma may be lower in Connecticut where the degree of sun exposure is less than in the US as a whole.

Hip fracture incidence rates have been reported in other populations from hospital discharge data. They increase exponentially with age in White women (1.63/1000 in 65-year-olds to 35.4/1000 in 95-year-olds) and less than exponentially with age in Black women (14). These data are consistent with the WHI finding of increased prevalence with age. The WHI ethnic differences in hip fracture are consistent with those reported elsewhere (14–16).

OS Black women had the highest prevalence of hysterectomy overall, and hysterectomy before age 40. In contrast, recent data from the National Hospital Discharge Survey (NHDS) do not show a difference by race in annual rates of hysterectomy (17), suggesting that this discrepancy may reflect past rather than current practice. Also, the NHDS diagnosis most often associated with hysterectomy was leiomyoma (fibroids) which was twice as common in Black compared with White women (17). Symptomatic fibroids may influence these differences since other published data show that Black women undergo hysterectomy for fibroids at an earlier age than White women (18). OS Black women were twice as likely as other participants to have never had a term pregnancy, suggesting an increase in both premature births and abortions. This is consistent with data showing an increased risk of prematurity among Black women (19). The higher rates of tubal ligation in OS Hispanic and Black women is consistent with the increased parity and abortion rates that we observed in these groups. Differences in the rates of breastfeeding may relate to cultural differences in the acceptability of this practice.

The prevalence of depression was greater in younger women despite the greater likelihood that older women are widowed or living alone. This observation may be partly explained by the greater contribution of minority women to the younger age group since Hispanic and American Indian women had a particularly high prevalence of depression. It is also possible that the scale measures stress more than depression (20) and that younger women are more stressed due to competing roles.

The Measurement Precision Study found that most risk factors were reliably reported, similar to findings by others (21). It also confirmed the reliability of most health conditions that will be followed in the OS. Notable exceptions were found for major cardiovascular endpoints, depression, and bone fracture at age 55 or older. Notwithstanding the lower reliability of self-report for specific prevalent diseases, incident events resulting in hospitalization for these conditions will be validated by medical record review. The reliability of most blood analytes was excellent, although insulin, fibrinogen, and carotenoids were less reliable than other measures. These reliability coefficients reflect the measurement error of using a single measure at one point in time, including the errors due to specimen handling, laboratory error and "within-subject" variation over a 3-month period but not long-term variability.

While a longitudinal study that depends on volunteers cannot be fully representative of the population from which it is drawn, the WHI OS includes a greater number of minority and economically disadvantaged women than have previously participated in any comparable study. The differences between ethnic groups, particularly the contrasts between Hispanic women and the other ethnic groups with regard to education, family income and reproductive history are striking, as are the contrasts between Black women and the other ethnic groups in cardiovascular risk and factors that lead to living alone.

The WHI OS, with its large sample size overall, minority representation comparable to US population levels by age, long duration, and large variety of exposure and outcome variables measured over time, offers unusual opportunities to study predictors of both common and uncommon health outcomes in postmenopausal US women.

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