

05/03/2011

W58 - CVD Biomarkers in Non-minority HT Participants

	N
All HT White participants	22,030
Exclude if not eligible for dbGap	-1,559
Exclude if missing hx of disease	-9
Exclude if inadequate serum (< 250 µl)	-906
Remaining	19,604

Among 19,604:

Number in WHIMS	5,795	
Number in M13 (GARNET)	4,201	
In M13 and not WHIMS	2,871	(1738 < age 65 at screening of which 870 are cases and 868 are controls)

M13 matching factors were age, race/ethnicity, hysterectomy status and enrollment date; history of disease added as additional factor for W58.

Part A. Age < 65 at screening

All HT, E-alone cohort, n=3550 (35%)

All HT, E+P cohort, n=6683 (65%)

Selection target is a sample size of 2000, where 35% are from E-alone (n=700) and 65% from E+P (n=1300).

Step 0: include all M13 controls

Step 1: add randomly selected M13 cases within each stratum so that total number (controls+cases) in stratum is representative of the respective strata

Step2: add additional participants randomly selected from those not already picked so that distribution across strata matches that of entire group of 3550 E-alone and 6683 E+P participants

E-alone cohort (without uterus at baseline) - Distribution of matching factors

Matching Factors			M13 Controls (n=436)		M13 Cases (n=456)		All HT (n=3,550)	
Year of enrollment	Hx Disease at baseline (MI, stroke, VT, or diabetes)	Age at screening	N	%	N	%	N	%
≤ 1996	No	50-54	60	13.8	57	12.5	596	16.8
≤ 1996	No	55-59	77	17.7	86	18.9	664	18.7
≤ 1996	No	60-64	105	24.1	117	25.7	717	20.2
≤ 1996	Yes	50-54	2	0.5	5	1.1	38	1.1
≤ 1996	Yes	55-59	7	1.6	10	2.2	63	1.8
≤ 1996	Yes	60-64	6	1.4	13	2.9	79	2.2
> 1996	No	50-54	17	3.9	22	4.8	133	3.8
> 1996	No	55-59	48	11.0	34	7.5	391	11.0
> 1996	No	60-64	105	24.1	87	19.1	740	20.9
> 1996	Yes	50-54	1	0.2	1	0.2	4	0.1
> 1996	Yes	55-59	2	0.5	4	0.9	39	1.1
> 1996	Yes	60-64	6	1.4	20	4.4	86	2.4

E+P cohort (with uterus at baseline)

Matching Factors			M13 Controls (n=448)		M13 Cases (n=428)		All HT (n=6,683)	
Year of enrollment	Hx Disease at baseline (MI, stroke, VT, or diabetes)	Age at screening	N	%	N	%	N	%
≤ 1996	No	50-54	55	12.3	45	10.5	1009	15.1
≤ 1996	No	55-59	105	23.4	93	21.7	1439	21.5
≤ 1996	No	60-64	117	26.1	119	27.8	1362	20.4
≤ 1996	Yes	50-54	2	0.5	7	1.6	51	0.8
≤ 1996	Yes	55-59	3	0.7	10	2.3	63	0.9
≤ 1996	Yes	60-64	6	1.3	8	1.9	84	1.3
> 1996	No	50-54	13	2.9	13	3.0	280	4.2
> 1996	No	55-59	62	13.8	42	9.8	928	13.9
> 1996	No	60-64	81	18.1	75	17.5	1330	19.9
> 1996	Yes	50-54	0	0	0	0	7	0.1
> 1996	Yes	55-59	0	0	5	1.2	39	0.6
> 1996	Yes	60-64	4	0.9	11	2.6	91	1.4

Age < 65 at screening

Final selection,

**E-alone
(35% of 2000)**

**E+P
(65% of 2000)**

Number of M13 controls =	436	448
Number of M13 cases =	86	85
Number of non-M13 participants =	179	767
Total	701*	1300*

* 11 E-alone and 23 E+P participants are in WHIMS because they used age at randomization instead of age at screening to select participants

By Strata:

Matching Factors			E-alone (n=701)		E+P (n=1300)	
Year of enrollment	Hx Disease at baseline (MI, stroke, VT, or diabetes)	Age at screening	N	%	N	%
≤ 1996	No	50-54	118	16.8	196	15.1
≤ 1996	No	55-59	131	18.7	280	21.5
≤ 1996	No	60-64	141	20.1	265	20.4
≤ 1996	Yes	50-54	7	1.0	10	0.8
≤ 1996	Yes	55-59	12	1.7	12	0.9
≤ 1996	Yes	60-64	16	2.3	16	1.2
> 1996	No	50-54	26	3.7	54	4.2
> 1996	No	55-59	77	11.0	181	13.9
> 1996	No	60-64	146	20.8	259	19.9
> 1996	Yes	50-54	2	0.3	1	0.1
> 1996	Yes	55-59	8	1.1	8	0.6
> 1996	Yes	60-64	17	2.4	18	1.4

Part B. Age ≥ 65 at screening, Not enrolled in WHIMS

All HT, E-alone cohort, n=1431 (39%)

All HT, E+P cohort, n=2276 (61%)

Selection target sample size of 1000, where 39% are from E-alone and 61% from E+P.

Step 0: include all M13 controls

Step 1: add randomly selected M13 cases within each stratum so that total number (controls+cases) in stratum is representative of the respective strata

Step2: if number in target stratum is greater than number selected in Step 1, randomly select from those not already picked, or if number in target stratum is less than number selected in Step 1, randomly select sample of target size from those selected in Step 1, so that distribution across strata matches that of entire group of E-alone or E+P participants

E-alone cohort (without uterus at baseline)

Matching Factors			M13 Controls (n=291), not in WHIMS		M13 Cases (n=276), not in WHIMS		All HT (n=1,431), not in WHIMS	
Year of enrollment	Hx Disease at baseline (MI, stroke, VT, or diabetes)	Age at screening	N	%	N	%	N	%
≤ 1996	No	65-69	123	42.3	91	33.0	565	39.5
≤ 1996	No	70-74	95	32.7	90	32.6	406	28.4
≤ 1996	No	75-79	32	11.0	25	9.1	156	10.9
≤ 1996	Yes	65-69	7	2.4	18	6.5	79	5.5
≤ 1996	Yes	70-74	12	4.1	19	6.9	73	5.1
≤ 1996	Yes	75-79	2	0.7	5	1.8	30	2.1
> 1996	No	65-69	7	2.4	8	2.9	40	2.8
> 1996	No	70-74	10	3.4	9	3.3	46	3.2
> 1996	No	75-79	3	1.0	2	0.7	14	1.0
> 1996	Yes	65-69	0	0	2	0.7	10	0.7
> 1996	Yes	70-74	0	0	5	1.8	9	0.6
> 1996	Yes	75-79	0	0	2	0.7	3	0.2

E+P cohort (with uterus at baseline)

Matching Factors			M13 Controls (n=277), not in WHIMS		M13 Cases (n=289), not in WHIMS		All HT (n=2,276), not in WHIMS	
Year of enrollment	Hx Disease at baseline (MI, stroke, VT, or diabetes)	Age at screening	N	%	N	%	N	%
≤ 1996	No	65-69	125	45.1	101	35.0	1045	45.9
≤ 1996	No	70-74	75	27.1	76	26.3	617	27.1
≤ 1996	No	75-79	35	12.6	46	15.9	243	10.7
≤ 1996	Yes	65-69	8	2.9	20	6.9	84	3.7
≤ 1996	Yes	70-74	6	2.2	13	4.5	66	2.9
≤ 1996	Yes	75-79	1	0.4	7	2.4	19	0.8
> 1996	No	65-69	14	5.1	11	3.8	85	3.7
> 1996	No	70-74	10	3.6	7	2.4	67	2.9
> 1996	No	75-79	3	1.1	5	1.7	35	1.5
> 1996	Yes	65-69	0	0	2	0.7	8	0.4
> 1996	Yes	70-74	0	0	1	0.4	7	0.3
> 1996	Yes	75-79	0	0	0	0	0	0

Age ≥ 65 at screening, Not enrolled in WHIMS

Final selection,

**E-alone
(31% of target N)**

**E+P
(61% of target N)**

Target N=1000

Number of M13 controls =	288	277
Number of M13 cases =	63	74
Number of non-M13 participants =	41	259
Total	392	610

Matching Factors			E-alone (n=392)		E+P (n=610)	
Year of enrollment	Hx Disease at baseline (MI, stroke, VT, or diabetes)	Age at screening	N	%	N	%
≤ 1996	No	50-54	154	39.3	280	45.9
≤ 1996	No	55-59	111	28.3	165	27.1
≤ 1996	No	60-64	43	11.0	65	10.7
≤ 1996	Yes	50-54	22	5.6	23	3.8
≤ 1996	Yes	55-59	20	5.1	18	3.0
≤ 1996	Yes	60-64	8	2.0	5	0.8
> 1996	No	50-54	11	2.8	23	3.8
> 1996	No	55-59	13	3.3	18	3.0
> 1996	No	60-64	4	1.0	9	1.5
> 1996	Yes	50-54	3	0.8	2	0.3
> 1996	Yes	55-59	2	0.5	2	0.3
> 1996	Yes	60-64	1	0.3	0	0