Evaluation of the American Heart Association Cardiovascular Disease Prevention Guideline for Women

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Background—The 2007 update to the American Heart Association (AHA) guidelines for cardiovascular disease prevention in women recommend a simplified approach to risk stratification. We assigned Women's Health Initiative participants to risk categories as described in the guideline and evaluated clinical event rates within and between strata.

Methods and Results—The Women's Health Initiative enrolled 161 808 women ages 50 to 79 years and followed them prospectively for 7.8 years (mean). Applying the 2007 AHA guideline categories, 11% of women were high risk, 72% at-risk, and 4% at optimal risk; 13% of women did not fall into any category, that is, lacked risk factors but did not adhere to a healthy lifestyle (moderate intensity exercise for 30 minute most days and <7% of calories from saturated fat). Among high risk, at-risk, and optimal risk women, rates of myocardial infarction/coronary death were 12.5%, 3.1%, and 1.1% per 10 years (P for trend <0.0001); the event rate was 1.3% among women who could not be categorized. We observed a graded relationship between risk category and cardiovascular event rates for white, black, Hispanic, and Asian women, although event rates differed among ethnic groups (P for interaction=0.002). The AHA guideline predicted coronary events with accuracy similar to current Framingham risk categories (area under receiver operating characteristic curve for Framingham risk, 0.665; for AHA risk, 0.664; P=0.94) but less well than proposed Framingham 10-year risk categories of <5%, 5% to 20%, and >20% (area under receiver operating characteristic curve for Framingham risk, 0.724; for AHA risk, 0.664; P<0.0001).

Conclusions—Risk stratification as proposed in the 2007 AHA guideline is simple, accessible to patients and providers, and identifies cardiovascular risk with accuracy similar to that of the current Framingham algorithm.

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Global risk stratification in the National Cholesterol Education Program Adult Treatment Panel III[1,2] is underpinned by the Framingham algorithm,[3] which has a number of limitations[4–6] and is underutilized by practitioners.[7,8] The 2007 update to the American Heart Association (AHA) Evidence-Based Guidelines for Cardiovascular Disease Prevention in Women[9] recommended a new risk stratification scheme, categorizing women as high-risk, at-risk, or optimal risk (Table 1). The guideline was endorsed by professional organizations representing primary care and specialty providers, women's health advocacy groups, the Centers for Disease Control and Prevention, and the National Heart, Lung, and Blood Institute, but the predictive accuracy of this approach to risk stratification has not been confirmed.

The Women's Health Initiative (WHI) is a large, diverse cohort followed prospectively for 7.8 years for cardiovascular events. To evaluate the new risk stratification scheme, we categorized WHI participants as described in the 2007 AHA guideline and assessed their cardiovascular event rates.

Methods

Study Population

The WHI includes 161 808 postmenopausal women, ages 50 to 79 years at baseline, enrolled at 40 clinical sites from 1993 to 1998 into 4 randomized trials and an observational study.[10] Recruitment and baseline data collection have been previously reported.[11–14] In brief, eligible women had anticipated longevity of at least 3 years and were likely to be residing in the same geographic area for at least 3 years. Women joining the dietary modification trial consumed an average American diet and had no history of breast or colon cancer[12]; those joining the hormone trials had no history of breast cancer or other cancers within the preceding 10 years.[13] Calcium/vitamin D trial

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WHAT IS KNOWN

- The 2007 American Heart Association guidelines for cardiovascular disease prevention in women recommended categorizing women as high risk, at-risk, or optimal risk on the basis of prevalent medical conditions, conventional coronary risk factors, diet, and physical activity.

WHAT THE STUDY ADDS

- In the Women's Health Initiative, a large, diverse cohort of postmenopausal women, prediction of cardiovascular risk by the American Heart Association guidelines did not differ from Adult Treatment Panel III modified Framingham categories of <10%, 10% to 20% and >20%, but the American Heart Association guidelines were less accurate than the Framingham categories of <5%, 5% to 20% and >20 ($P<0.0001$).
- Whether the American Heart Association guidelines will be used by practitioners and whether its use would improve clinical decision-making and patient outcomes remain to be demonstrated.

participants were a subset of women in the diet and hormone trials.[10] The protocol and consent forms were approved by institutional review boards of the participating institutions; all trial participants provided written informed consent.

Variables

Women reporting prior myocardial infarction (MI) or coronary revascularization were considered to have established coronary disease and those with prior stroke to have established cerebrovascular disease. Women reporting carotid or peripheral arterial revascularization were considered to have established peripheral arterial disease. Diabetes mellitus requiring dietary or pharmacological therapy (excluding gestational diabetes), high cholesterol requiring drug treatment, family history of coronary disease (male first-degree relative with MI before age 55 or female relative before age 65), and cigarette smoking were assessed by self-report at baseline. Hypertension included both measured high blood pressure and self-reported high blood pressure requiring pills. If a woman had missing data for a given risk characteristic, she would be classified on the basis of other reported factors; in their absence, she would be considered to have no risk factors. Lipid profiles and fasting glucose levels were not available for most women, so for this analysis, body mass index $\geq$30 kg/m^2 with waist circumference >35 inches was used as a surrogate for the metabolic syndrome.[15,16]

The AHA guideline includes several criteria that are not explicitly defined. For this analysis, poor exercise capacity was identified by self-report of being limited "a lot" in climbing multiple flights of stairs or walking several blocks. Total physical activity was assessed by questions on a frequency and duration scale for walking and other types of activity.[17] We defined physical inactivity as the lowest quintile, <1.25 metabolic equivalent (MET)-hours/week. For the optimal risk category, we defined the physical activity component of a healthy lifestyle as $\geq$10 MET-hours/week, which approximates 30 minutes of walking, 6 days per week, consistent with the physical activity component of healthy lifestyle as described in the 2007 AHA guideline.

We assessed dietary nutrient consumption by food frequency questionnaire.[18] The AHA guideline considers women consuming a "poor diet" as at risk for cardiovascular disease without an explicit definition. For this analysis, we defined poor diet as consuming >10% of calories from saturated fat. For a healthy diet, the guideline recommends a diet rich in fruits and vegetables, whole-grain, high-fiber foods, fish at least twice weekly, saturated fat <10% of energy, and if possible, <7%, cholesterol <300 mg/day, alcohol <1 drink/day, sodium <2.3 g/day, and trans fat <1% of energy. In view of (1) the limited dietary assessment likely to be available to practitioners using this guideline and (2) the fact that very low saturated fat consumption (<6.1% of calories) was required to demonstrate cardiovascular event reduction in the dietary modification trial,[19] we elected to use the AHA guideline saturated fat criterion (<7% of total calories) as shorthand for a healthy diet. In prior analyses, WHI participants adhering to saturated fat restrictions generally met recommendations for fruit and vegetable and dietary cholesterol consumption.[20]

Table 1. Risk Categories in 2007 AHA Cardiovascular Prevention Guidelines for Women

Risk Category	Risk Characteristic
High risk	Established cardiovascular disease
	Diabetes mellitus
	End-stage or chronic renal disease
	10-y Framingham global risk >20%
At risk	>1 major risk factor of cardiovascular disease including
	Cigarette smoking
	Poor diet
	Physical inactivity
	Obesity, especially central adiposity
	Family history of premature cardiovascular disease (<55 y in male relative or <65 y in female relative)
	Hypertension
	Dyslipidemia
	Evidence of subclinical vascular disease
	Metabolic syndrome
	Poor exercise capacity on treadmill test and/or abnormal heart rate recovery after stopping exercise
Optimal risk	Framingham global risk <10% and a healthy lifestyle with no risk factors

Framingham Algorithm

The Framingham algorithm at baseline was calculated in the random subsample of women with fasting lipid profiles: 1% of observational study, 8.6% of hormone trial, and 4.3% of dietary modification trial participants, oversampled for minority women. High-sensitivity C-reactive protein was not measured in these samples. The Framingham algorithm assigns points for each of the following factors: age, total and high density lipoprotein cholesterol levels, systolic blood pressure, treatment for hypertension, and current cigarette smoking.[1] Each calculated point total is assigned a corresponding 10-year risk for MI/coronary heart disease (CHD) death. The high-risk category includes those with 10-year risk >20%, prior MI, stroke coronary revascularization procedure, or diabetes mellitus.

Outcomes Ascertainment

Participants reported emergency room visits, overnight hospital stays, and outpatient coronary revascularization procedures at least annually. Medical records for all deaths, overnight hospitalizations, and outpatient coronary revascularization procedures were scrutinized for potential outcomes of interest. Centrally trained physician adjudicators classified outcomes on the basis of medical record review. MI was categorized using an algorithm that included symptoms, ECG findings, and cardiac enzymes.[21] Stroke required

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rapid onset of a persistent neurological deficit not due to trauma, tumor, infection, or other cause.[22]

Statistical Analysis

Differences in baseline characteristics across risk strata were evaluated with ANOVA F tests for continuous covariates and χ^2 tests for categorical covariates. Annualized event rates were compared across subgroups using likelihood ratio testing from generalized linear models with a Poisson distribution and log-link function. Hazard ratios, 95% confidence intervals, and associated probability values were from Cox proportional hazards models. Areas under receiver operating characteristic curves (AUCs) were computed using logistic regression. Curves were compared using nonparametric methods for correlated AUCs.[23] Analyses were performed using SAS for Windows version 9 (SAS Institute, Cary, NC) and R version 2.7.2 (R Foundation for Statistical Computing). The authors had full access to the data and take responsibility for its integrity. All authors have read and agree to the manuscript as written.

Results

The cohort included 161 808 women ages 50 to 79 years at study entry, with follow up of 7.8±1.6 years (mean±standard deviation). High risk, at-risk, and optimal risk women constituted 11%, 72%, and 4% of the cohort, respectively. A considerable proportion of women (13%) did not fall into any category, that is, they lacked risk factors but did not adhere to a healthy lifestyle. The uncategorized women consumed 7% to 10% of calories in the form of saturated fat and performed 1.25 to <10 MET-hours/week of physical activity, thus meeting neither our definition of "poor diet" (>10% of calories from saturated fat) nor physical inactivity (<1.25 MET-hours/week), either of which would have placed them in the at-risk category. Neither did they meet our definition of healthy lifestyle (not smoking, <7% of calories from saturated fat, and ≥10 MET-hours/week of physical activity), which would have qualified them for the optimal risk category.

The number and percentage of women with each risk characteristic are shown in descending order of frequency within each risk stratum (Table 2). Among women in the high-risk category, self-reported diabetes mellitus was the most common qualifying characteristic (6%), followed by prevalent CHD (3%). Among women in the at-risk category, "poor diet," defined in this analysis as >10% of calories from saturated fat, was the most common characteristic (43%), followed by hypertension (26%) and obesity (25%).

Among high-risk women, the rate of MI/CHD death ranged from 12.3% to 20.3%/10 years. Women with at-risk characteristics had coronary event rates ranging from 3.0% to 5.4%/10 years, whereas optimal risk women had the lowest coronary event rate, 1.1%/10 years. The event rate among women who could not be categorized was similar to that of optimal risk women (1.3%/10 years). Clinical event rates for individual risk characteristics did not overlap between categories.

Selected baseline characteristics are shown by risk category (Table 3). Age and ethnicity differed between risk categories (P<0.0001 for each); women in lower-risk categories were younger and more likely to be white or Asian.

The number of cardiovascular events and annualized event rate are shown by risk category (Table 4). Among women in the high-risk category, the rate of MI/CHD death was 12.5%/10 years and of MI/CHD death/stroke was 19.0%/10 years. In contrast, these events occurred at ≈1/10th that frequency among optimal risk women, whereas at-risk women had intermediate event rates (P for trend <0.0001 across risk strata). Women who did not fall into any risk category had event rates similar to the optimal risk group.

Table 2. No. (%) of Women Meeting Each Risk Criterion, Assessed at Baseline, and 10-Year Event Rate

	n (% of Cohort)	MI/CHD Death, n (%/10 y)	MI/CHD Death/Stroke, n (%/10 y)
High risk			
Diabetes mellitus	9618 (5.9)	871 (12.7)	1273 (18.9)
Prior MI or coronary revascularization	5060 (3.2)	705 (20.3)	943 (27.8)
Established peripheral arterial disease	3270 (2.0)	313 (13.6)	458 (20.2)
Prior stroke	2165 (1.3)	187 (12.3)	363 (24.8)
Aortic aneurysm	301 (0.2)	40 (19.5)	57 (28.7)
At risk			
Poor diet	69 627 (43.0)	1605 (3.0%)	2864 (5.4%)
Hypertension	41 926 (25.9)	1414 (4.5%)	2521 (8.1%)
Body mass index ≥30 kg/m^2	40 071 (24.8)	1020 (3.3%)	1754 (5.7%)
Body mass index ≥30 kg/m^2 with waist >35 in	35 115 (21.7)	936 (3.5%)	1600 (6.0%)
Physical inactivity	25 572 (15.8)	659 (3.4%)	1167 (6.1%)
Family history of premature MI	23 905 (14.8)	692 (3.8%)	1180 (6.5%)
Dyslipidemia	16 949 (10.5)	515 (4.1%)	854 (6.8%)
Poor exercise capacity	15 557 (9.6)	624 (5.4%)	1079 (9.5%)
Current smoker	9683 (6.0)	334 (4.5%)	558 (7.7%)
Optimal risk	6784 (4.2)	59 (1.1%)	119 (2.2%)
Not in any category	20 820 (12.9)	217 (1.3%)	441 (2.6%)

Women were assigned to the highest risk category for which they qualified. A woman with diabetes and prior stroke would be counted in both rows.

Cardiovascular event rates were examined among women from different ethnic groups by risk category (Table 5). The numbers of events in the low-risk categories are small for ethnic minority women. A graded increase in event rate across risk groups was consistently observed in all ethnic groups, although the absolute event rates differed between groups (P for interaction=0.002). For each risk category, event rates were higher among white and black women compared with Hispanic or Asian women.

In a random subsample of women with measured lipids at baseline, the numbers of women with and without MI/CHD death are shown by risk category for the 2007 AHA guideline and Framingham algorithm (Figure). Mean calculated Framingham 10-year risk was 2% for the entire subsample, with 80%, 6% and 14% in the low-, intermediate-, and high-risk categories, respectively (including assignment to the high-risk group on the basis of clinical characteristics). Among women in the AHA at-risk category, Framingham 10-year risk was <10% for 3640 (92%) and 10% to 20% for 322 (8%). AUC for prediction of CHD events was no different for

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Table 3. Baseline Characteristics by AHA Risk Category

	High Risk		At Risk		Optimal Risk		Not in Any Category		
	n	Mean (SD) or %	N	Mean (SD) or %	n	Mean (SD) or %	n	Mean (SD) or %	*P* Value
Age at screening, y	17 578	65.5 (7.1)	116 626	63.1 (7.2)	6784	62.0 (7.2)	20 820	62.2 (7.2)	<0.0001
50–59	3772	21.5	39 013	33.5	2669	39.3	8104	38.9	
60–69	8216	46.7	52 517	45.0	2945	43.4	8908	42.8	
70–79	5590	31.8	25 096	21.5	1170	17.2	3808	18.3	
Body mass index, kg/m^2	17 409	30.5 (6.7)	115 630	28.5 (6.0)	6713	23.7 (2.8)	20 611	24.4 (2.8)	<0.0001
<25	3635	20.9	36 157	31.3	4536	67.6	12 003	58.2	
25 to <30	5481	31.5	39 402	34.1	2177	32.4	8608	41.8	
≥30	8293	47.6	40 071	34.7	0	0.0	0	0.0	
Waist circumference, inches	17 514	93.9 (15.2)	116 205	87.5 (13.6)	6764	76.2 (8.3)	20 744	78.1 (8.6)	<0.0001
≤35	6806	38.9	66 987	57.6	6280	92.8	18 513	89.2	
>35	10 708	61.1	49 218	42.4	484	7.2	2231	10.8	
Physical activity quintiles	16 890	10.0 (12.3)	111 848	11.2 (13.0)	6784	26.8 (15.9)	18 818	16.6 (14.4)	<0.0001
<1.25 (MET-h/wk)	4147	24.6	25 572	22.9	0	0.0	0	0.0	
1.25 to <5.5	4011	23.7	23 688	21.2	0	0.0	4022	21.4	
5.5 to <11.6	3376	20.0	21 952	19.6	542	8.0	4887	26.0	
11.63 to <21.0	2804	16.6	20 612	18.4	2492	36.7	4483	23.8	
≥21.0	2552	15.1	20 024	17.9	3750	55.3	5426	28.8	
Ethnicity									<0.0001
White	12 696	72.2	96 547	82.8	6024	88.8	18 266	87.7	
Black	3016	17.2	10 594	9.1	222	3.3	795	3.8	
Hispanic	919	5.2	4705	4.0	181	2.7	707	3.4	
American Indian	171	1.0	480	0.4	15	0.2	49	0.2	
Asian/Pacific Islander	479	2.7	2707	2.3	262	3.9	744	3.6	
Unknown	297	1.7	1593	1.4	80	1.2	259	1.2	
% of calories from saturated fat	16 763	10.5 (3.4)	113 741	10.8 (3.3)	6784	5.6 (1.1)	19 771	8.1 (1.4)	<0.0001
<7	2513	15.0	14 868	13.1	0	0.0	3121	15.8	
7–10	5199	31.0	29 246	25.7	0	0.0	16 650	84.2	
>10	9051	54.0	69 627	61.2	0	0.0	0	0.0	

P value is from ANOVA for continuous variables (age, body mass index, waist circumference, physical activity, calories from saturated fat), or χ^2 test for categorical variables.

the 2 approaches to risk stratification (P=0.94). We also considered Framingham categories of <5%, 5% to 20%, and >20% (Figure 1). Among women in the AHA at-risk category, Framingham risk was <5% for 3695 (68%) and 5% to 20% for 1267 (32%). These modified Framingham categories more accurately predicted CHD events; AUC was 0.724 for the Framingham algorithm compared with 0.664 for the AHA guideline (P<0.0001).

Table 4. No. and Percent (per 10 Years) of Women With Cardiovascular Events by AHA Risk Category

	High Risk		At Risk		Optimal Risk		Not in Any Category	
	n (%/10 y)	HR (95% CI)	n (%/10 y)	HR (95% CI)	n (%/10 y)	HR	n (%/10 y)	HR (95% CI)
MI	1141 (9.1)	10.58 (7.90–14.16)	2224 (2.5)	2.86 (2.14–3.81)	47 (0.9)	1.00	178 (1.1)	1.21 (0.88–1.67)
CHD death	631 (4.9)	19.46 (11.46–33.05)	747 (0.8)	3.20 (1.89–5.44)	14 (0.3)	1.00	52 (0.3)	1.16 (0.64–2.09)
Stroke	936 (7.4)	6.44 (4.99–8.31)	2366 (2.6)	2.26 (1.76–2.90)	63 (1.2)	1.00	235 (1.4)	1.19 (0.90–1.57)
Hospitalized angina	1902 (15.7)	12.19 (9.59–15.50)	3011 (3.4)	2.62 (2.06–3.33)	69 (1.3)	1.00	267 (1.6)	1.24 (0.95–1.62)
MI/CHD death	1568 (12.5)	11.63 (8.97–15.09)	2749 (3.1)	2.81 (2.17–3.64)	59 (1.1)	1.00	217 (1.3)	1.17 (0.88–1.56)
MI/CHD death/stroke	2342 (19.0)	8.76 (7.29–10.54)	4922 (5.5)	2.51 (2.09–3.01)	119 (2.2)	1.00	441 (2.6)	1.18 (0.96–1.45)
MI/CHD death/angina	3204 (27.2)	11.76 (9.83–14.06)	5575 (6.3)	2.70 (2.26–3.23)	125 (2.3)	1.00	473 (2.8)	1.21 (0.99–1.47)
MI/CHD death/stroke/angina	3868 (33.4)	9.78 (8.44–11.33)	7642 (8.7)	2.52 (2.17–2.91)	185 (3.5)	1.00	688 (4.1)	1.19 (1.01–1.40)

HRs are from Cox proportional hazards analyses, where the "Optimal" group is the referent for risk category. *P* value for each individual or composite event was <0.0001. This was the case whether "Not in any category" women were omitted, combined with "Optimal" or with "At risk" women or included as a separate category. HR indicates hazard ratio.

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Table 5. No. of Cardiovascular Events and 10-Year Event Rate by Ethnicity and AHA Risk Category

	N (%/10 Years)			
	High Risk	At Risk	Optimal Risk	Not in Any Category
White	3011 (36.0%)	6498 (8.9%)	172 (3.6%)	637 (4.4%)
Black	581 (29.1%)	694 (8.9%)	7 (4.0%)	17 (2.7%)
Hispanic	115 (18.9%)	185 (5.5%)	3 (2.2%)	15 (2.8%)
Asian	71 (22.3%)	121 (6.1%)	2 (1.0%)	12 (2.1%)

Cardiovascular events included MI/coronary death/stroke/hospitalized angina. *P* value from a likelihood ratio test examining the interaction of ethnicity with risk category=0.002; result was the same when "Not in any category" women were combined with "Optimal" or with "At risk" women or when "Not in any category" women were excluded.

	Framingham 10-year risk			
	<10%	10-20%	>20%*	Total
2007 AHA risk category				
High risk	0 / 0	0 / 0	69 / 659	69 / 659
At risk	81 / 3559	17 / 305	0 / 0	98 / 3864
Optimal risk	0 / 133	0 / 4	0 / 0	0 / 137
Not in any category	4 / 547	1 / 8	0 / 0	5 / 555
Total	85 / 4239	18 / 317	69 / 659	172 / 5215
	Framingham 10-year risk			
	<5%	5-20%	>20%*	Total
2007 AHA risk category				
High risk	0 / 0	0 / 0	69 / 659	69 / 659
At risk	37 / 2658	61 / 1206	0 / 0	98 / 3864
Optimal risk	0 / 121	0 / 16	0 / 0	0 / 137
Not in any category	3 / 492	2 / 63	0 / 0	5 / 555
Total	40 / 3271	63 / 1285	69 / 659	172 / 5215

Figure. Numbers of women in 2007 AHA guideline and Framingham risk categories with and without MI/CHD death. Each cell includes the number of MI/CHD death cases (white background) and noncases (shaded background). Analyses include only the subsample with measured lipids. Upper panel shows Framingham risk categories of <10%, 10% to 20%, and >20%. For Framingham 10-year risk, AUC=0.665; for AHA risk, AUC=0.664 (*P*=0.94 versus Framingham). Lower panel shows Framingham risk categories of <5%, 5% to 20%, and >20%. For Framingham 10-year risk, AUC=0.724; for AHA risk, AUC=0.664 (*P*<0.0001 versus Framingham). *CHD or equivalent, including Framingham risk score >20%.

Discussion

We classified a large, diverse cohort into optimal, at-risk, and high-risk categories as proposed in the 2007 update of the Evidence-Based Guidelines for Cardiovascular Disease Prevention in Women. Most women were at risk, but a significant proportion (13%) could not be categorized. Incident cardiovascular events increased across risk strata (*P* for trend <0.0001); this relationship was apparent among white, black, Asian, and Hispanic women, although absolute event rates varied among ethnic groups (*P* for interaction=0.002). Event rates did not overlap for individual characteristics defining at-risk versus high risk women. The 2007 AHA guideline and Framingham 10-year risk categories (<10%, 10% to 20%, >20%) predicted coronary events with similar accuracy. In contrast, modified Framingham 10-year risk categories of <5%, 5% to 20%, and >20%, predicted coronary events more accurately than the 2007 AHA guideline (AUC, 0.724 versus 0.664; *P*<0.0001).

Strengths of this analysis include the large, diverse population, careful prospective collection and adjudication of cardiovascular events, and richness of the baseline dataset including dietary and physical activity variables. Limitations include the lack of available data on renal function, the fact that lipoproteins were only measured in a random subsample of participants and the potential inaccuracy of self-reported medical conditions such as diabetes mellitus or hypercholesterolemia. High-sensitivity C-reactive protein was not measured in the random sample, precluding assessment of the Reynolds risk score.

Age is not a specified criterion for risk categorization in the 2007 AHA guideline. The prevalence of several high-risk and at-risk criteria such as diabetes, hypertension, and dyslipidemia increase with age,[12–14] thereby incorporating, at least in part, the cardiovascular risk associated with aging. Further, this approach focuses on long-term effects of risk factors, potentially avoiding the false reassurance that a low 10-year Framingham risk may provide to younger individuals with clinically important risk characteristics.[6,24]

The 2007 AHA guideline for women recommends a diet rich in vegetables and fruits, whole-grain, high-fiber foods, oily fish at least twice weekly, limiting alcohol, salt <2.3 g/day, saturated fat <7% of calories, trans fats <1% of calories, and dietary cholesterol <300 mg/day, an assessment well beyond the scope of most practitioners' office visits. Applying just the salt, beverage, saturated and trans fat, and dietary cholesterol criteria to the WHI, fewer than 1% of women fell into the optimal risk category and 16% could not be categorized, that is, had no risk criteria but did not adhere to a healthy lifestyle. For this analysis, we chose saturated fat <7% of calories as shorthand for a healthy diet (1) to reflect a feasible degree of dietary assessment in community practice, (2) with knowledge that WHI participants adhering to the saturated fat restriction generally are consuming at least 5 daily servings of fruits/vegetables and <300 mg/day of cholesterol,[20] and that (3) cardiovascular event reduction in the dietary modification trial was only observed at very low levels of saturated fat consumption (<6.1% of calories).[19]

A shortcoming of the 2007 AHA guideline in this analysis was its inability to classify all women. Certainly the 13% of women who remained uncategorized could be addressed by changing our definition of "optimal lifestyle," which included consuming <7% of calories from saturated fat and performing physical activity equivalent to 30 minutes of walking, 6 days per week. On the other hand, the no man's land, or no woman's land, between poor diet/physical inactivity and optimal lifestyle warrants scrutiny. In our analysis, this encompasses women consuming between 7% and 10% of calories from saturated fat and/or with physical activity levels

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between 1.25 and 10 MET-hours per week. In fact, the event rates among the uncategorized women were similar to the optimal risk women, from which limited cardiovascular benefit from prudent lifestyle could be inferred. One approach to resolving the problem of uncategorizable women would be to combine them with the optimal risk group because their event rates are similar. This could lead to the inference that lifestyle does not matter. Alternatives would be to combine them with the at-risk group or to eliminate the gap between definitions of optimal lifestyle and poor diet/sedentary lifestyle.

Risk stratification permits providers and payors to efficiently direct attention and resources toward patients likely to benefit from initiation or intensification of preventive therapies. An at-risk label may also focus patients' attention on adherence to lifestyle or other interventions. For risk stratification to be effective, it must be (1) used and understood by providers, (2) comprehensible to patients, and (3) valid across a spectrum of individuals.

Incorporation of ATP III into clinical practice has lagged behind provider awareness of the guideline.[25] Doubtless many factors contribute to the gap between what clinicians do and what scientific evidence supports; one potential obstacle to risk stratification using ATP III is its complexity. The 2007 AHA prevention guideline for women requires no mathematical calculation but does require knowledge of a list of qualifying risk characteristics. The idea that specific characteristics or behaviors increase an individual's likelihood of having a cardiovascular event may be more accessible to both providers and patients than concepts of global risk and extrapolation from population to individual risk.

Another advantage of the AHA guideline is that a qualifying risk characteristic directly pinpoints the target for intervention. Broadly recommended healthful behaviors such as physical activity, attainment and maintenance of ideal body weight, avoidance of cigarette smoking, and consumption of a prudent diet[1,26] are directly addressed in laymen's terms, so that a woman told she was at risk because of physical inactivity could undertake appropriate remedial action.

If validity is the property of a measurement method to measure what it is intended to measure,[27] then the 2007 AHA risk stratification scheme is valid. Our findings support its predictive accuracy among older women from a variety of ethnic groups. Accuracy among younger women or among men remains to be demonstrated.

The ultimate measure of a guideline is whether it improves clinical decision-making, thereby enhancing efficiency and reducing clinical events. Global risk assessment appears to improve risk factor management only modestly in practice.[28] The impact of the risk stratification approach proposed in the 2007 AHA prevention guideline for women will need to be demonstrated in the field.

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Disclosures

Dr Hsia is employed by and owns stock in AstraZeneca. The other authors report no conflicts.

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Evaluation of the American Heart Association Cardiovascular Disease Prevention Guideline for Women

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