Chapter 5: Future Research

Based on our reviews of published studies that include data on women, we believe that a systematic review of the literature is probably not feasible for 19 of the 42 key questions (Table 3). However, systematic reviews of some of these questions might be feasible if unpublished gender-specific findings can be obtained. Systematic reviews of the remaining 23 topics are likely feasible. For some questions, however, we did not recommended a systematic review because the question appears to have been adequately addressed by completed clinical trials or a definitive clinical trial is currently in progress (Table 3).

We believe that a systematic review is feasible and should be recommended for the subtopics listed below (Table 3).

Exercise tolerance testing
Exercise echocardiogram
Aspirin - secondary prevention
Beta-blockers - secondary prevention
Hypertension as a risk factor
Diabetes as a risk factor
Hyperlipidemia as a risk factor
Hyperlipidemia treatment
Homocysteine as a risk factor
Smoking as a risk factor
Smoking cessation
Obesity as a risk factor
Age as a risk factor
Differences in utilization between men and women

The major limitation in performing these systematic reviews will be the availability of data on women and minority populations. Women typically comprise only 20 to 30 percent and minorities a substantially lower proportion of participants in randomized trials. For questions where several trials have been completed, data on women and minorities could be summarized in a systematic review. However, risk estimates for women and minorities are infrequently published. Thus, investigators attempting to systematically review the medical literature must attempt to contact investigators and obtain unpublished risk estimates. For a variety of reasons, these subgroup analyses are often not obtainable. Randomized trials of the benefit of beta-blockers in CHF provide an excellent example of this problem. At least 20 randomized trials of the effect of beta-blockers on mortality in persons with CHF have been published. Most of these have included women, but only 4 that we were able to identify included analyses among women and these data were generally limited to the primary outcome. Thus, even though the National Institutes of Health and other funding agencies appear to have succeeded in assuring that women and minorities are included in randomized trials, data from such participation is not generally available. We recommend that, in addition to demanding

participation of women and minorities in research, the National Institutes of Health, Federal Drug Administration and other funding sources should insist that primary and secondary outcome data by subgroup be published or archived.

Similarly, most systematic reviews of the literature do not provide subgroup estimates for women or minorities. This is due primarily to the difficulty of obtaining unpublished subgroup estimates, as noted above. However, as demonstrated by several excellent systematic reviews included in this report, it is possible with additional effort to obtain subgroup estimates for women and minorities. We recommend that funding agencies that support systematic reviews require inclusion of subgroup estimates in women and minorities whenever possible.

Table 5: Findings by Level of Evidence and Recommendation for Systematic Review

		Systematic Review Feasible		
Level of Evidence	Number of Key Questions	no	yes	maybe
None	13	13	0	0
Weak	15	5	6	4
Fair	8	0	8	0
Good	6	1	5	0