

January 23, 2001

**Ancillary Study #110: Sex Steroid Hormones and Risk of CHD
Summary of Case-Control Selection**

Study Population:

As of August 27, 2000, the WHI Observational Study consists of 93,720 participants. Of these, 35,247 meet the eligibility criteria of this ancillary study including adequate available serum.

Cases:

The number of cases of MI, coronary death or revascularization among the 35,247 participants is 441. I defined coronary death as a death with the underlying cause reported as either “definite coronary heart disease” or “possible coronary heart disease”. (This is slightly different than the definition used in AS83-Ridker. They included underlying causes of “other cardiovascular” and “unknown cardiovascular”, but may be excluding cases with these death subclasses from further analyses.)

The number of cases selected for AS83 (excluding death subclasses of “other cardiovascular” or “unknown cardiovascular”) that are eligible for this study is 171. Seventy-nine of these cases also have an eligible control, 92 do not. New controls will be matched to these 92 participants.

The design of ancillary study #110 specifies selection of a total of 385 cases with AS83 cases used if possible. From the total number of cases available (441) after subtraction of the AS83 eligible cases (171), 270 cases remain. Two hundred fourteen cases (385 minus 171) will be randomly selected from these 270 cases. Controls will be matched to these 270 cases.

Control Selection:

Control selection was done in a time-forward manner, selecting one control for each case from the risk set at the time of the case’s event. Matching criteria are given below. All participants (cases included) are contained in the risk set until they had the event, or until they dropped from the study (loss to follow up). Cases can be a potential control for cases whose events happen earlier. The 79 controls already matched to a case were not included in the risk set.

Matching was done on age at screening (+/- 2 years), race/ethnicity (White, Black, Hispanic, Asian, American Indian, Other/unspecified), smoking status (never, former, current) and date of study enrollment (+/- 6 months). Race/ethnicity and smoking status were matched exactly, and the continuous matching variables were selected based on a criteria to minimize an overall distance measure.

Matching Summary:

A control meeting the matching criteria was matched to each of the 306 cases (214 new cases and 92 AS83 cases needing a control). By design, race/ethnicity and smoking status matched exactly; 96% of the cases matched exactly on age and 97% of the cases matched within one month on date of enrollment. Four cases were also selected as a control for participants with an earlier event leaving a total of 608 unique participants.