

November 7, 2003

Ancillary Study #146: A Prospective Study of Pancreatic Cancer Pathogenesis
In the WHI Observational Study

Case selection:

All locally adjudicated cases of pancreatic cancer cases occurring through August 31, 2003.

Exclusion criteria include missing baseline smoking status, baseline history of any type of cancer except non-melanoma skin cancer, any cancer occurring after baseline but before the diagnosis date of pancreatic cancer, no available buffy coat sample and non-availability of adequate plasma EDTA sample.

As of August 31, 2003, 130 cases of pancreatic cancer had occurred. Twenty-six cases were excluded for the following reasons:

| Reason for exclusion | Number of cases |
|--|------------------------|
| Missing baseline smoking status | 3 |
| Baseline history of cancer | 16 ^a |
| Cancer after baseline and before pancreatic diagnosis date (locally confirmed) | 4 ^b |
| Refused DNA testing | 0 |
| No buffy coat sample | 0 |
| No or inadequate plasma EDTA sample | 5 ^c |
| Total remaining | 104 |

- a. Nine breast cancers, 2 colorectal cancers, 1 endometrial cancer, 2 melanoma, 1 other, and 1 missing data.
- b. One breast cancer, 1 lung cancer, 1 thyroid cancer and 1 other.
- c. Two also reported history of cancer at baseline.

Control selection:

Control selection was done in a time-forward manner, selecting three controls for each case from the risk set at the time of the case's event. Matching criteria are listed below. The same exclusion criteria listed above for cases also applies to the potential controls with one modification. Controls may not have had a diagnosis of cancer (except non-melanoma skin cancer) up to the time of the case's diagnosis date. The total number of eligible controls was 75,866.

Matching criteria:

Matching was done on year of birth, smoking status (never, former, current), fasting status (fasting, non-fasting/missing fasting status), and month of blood draw. Smoking and fasting status were matched exactly. (Fasting was defined as at least 8 hours since last ate.) Matching windows were not set for year of birth or month of blood draw. Instead, the matching algorithm was allowed to select the closest match based on a criteria to minimize an overall distance measure (Bergstralh EJ, Kosanke JL. Computerized matching of cases to controls. Technical Report #56, Department of Health Sciences Research, Mayo Clinic, Rochester MN. April 1995). SAS code was available to implement this matching scheme.

Matching results/summary:

Three controls meeting the matching criteria were matched to each of the 104 cases, resulting in a total of 312 controls. By design, smoking and fasting status matched exactly. For all cases, the matching algorithm also found exact matches for year of birth and month of blood draw for all three controls in each case/control set.