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ATTACHMENT 2

Tables and excerpts from the draft protocols that contain raw data C-8 blood levels.

Preliminary analyses were conducted on the pregnancies data including 18,276 women yielding 48,007 pregnancies. Of those pregnancies, 17,263 women reported 41,408 pregnancies occurring in 1960 or later. Nearly 40% of the women reported three or more pregnancies, and 23% reported only one pregnancy. Among the reported pregnancies, 11.0% (4,569) ended in miscarriage and 0.69 (287) ended in stillbirth. Among live births, 13.7% (4,824) were reported to be preterm, 5.9% (2,069) were reported to be low birth weight, and 1.7% (598) were term low birth weight. Preeclampsia was reported for 1,528 pregnancies. Birth defects were reported among 1,490 pregnancies, with the most common being congenital heart defects (275), club foot (91), eye defect (81), genitourinary defects (75), and oral clefts (52). Given that these preliminary analyses were based on 52,000 records out of an expected total of 69,000 participants, constituting 75.4% of the total, we generated the following estimates for the total number available for the analysis by multiplying the numbers by 1.33:

55,073 pregnancies after 1960
6,077 miscarriages
382 stillbirths
48,614 live births
6,416 preterm births
2,752 low birth weight births
795 term low birth weight births
2,032 preeclampsia

1,982 birth defects
 366 congenital heart defects
 121 club foot
 108 eye defects
 100 genitourinary defects
 69 oral clefts

3.8 Power

Power is computed for 2 scenarios:

- comparing exposed to some extent (n=80k) to not exposed (n=420k)
- comparing top 20% exposed areas (n=16k) to less exposed (n=64k)

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Power is presented in Table 3.4 as the chance of being able to detect a significant result for a modest increase in RR (1.25) in scenario 1 and a more substantial increase in RR 2.0 in scenario 2. [With alpha 0.05, two sided. Calculated with 'sampsize' in STATA.] Note that this underestimates power relative to analyses that consider the full range of exposure or ordered categories, but ignores more complex models with multiple covariates which can reduce power somewhat. Nonetheless, these estimates convey a good impression of the magnitudes of association we will be capable of detecting.

Table 3.4 Summary of power calculations

	% Power to detect RR of:	
	1.25	2.0
	(80k vs 420k)	(16k vs. 64k)
Bladder	88	88
Breast (fem)	100	100
Kidney	65	94
Liver	25	50
Pancreas	54	87
Testes	30	58
All	89 (RR 1.05)	100 (RR 1.25)

3.1 Study population

Brookmar are currently nearing completion of the C8 health project. They anticipate completing data collection in May/June 2006, and carrying out some data cleaning and validation over the subsequent months. We can expect a provisional data set from Brookmar shortly after June and a final dataset around December 2006. We have received and have been able to examine provisional data for the first 30,000 participants and (for fewer variables 50,000) which have been very useful for assessing patterns of available data. C8 has been measured in all participants, and included in the questionnaire were questions on whether they had every been diagnosed with cancer, a list of specific named cancers, and in each case the year of diagnosis was requested.

Based on reported diagnoses of cancer in the first 30,000 participants, the reported numbers and prevalence (all ages) of each cancer site is given in table 3.1

Of the sites of primary interest liver and pancreas have low survival so self reported cases in survivors will be uninformative. This leaves Bladder, Breast, Kidney, Skin and Testes with 106, 559, 113, 1135 and 59 cases, respectively.

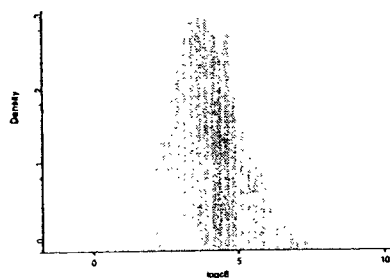
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Table 3.1 Numbers and prevalence of participants reporting diagnoses of cancer in first tranche of 30,629 participants in C8 health project and estimated numbers to be expected in complete dataset. Sites with more interest for follow up are highlighted and the typical 5 year % survival is shown, for these sites.

Site	#/ 30,629	% prevalence	#/ 69,000	% 5 year survival (ACS 1995-2001)
Bladder	47	0.15	106	82
Blood	27	0.09	61	
Bone	17	0.06	38	
Brain	13	0.04	29	
Breast (left)	248	0.81	559	88
Cervix	319	1.04	719	
Colon	110	0.36	248	
Esophagus	19	0.06	43	
Gall bladder	1	0.01	2	
Kidney	50	0.16	113	65
Larynx	19	0.06	43	
Leukemia	27	0.09	61	
Liver	3	0.01	7	9
Lungs	56	0.18	126	
Lymphoma	65	0.21	146	
Melanoma	142	0.46	320	92
Mouth	19	0.06	43	
Ovarian	71	0.23	160	
Pancreas	2	0.01	5	4
Prostate	174	0.57	392	100
Rectum	20	0.07	45	
Skin	504	1.65	1135	
Stomach	8	0.03	18	
Testes	26	0.08	59	96
Thyroid	34	0.11	77	
Uterine	94	0.31	212	
Total	2115	6.91	4765	

Figure 3.1 Distribution of log C8 in blood



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