

AR 226 - 3738

Attachment 2

Tables and excerpts from the draft protocols that contain information related to C-8 blood levels.

Table 1. Descriptive statistics for the community cohort age ≥ 20 at baseline in 2005 (n=23,942)

Mean age in 2005	46
Age <20	20%
Age 20-39	31%
Age 40-49	18%
Age 50-59	15%
Age 60-69	10%
Age 70+	6%
Median Body Mass Index	27.9
Mean C8 level	130 ppb
Median C8 level	48 ppb
Percent ≥ 60 yrs age	20%
Percent BMI ≥ 30	36%
Percent white	98%
Percent male	46%
Percent current smokers	26%
Percent finished college	13%

Table 2. Anticipated distribution of C8 in study participants.

C8 median	48 ppb
C8 mean	130 ppb
C8	
<10 ppb	8%
10-49	43%
50-99	20%
100-149	9%
150-199	5%
200-299	5%
300-550	5%
505+	4%

Table 1. Descriptive data on subjects > age 20 (n=23,942)

Age	
20-39	38%
40-49	23%
50-59	19%
60-69	12%
70-79	6%
80+	2%
White	98%
Female	54%
Current smoker	26%
School	
<12	11%
High School/GED	43%
Some College	34%
College degree	12%
C8 median	48ppb
C8 mean	130ppb
C8	
<10 ppb	8 %
10-49	43%
50-99	20%
100-149	9 %
150-199	5%
200-299	5%
300-550	5%
550+	4%
BMI mean	28.9
BMI median	27.9
BMI 30+	30%
% prevalent heart disease	8.5%
% prevalent stroke	2%
Cholesterol mean	200 mg/dl
Cholesterol median	196 mg/dl

Table 3.2 Blood C8 in participants by water district reported as source of drinking water (last address, ignoring those not reporting one of the six water districts as source). Mean, median and 10th and 90th percentiles. (Units ug/1).

District of last address (DW)	N	mean(c8)	med(c8)	p10(c8)	p90(c8)
1: City of Belpre, OH	2,831	71.6	45.2	17.6	134.9
2: Tupper Plains	4,807	63.0	48.9	18.5	111.7
3: Little Hocking Water Association	4,338	396.9	290.0	83.6	820.5
4: Lubeck Public Service District	5,494	131.7	90.4	30.9	237.0
5: Mason County	3,522	19.1	15.5	7.4	34.2
6: Village of Pomeroy	734	18.6	15.6	7.1	32.6
Other	8,903	82.6	29.1	91	138.3
Total	30,629	123.0	47.8	11.7	284.9

Table 3.3 Mean, median and range within some percentile fractions (Units ug/1).

	N	mean(c8)	med (c8)	min	max
Lowest 10%	3,117	8.0	8.5	.25	11.7
Upper 10%	3,063	664.4	479	285	11391.9
Lower 50%	15,323	22.9	21.2	.25	47.8
Upper 50%	15,306	223.2	113	47.9	11391.9

Figure 3.1 Distribution of log c8 in blood

3.3 Power

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) and a substantial increase in RR 2.0 for the simplest comparison between the upper and lower half of the population (with C8 in blood, mean 223 ug/l and 23 ug/l respectively). [With alpha 0.05, two sided. Calculated with 'sampsize' in STATA.] Note that this may underestimate 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 sense of the magnitudes of association we will be capable of detecting.

Table 3.4 summary of power calculations

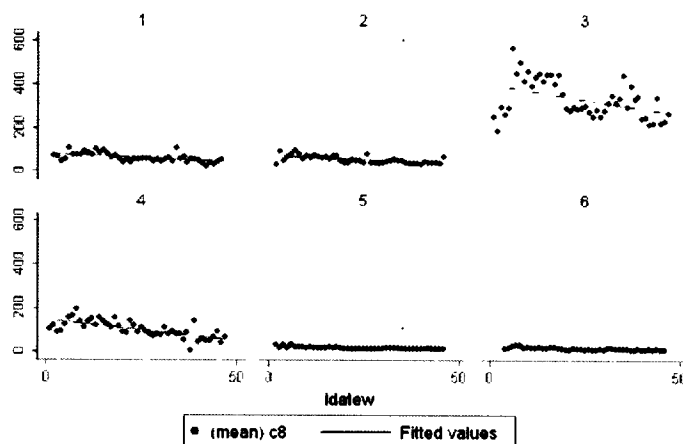
		% Power to detect RR of:	
		1.25	2.0
	Expected n		
Bladder	106	18	92
Breast (fem)	559	75	100
Kidney	113	19	93
Testes	59	11	68

The Science Panel also reports the following with respect to a trend observed in the C-8 blood levels:

3 The C8 health project data and trends in PFOA levels in the study area

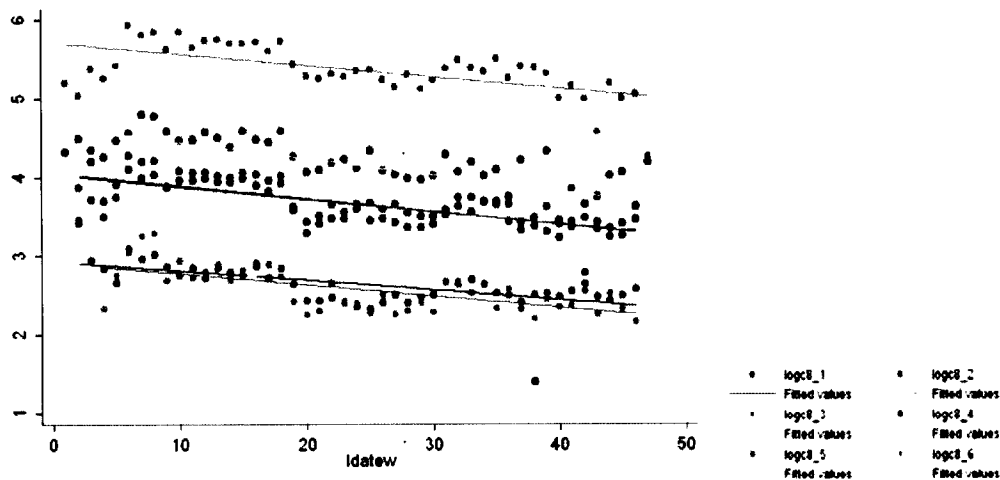
[The Science Panel has] a very detailed source of good quality data on C8 levels at an individual level by virtue of the large amount of data collected by the Brookmar team. This will be supplemented by a detailed assessment of the patterns of metabolism and clearance of C8 in the half life study component.

This data have been assembled over nearly a year and an initial examination of it reveals a significant trend in C8 by community, which has implications for the design of our study. The following figure shows the pattern of C8 levels for people classified by the current water district in which they live (after excluding those who live outside the catchment area of the 6 water districts). Each point is the average of a weeks' collection of blood samples over 47 weeks of data collection. In each water district they appear to have a downward slope.



Graphs by if water source was-is public, select district

The trends are more readily seen in the log-transformed C8 data: the following graphs illustrate the similar proportional trend in average weekly mean log c8 within each of the six water districts:



The magnitude of the slope is about a 7% drop per month:

If the within-individual trend is comparable to the observed slope for the community (i.e. the observed slope is not due to a downward trend in the proportion of individuals who happen to have relatively high C8 in blood – unlikely to have been repeated in each water district) then this would indicate a rather steep decline: the combination of reducing intake and clearance would then appear to be associated with a half life of less than a year. At this rate the c8 level in the blood has fallen by nearly 60% in a year.