Reliability of statements about smoking habits

Report on RSGB Salivary Cotinine Study

Author : P.N. Lee and Dr. J. Fry Date : 6.8.86

SUMMARY

1775 men and women aged 16-74 completed an at-home interview which included questions on their smoking habits and use of other nicotine-containing products and on the smoking habits of their spouse. At the end of the interview 1537 subjects provided a sample of saliva for salivary cotinine analysis. Subsequent to the interview, an attempt, successful in 85% of cases, was made to recontact all respondents during which a backcheck question on manufactured cigarette smoking was asked.

Successful cotinine analyses were carried out for 808 of the 848 subjects who reported no smoking or nicotine use at all ("non-users") and for 176 of the 689 subjects who reported smoking and/or some nicotine use ("users"). Median cotinine values were very much higher in users (males 319 ng/ml, females 311 ng/ml) than in non-users (males 0.85 ng/ml, females 0.4 ng/ml).

Analysis of the distribution of cotinine values among self-reported non-users and their relationship to spouse smoking habits, demographic variables consistent with increased passive smoke exposure and consistency of statements about manufactured cigarette smoking habits on backcheck suggests that the 808 subjects could be categorised by cotinine value into 4 main groups; (A) 220 subjects value who were non-users with (27.2%) with a zero cotinine effectively no passive smoke exposure, (B) 568 (70.3%) subjects with cotinine values in the range 0.1-30 ng/ml who were likely to be true non-users with varying degrees of passive smoking exposure (C) 9 (1.1%) subjects with cotinine values in the range 30-100 ng/ml who were probably misallocated occasional users and (D) 11 (1.4%)

subjects with cotinine values in the range >100 ng/ml who were almost certainly regular users of nicotine-containing products. Overall it is estimated that 2.5% of self-reported non-users are actually true users, while 3.2% of true users fail to report their current use of tobacco.

5 (2.7%) of 184 self-reported non-users married to smokers had cotinine values above 30 ng/ml, as compared with 10 (2.4%) of 416 self-reported non-users married to non-smokers. This comparison may, however, be biased since spouse smoking habits were not validated by cotinine and may be especially unreliable for subjects with such high values.

Among self-reported non-users, cotinine values were increased in exposure. relation to correlates of passive smoke Among self-reported users, however, no such relationship was seen, cotinine values apparently being only materially affected by active habits. Compared with smokers of manufactured cigarettes, smokers of handrolled cigarettes had higher and smokers of cigars had lower Smokers of pipes and users of snuff, nicotine cotinine values. chewing gum, chewing tobacco or tobacco teabags were too few for conclusions to be made. Cotinine was positively correlated with numbers of manufactured cigarettes smoked, but only weakly.

Of the 176 self-reported users, 152 (86.4%) had cotinine values above 100 ng/ml and could be classed as regular users, while a further 9 (5.1%) had values above 30 ng/ml and could be classed as occasional users. It was not so clear which of the remaining 15 (8.5%) were very occasional users and which were misclassified non-users. One statistical method indicated 4 (2.3%) in the latter category, based on a cut-off of 3 ng/ml. Whether based on self-reported smoking habits or on cotinine values, smokers were much more likely to be married to smokers than were non-smokers.

The extent to which misclassification of regular smokers as non-smokers, coupled with concordance between spouse's smoking habits, supports the possibility of bias in studies of the relationship of passive smoking and lung cancer will be discussed in a separate document.

1.	Introd	luction	1
2.	Method 2.1 2.2 2.3 2.4 2.5 2.6 2.7 2.8 2.9 2.10	Outline of main study Outline of pilot study Interviewers and sampling method Transportation of saliva collection packs to interviewers Administration of interview Return of saliva samples to HLE Identification of samples to be analysed Determination of salivary cotinine Follow-up (backcheck) interviews Data processing by RSGB	2-10 2 3 4 4 6 7 8 9 9
	2.11	Statistical methods	10
3.	Result	ts from pilot study	11-12
4.	Result 4.1 4.2 4.3 4.4	ts from main study Distribution of variables Non-response Smoking and use of other nicotine products Relationship of smoking and use of other nicotine products to probability of cotinine determination being	
	4.5	made Back-check	19
	4.6	Cotinine levels in relation to smoking and use of other	20
	4.7	nicotine products - preliminary analyses Using a cut-off point to discriminate nicotine users and non-users	23
	4.8	Factors affecting cotinine value among self-reported non-users of nicotine containing products	24
		4.8.1 Spouse smoking habits	25
		4.8.2 Demographic characteristics	26
		4.8.3 Possible methodological biassing factors	29
		4.8.4 Presence of other people	29
		4.8.5 Backcheck on manufactured cigarette smoking	29
		habits	30
	4.9	4.8.6 Subjects with high cotinine values Factors affecting cotinine value among self-reported	
	4.2	users of nicotine containing products	
		4.9.1 Sex	30
		4.9.2 Numbers of manufactured cigarettes smoked	31
		4.9.3 Handrolled cigarette only smokers	31
		4.9.4 Cigar only smokers	32
		4.9.5 Pipe only smokers	32
		4.9.6 Users of other nicotine containing products	32
		4.9.7 Other factors	33
		4.9.8 Subjects with low cotinine values	33

- 4.10 Misclassification of subjects as users or non-users of 34 nicotine containing products
- 4.11 An interpretation of the data and its use in estimating 38 misclassification rates
- 4.12 Misclassification rates as a proportion of actual users 41 and non-users
- 4.13 Sources of error in estimates of misclassification rates 42
- 4.14 Spouse's smoking habits in relation to nicotine use and 43 level of misclassification
- 4.15 Comparison of smoking habits with the 1985 Annual Consumer 44 Survey

5. Discussion

45-49

INDEX - TABLES

+

1.	Failure to supply sample of saliva
2.	Observed and expected numbers of subjects with various
	characteristics by whether or not saliva sample supplied
3.	Refusal to supply a sample of saliva by sex, age, manufactured
	cigarette smoking habits and presence of other persons
4.	Self-reported smoking and chewing habits by sex
5.	Response rates by smoking habits
6.	Success of backcheck
7.	Manufactured cigarette smoking habits as originally reported and as stated in the backcheck
8.	Discrepancy of manufactured cigarette smoking habits on
0,	backcheck by spouse manufactured smoking habits
9.	Salivary cotinine by nicotine use
10.	Histogram of log (cotinine + 0.05) values by self-reported
	use of nicotine containing products
11.	Discriminating nicotine users and non-users by cotinine value
12	Cotinine level by spouse smoking habits among self-reported
1.0	non-users of nicotine containing products
13.	Median cotinine level by various demographic characteristics
7.7	among self-reported non-users of nicotine containing products
14.	Percentage with various demographic characteristics by
	cotinine group among self-reported non-users of nicotine
.	containing products
15.	Percentage with other people present by cotinine group among
10	self-reported non-users of nicotine containing products
16.	Self-reported non-users of nicotine containing products with
17	high cotinine values
17.	Salivary cotinine by type of product smoked (for non-users of
18.	other nicotine containing products)
10.	Salivary cotinine by number of cigarettes smoked among smokers
19.	of manufactured cigarettes only
20.	Details of those who use other nicotine-containing products
20.	Median cotinine level by various factors among smokers of manufactured cigarettes only
21.	Self-reported users of nicotine-containing products with low
ΖΙ.	cotinine values
2.2	
22.	Estimated misclassification rates
23.	Self-reported non-users of nicotine containing products who have high cotinine levels by spouse smoking habits
24.	Concordance of spouse's smoking habits with (a) the subject's
24.	self-reported reported smoking habits (b) the subject's
	• • •
	cotinine value

,

INDEX - APPENDICES

- A. Sampling points used in the main study
- B. Letter from Dr. F.J.C. Roe to participants
- C. Questionnaire used in main study
- D. Interviewer instructions
- E. Follow-up (backcheck) questionnaire
- F. Salivary Cotinine Study. Summary Frequency Table
- G. Comparison of Smoking Habits from the Salivary Cotinine Study and the 1985 Annual Consumer Survey

1. Introduction

The reliability of statements about smoking habits is of crucial importance to the conclusions of studies relating smoking to disease. In particular, this is true for studies of the possible effects of passive smoking on health, since misclassification of active smokers as non-smokers can cause an appreciable bias.

The study described in this report uses an objective measure (salivary cotinine) to assess the reliability of statements made at one point of time concerning current smoking habits. In another study, reported separately, consistency of statements about smoking habits made at two different points of time is being studied by reinterviewing 5 years later people first interviewed in the Annual Consumer Survey in 1980.

2. Methods

2.1 Outline of main study

1775 men and women aged 16-74 were interviewed at home in England, Wales and Scotland in September and October 1985 by Research Surveys of Great Britain (RSGB) and asked to participate in a survey on "Life-Style and Appetite" which included questions on smoking by the subject and his or her spouse and on the use by the subject of other nicotine containing products (chewing tobacco, nicotine gum, snuff, After completion of the questionnaire the tobacco teabags). respondents were asked to provide a sample of saliva in a glass collection tube. 1537 respondents did so and these samples were sent to Hazleton Laboratories Europe (HLE). Following provision of summary information on the responding smoking habits and use of other nicotine containing products by RSGB to HLE, HLE attempted to carry out an analysis for salivary cotinine to the nearest 0.1 ng/ml for all non-smokers, for all users of other nicotine containing products and for a proportion of smokers.

2.2 Outline of pilot study

A pilot study was carried out in the Midlands in April 1985 on 226 men and women aged 16-74. The intention of the pilot was to determine whether an adequate proportion of respondents would supply a sample of saliva, and as 196 respondents did so the decision was made to continue with the main study. The pilot was carried out along similar lines to the main study, the major differences being

-2-

- (i) questions on the use of other nicotine containing products were not asked,
- (ii) an attempt was made to carry out salivary cotinine measurements on all samples,
- (iii) low levels of cotinine were only recorded as <10 ng/ml,
- (iv) some repeat measurements were made to assess the magnitude of measurement error.

2.3 Interviewers and sampling method

In the main study, 40 interviewers were asked to contact up to a maximum of 60 adults in an attempt to collect samples of saliva from 40. In the pilot study, 10 interviewers were to collect 20 samples from a maximum of 30 adults per interviewer.

In both studies quotas were set on the sample to be achieved where saliva samples were successfully collected, with parallel controls employed within the sexes. These quotas, together with the profile achieved are indicated below:

		Males			Females		
	Achie	eved	Target	Achie	eved	Target	
	N	8	90	N	℅	8	
AGE							
16-34	311	42	40	316	40	38	
35-54	232	31	34	281	35	33	
55+	197	27	26	200	25	29	
SOCIAL CLASS ABC1 C2DE	295 445	40 60	40 60	334 463	42 58	40 60	
WORKING STATUS Full/Part time Non working	445	00	00	380 417	48 52	46 54	

-3-

Appendix A lists the 40 sampling points used in the main study.

2.4 <u>Transportation of saliva collection packs to interviewers</u>

Prior to interviewing, each interviewer was sent the saliva collection packs by HLE. Each "pack" consisted of a Jiffy Bag a prepaid 1st Class postage label, (with HLE-addressed) containing a protective plastic cocoon, on which rested the plastic collection tube. This glass tube was labelled "STERILE", sealed in a plastic wrapper and then sterilised by exposure to 25 kilograys of gamma radiation from a Cobalt 60 radioactive source (Isotron PLC, Bradford, Yorkshire). Fixed to each glass tube was a label with a unique 4 digit number between 2001 and 3600. The label was positioned on the tube such that its lower edge indicated the level of saliva required. HLE supplied each interviewer with a note describing the saliva collection method.

2.5 Administration of interview

In order to ensure that saliva samples would not be held up in the postal system, interviews were only conducted from Monday to Wednesday in any given week.

In order to avoid influencing responses, considerable care was taken not to focus attention on smoking when conducting the interview. The interviewers were not informed of the objective of the study and the survey was introduced simply as a survey on lifestyle and appetite. To this end a number of questions were

-4-

included on the questionnaire concerned with various aspects of eating and drinking. The request for the saliva sample was made only after the questionnaire had been administered and at the same time, the respondent was given a letter of assurance signed by Dr. Roe (Appendix B). The letter was left with all those who provided a sample of saliva.

Copies of the questionnaire and interviewer instructions used in the main study are attached as Appendices C and D respectively.

The questionnaire differed in a number of respects from that used in the pilot:

- (c) the question on marital status was moved from the first page to just before the questions on spouse smoking to attempt to ensure all married people were asked these questions;
- (b) question 11, regarding "things which might leave a taste in the mouth or affect the taste of the food that you eat" which included questions on chewing tobacco, nicotine chewing gum, tobacco tea bags and snuff, was not included in the pilot questionnaire;
- (c) the questions on smoking cigarettes in the last 7 days, 12 (a) and (b) were slightly reworded to make it clearer that the answer concerned the average per day, since the pilot, which asked "how many ... <u>a</u> day, on average, have you smoked in the last 7 days?" had elicited some answers such as 140, suggesting it had been misunderstood;

- (d) the question on pipe tobacco, 12 (c) had been altered to allow answers in ounces or grams;
- (e) the lead in to question 12 (e) on smoking at all in the last 7 days had been extended to try to make it clearer that only those who had claimed not to smoke in questions 12 (a) - (d) should be asked,

It should be noted that questions 1-10, part of 11 and questions 16-19 were only included as dummy questions, to attempt to conceal the objective of the study.

2.6 Return of saliva samples to HLE

Having copied the sample bottle number onto the questionnaire, to enable subsequent matching of survey data with cotinine readings, the interviewer then returned the sample to HLE by 1st Class Mail. Each sample was posted on the day of interview where possible. If the last post had gone, interviewers were requested to store each sample overnight in a refrigerator and post as early as possible next day. HLE recorded the date of receipt for each sample, made a note if the volume was below 1 ml and then stored the samples at -20 C pending analysis.

2.7 Identification of samples to be analysed

The interviewers returned the questionnaires to RSGB. These were used to manually identify the claimed usage of tobacco/nicotine products of the respondent as follows:-

- Smoker (of manufactured cigarettes, hand-rolled cigarettes, pipe or cigars),
- 2. User of other nicotine products but not a smoker,
- 3. Smoker and user of other nicotine products,
- 4. Non-smoker and non-user of nicotine products.

RSGB informed HLE of this code by telex.

The interviewers also kept a list relating bottle number to name and address of subjects providing a sample. This list was returned after completion of interviews to RSGB and used as a cross-check to ensure that the correct bottle number was assigned to the correct interview, thus guarding against the possibility of mistranscription of bottle number onto the questionnaire.

HLE analysed saliva samples for all non-smokers and users of other nicotine products (groups 2 to 4) and for a randomly selected 20% sample of smokers (group 1).

-7-

2.8 Determination of salivary cotinine

Samples were analysed by gas liquid chromatography using a Hewlett Packard, Model 5890 gas chromatograph fitted with an alkali flame ionisation detector and computerised peak integrator. The method used was a modified variation of that of Feyerabend and Russell (Analyst, 105, 998, 1980).

As noted above, salivary cotinine values were estimated to the nearest 0.1 ng/ml in the main study, whereas in the pilot study low levels were only recorded as <10 ng/ml. Originally it had been thought that measurements at levels <10 ng/ml would require duplicate determinations but in the event change of the pH for extraction of the saliva to pH11, use of a more modern gas chromatograph, and insistence on a very clean environment allowed these more accurate determinations in the main study with a single measurement. In some cases, however, where there was insufficient saliva or where the saliva contained components which invalidated chromatographic analysis, cotinine estimation was not possible.

In the pilot study, 27 samples were evaluated more than once in order to assess reproducibility. No repeat measurements were made in the main study.

In the main study, analysis commenced immediately after start of fieldwork and continued until February 1986. The results of the analyses were transmitted to RSGB and to P.N. Lee Statistics and Computing Ltd. (PNLSC) early in March.

- 8 -

2.9 Follow-up (backcheck) interviews

As at the pilot stage, attempts were made in the main study to follow-up all respondents interviewed, in order to check the consistency of claimed usage of manufactured cigarettes. Respondents were recontacted by telephone where possible, with further attempts being made in person by interviewers to maximise response. Over 80% of respondents were successfully reinterviewed with the bulk of recontacts being completed by mid-November 1985.

The questionnaire used is shown in Appendix E. This consisted of a photocopy of the front page of the original questionnaire with the bottom right hand corner masked out and replaced by "back-check extra details". The classification data were checked and the extra details section, which consisted of a repeat of question 16 on travel and question 11 (a) on smoking of manufactured cigarettes, together with a summary of the success of the backcheck, was then completed.

2.10 Data processing by RSGB

Data from completed questionnaires were transferred to punched cards and subjected to a computer edit. On receipt of cotinine readings from HLE this information, together with . saliva sample receipt dates and data from follow-up interviews were added to the data file, in order to produce a computer tape for subsequent analysis by P.N. Lee Statistics and Computing Ltd. This was provided in mid-March 1986.

-9-

2.11 Statistical methods

As a first step, a number of cross-checks of the data were made. These threw up a small number of inconsistences which were subsequently resolved in discussion with RSGB and HLE.

The analyses described in section 4 of this report are based on the data file amended to take into account these inconsistencies.

Statistical methods used include:

- (a) stratified contingency table methods, with the observed (0) numbers with a given characteristic compared with those expected (E) assuming that the factor of interest is unrelated to the characteristic,
- (b) parametric one-way analysis of variance,
- (c) non-parametric (rank) one-way analysis of variance (Kruskal-Wallis) together with its stratified analogue,
- (d) non-parametric (rank) correlation coefficients (Spearman)
 and
- (e) fitting of log-normal distributions and assessment of changes in residual sum of squares and log-likelihood following deletion or inclusion of additional observations.

Two-tailed probability (p) values are presented as <0.001, <0.01, <0.05, <0.1 or N.S. (not significant) as appropriate.

-10-

3. Results from pilot study

Two detailed reports on the pilot stage were prepared, one by RSGB (TG 1204) and the other a statistical analysis by myself (TG 1206).

The main findings from the pilot could be summarised as follows:

- (a) a satisfactory proportion of people (196/226 = 86.7%) are prepared to give a saliva sample. Subjects had the chance to write or phone Dr. F.J.C. Roe to complain, but none did.
- (b) while certain improvements to the logistics and the questionnaire should be incorporated in the main study, the pilot study in general went smoothly with no unsurmountable problems.
- (c) while 20 of the 196 samples (10.2%) received by HLE could not be analysed for salivary cotinine, due to an insufficient sample or to the sample not being saliva at all (!), there is no reason that logistical improvements in the main study could not reduce this percentage very considerably.
- (d) between subject cotinine variation was very much greater than assay variation within subject. Reproducibility of results was particularly good in those with cotinine values above 50.0 ng/ml (on average <u>+</u> 8%). For lower values, variation was larger.
- (e) generally the cotinine values discriminated smokers and non-smokers very well indeed. This is illustrated below:

-11-

Cotinine(ng/ml)	Number of subjects	Self-reported smokers of any product	% self- reported smokers
<10.0	106	2	1.9
10.0 - 100	18	10	55.6
101+	52	51	98.1

- (f) within smokers of manufactured cigarettes and not other products, quite a strong correlation (r = 0.65, p<0.001) was seen between salivary cotinine value and average number reported to be smoked in the last 7 days.
- (g) after adjusting for manufactured cigarette smoking habits, no clear relationship of cotinine value to spouse smoking or to any covariable (such as age or social class) could be detected. Conclusions regarding spouse smoking are limited by the low cotinine values only being determined so far as <10.0 ng/ml.</p>
- (h) of the 113 subjects who reported not having smoked any product at all and who had cotinine measured, 1 had a very high cotinine value (325 ng/ml), 3 had moderately high cotinine values (78.6, 92.4, 99.7 ng/ml), all of which were confirmed on repeat measurements and could be considered as "certain" or "probably" true smokers. There were also 5 other subjects who had cotinine values above 10 ng/ml (12.9, 17.3, 21.7, 25.2 and 41.0 ng/ml), the remaining 104 subjects all having cotinine values recorded as <10 ng/ml.</p>

-12-

4. Results from main study

4.1 <u>Distribution of variables</u>

Appendix F gives the distribution of the findings recorded for the 1775 subjects interviewed, divided into 4 groups:

- <u>No sample</u> : 238 subjects who refused to supply a saliva sample.
- <u>Not analysed</u> : 519 subjects who supplied a saliva sample but for whom no attempt was made to analyse it for cotinine.
- <u>Nicotine user</u> : 182 subjects who supplied a saliva sample, for whom an attempt was made to analyse it, and who reported smoking or using any nicotine containing product.
- <u>Non-user</u> : 836 subjects who supplied a saliva sample, for whom an attempt was made to analyse it, and who reported that they did not use any nicotine containing product.

The distributions relate to 10 groups of characteristics:

- <u>Interview</u> : bottle and questionnaire serial number, date and length of interview and interview number.
- Demographic details : Age, social class, respondent working status, presence of children in household, household size and marital status.

<u>Respondent's smoking</u>: Whether or not respondent reported being <u>habits</u>: <u>a current smoker of manufactured and</u> <u>handrolled cigarettes, pipe or cigars</u> together with an estimate of consumption in the last 7 days. Also the results of additional questions asked of non-smokers concerning smoking habits in the last 7 days.

<u>Chewing/snuff-taking</u>: Whether or not the respondent reported chewing nicotine gum, chewing tobacco, chewing or sucking tobacco "tea bags" or taking snuff.

- : Whether or not the subject reported Spouse's smoking habits smoking the 4 major types of tobacco product and whether other people were present when this statement was made. Results of back-: Whether or not the back-check revealed check the subject smoked manufactured cigarettes and the outcome of the back-check. Sample : Time when the sample was received by HLE
- Drinking habits: Results of dummy questions 6-10 andEating habits16-19. These have not further beenTravel etcanalysed
- <u>Travel etc.</u> analysed. Note that the dummy parts of Qll which related to "things that might leave a taste in the mouth or affect the taste of the food that you eat" have not been punched, so are not on my data file.

Some points to note on Appendix F are as follows:

- No data : No answer to question or value available.
- Not recorded : Applies only to questions about smoking in last 7 days by non-smokers. These are people who should have been asked the question but were not, distinguishing them from those who should not have been asked the question who are coded as no data.
- Respondent code This is the 4 level code used to distinguish categories of smoking/ nicotine use for samples sent to HLE. In some cases computer editing by RSGB showed that the original codes sent to HLE were incorrect. Appendix F contains the corrected codes.

Not included in Appendix F are details concerning the frequency with which Dr. Roe was contacted following interview. There were in fact only 3 calls, one was from an ex-nurse who had participated in research in the past, whose mother was interviewed, and who was curious to know the purpose of the study. A second was from a male respondent who was concerned that the sample might be a surreptitious survey related to AIDS. The third was from a woman whose husband had provided saliva and wanted to know why. Dr. Roe was able to reassure all, although the purpose of the study was only revealed, and then in confidence, to the first caller. For the other two he offered to reveal the true purpose later, if they phoned back after the study was complete, but neither did.

4.2 Non-response

The overall rate for refusing to supply a saliva sample was 13.4%, similar to that in the pilot. As shown in <u>Table 1</u>, there was a tendency for refusal rates to be higher in older age groups, particularly in women. Thus, in men refusal rates were around 10% for ages 16-64 but rose to almost 20% for ages 65-74, while in women rates were around 10% for ages 16-34, 15% for ages 35-64 and almost 30% for ages 65-74. The trend by age was highly significant in women (p<0.001) and was almost significant in men (p = 0.055). The general age and sex relationship was similar to that seen in the pilot.

As can be seen in Appendix F, the interview time for refusers was markedly less than that for non-refusers. Median length of interview was 10 minutes in both sexes for refusers as against 15 minutes in males and 16 minutes in females for non-refusers. Length of interview was not age-related in men, or in women who did not supply a sample. In women who did supply a sample, there was a significant (p<0.01) tendency for the interview to be longer in the more elderly, with the median up to 20 minutes for 65-74 year olds.

-15-

The relationship of refusal to give a sample of saliva to certain other characteristics, after standardising for age and sex, was also studied. As shown in <u>Table 2</u>, a number of significant relationships were seen:

- (a) To some extent in both sexes, and significantly (p<0.05) overall, the lower social classes tended to be less ready to supply a sample. Overall 18.1% of social class C2DE refused as against 11.8% of social class ABC1, though part of this difference could be explained by the C2DE group containing relatively more in the oldest age group.
- (b) In women only, those who were part-time or unemployed tended to be more likely to refuse to supply a sample. This marginally significant (p<0.05) association could not be explained by additional standardisation for social class.
- (c) In both sexes, and significantly (p<0.05) overall, manufactured cigarette smokers tended to be more likely to supply a sample of saliva. Overall, only 11.2% of manufactured cigarette smokers refused as against 18.0% of those who did not smoke manufactured cigarettes.
- (d) Men were significantly (p<0.05) <u>less</u> likely to supply a sample when no other person was present, i.e. when the (female) interviewer was the only person there. In contrast, women were significantly (p<0.01) <u>more</u> likely to supply a sample when no other person was present, i.e. when it was just woman and woman.

-16-

Other factors studied, presence of children, household size, marital status and spouse smoking habits, were not significantly related to refusal rate.

<u>Table 3</u> summarises for convenience refusal rates jointly by the more important factors. As can be seen the highest refusal rates are for women aged 55-74 where others are present, regardless of manufactured cigarette smoking habits. The rates here are 36% (13/36).

4.3 Smoking and use of other nicotine products

From the questionnaire it is possible to classify respondents according to whether or not they reported:

- a) being a smoker of manufactured cigarettes,
- b) being a smoker of other products (handrolled, pipe, cigar) and/or
- c) being a user of other nicotine products (chewing tobacco, nicotine chewing gum, tobacco "tea bags" and snuff.

Among those who reported doing none of these, one can also isolate:

(d) those who reported having been a smoker of manufactured cigarettes or other products in the last 7 days. <u>Table 4</u> gives the distribution of the total sample by sex and all combinations of the smoking habit. Overall, 1000 (56.3%) of subjects reported that they did not smoke/chew and had not smoked in the last 7 days, while 775 (43.7%) reported that they either were smokers or chewers/snuff-takers or had smoked in the last 7 days. Of these, 632 were smokers of manufactured cigarettes, 135 were smokers of other products but not manufactured cigarettes (mainly men = 127), 2 were chewers/snuff-takers but not smokers and 3 reported not being smokers.

4.4 <u>Relationship of smoking and use of other nicotine products to</u> probability of a cotinine determination being made

<u>Table 5</u> gives the percentages who supplied a saliva sample, for whom an attempt to carry out analysis was made and for whom a valid cotinine measurement was made by smoking habits.

Overall, a sample was provided by 84.8% of subjects who gave no positive report on smoking or other nicotine use and by 88.9% of others.

Of those where a sample was provided, an attempt to analyse was made in 98.6% of nonsmokers/users and 26.4% of others. The former figure should have been 100%, the minor discrepancy (12/848) being due to the provisional smoking classification data supplied to HLE not being completely correct and/or a small number of oversights. Similarly, although it was planned to attempt analyses for all subjects who reported use of other nicotine products and who provided a sample of saliva, in practice attempts were not made in 2 of the 6 cases.

Of those samples where an attempt to analyse was made, no cotinine reading was possible in respect of 3.3% (34/1018), the percentage being similar regardless of smoking habit.

4.5 Back-check

An attempt was made to reinterview all respondents $(\underline{\text{Table 6}})$. Information was obtained from the respondent in 82% of cases and from other persons in 2.5% of cases. Of the 276 (15.5%) of subjects for whom no information was obtained, refusal was the reason in only 13 (0.7%) of subjects, no contact (13.7%) and moved/no longer at address (1.1%) being the other reasons.

For those subjects for whom back-check information on manufactured cigarette smoking habits was obtained, the relationship to the original information is given in Table 7. Overall, it can be seen that there were 68 out of 1496 subjects (4.5%) for whom the information on manufactured cigarette smoking habits differed. This discrepancy rate was similar in males (5.5%) and females (3.8%) but varied markedly by source of Where the spouse or another person supplied the information. information the second time, there was 100% agreement - no discrepancies in 40. Where the subject supplied the information from a phone interview, the discrepancy rate was 3.8% (41/1085). Where the subject supplied the information from a personal interview, the discrepancy rate was highest at 7.3% (27/371). While the 0% discrepancy rate where the spouse or another person

-19-

supplied the information is based on a small sample and does not differ significantly from the other 2 rates, the last 2 rates do differ significantly (p<0.01). The explanation for this apparently surprising finding is not clear.

It should be noted that of the 26 cases in males and 14 in females where the back-check discrepantly reported the subject smoked manufactured cigarettes, there were 23 cases in males and 3 in females where the subject had reported smoking another tobacco product and 1 in males where the subject had reported smoking nicotine chewing gum.

<u>Table 8</u> shows how the overall discrepancy rate on backcheck (in either direction) varies by other relevant factors. As can be seen, in males but not in females, there is a tendency for the discrepancy rate to be highest where the spouse is also a manufactured cigarette smoker. There is also a tendency in both sexes, significant only in males, for the discrepancy rate to be highest where the spouse was not present originally. Where the spouse is a manufactured cigarette smoker <u>and</u> was present at interview, the discrepancy rate is highest, 9.0% (9/100).

4.6 <u>Cotinine levels in relation to smoking and use of other nicotine</u> products - preliminary analyses

Cotinine values are available for 176 subjects who reported any smoking, chewing or snuff-taking at all ("nicotine users") and for 808 subjects who reported that they had not done so ("non-users").

-20-

<u>Table 9</u> presents the distribution of cotinine values and the median by sex and by whether the subject was a nicotine user or not. <u>Table 10</u> presents a histogram of $\log_e(\text{cotinine} + 0.05)$ for the sexes combined for the two groups. These results suggest a number of conclusions which are elaborated upon in the sections that follow.

- (a) Nicotine users generally have cotinine values some hundreds of times higher than non-nicotine users. This difference is of course very highly significant indeed.
- (b) Variation in cotinine level by sex is only relatively minor. Within self-reported nicotine users males and females did not have significantly different cotinine values at all (medians 319.2 and 310.6 ng/ml respectively), while within self-reported non-users, though males did have significantly (p<0.001) higher values than females, the difference in median value (0.85 as against 0.4 ng/ml) was much smaller than the increase in relation to nicotine use.
- (c) Cotinine values among self-reported non-users appear to fall into 4 separate distributions:
 - (i) an approximately log-normal distribution of around 70% of the subjects centred around 1 ng/ml with cotinine values in the range up to about 20-30 ng/ml. This distribution probably only contains 10 or so subjects with zero measured cotinine;

- (ii) most of the remaining subjects with zero cotinine and perhaps a small number of those with a cotinine of 0.1 or 0.2 ng/ml;
- (iii) a small group of some 1% of subjects with cotinine values in the range 30-100 ng/ml, cotinine values which are below the values seen in the great majority of smokers, but which seem too numerous to form a plausible tail to the main distribution;
- (iv) another small group of some 1% of subjects with cotinine values above 100 ng/ml, well in the normal range of values seen in smokers.
- (d) Cotinine values among self-reported users appear to fall into 3 distributions:
 - (i) a main distribution involving 90% of the users with values above about 30 ng/ml. This distribution is reasonably log-normal except that there is a tendency for there to be few values in the tail at the high end, perhaps consistent with some sort of upper limit to cotinine formation;
 - (ii) a group of some 6% of users with relatively low values in the range of about 3-30 ng/ml;
 - (iii) a very small number of users with remarkably low values.
- (e) Absolute variability in cotinine values is markedly greater among nicotine users, but relative variation is clearly less.

(f) Separating the two main groups of non-smokers will inevitably be made more difficult by the fact that measurements are only made to the nearest 0.1 ng/ml and that the measured zero group doubtless contains a number of true small positive values.

4.7 Using a cut-off point to discriminate nicotine users and non-users

The distribution of cotinine values summarized in Tables 9 and 10 can be used to determine the cut-off point which best discriminates self-reported nicotine users and non-users. This is illustrated further in Table 11 which gives, for a number of possible cut-off points, the numbers of self-reported users and non-users which would fall above and below the cut-off and the percentage "correctly" allocated (i.e. to the self-reported usage category) by the simple rule "user if above, non-user if The percentage correctly allocated rises virtually below". continuously from 0 to 10 ng/ml and falls virtually continuously above 89.4 ng/ml. Table 11 gives the percentage correctly allocated for cut-off points in relation to every observed cotinine value in the study between 10 and 100 ng/ml. It can be seen that throughout this range, the percentage "correctly" allocated is always above 93%. It reaches a maximum of almost 96% over the range 13 to 20 ng/ml.

It should be noted that the percentage misallocated is presumably composed of those misallocated due to the overlapping distributions and those misallocated due to their true user status being misrepresented.

4.8 Factors affecting cotinine value among self-reported non-users of other nicotine containing products

As noted in section 4.6 the histogram of log_e(cotinine + 0.05) shown in Table 10 suggests 4 separate distributions of cotinine values among non-users of nicotine. In order to study the role of other factors on cotinine values among non-users and to understand further why there are these apparent separate distributions it is convenient to define 4 groups of non-users:

- A. The 220 with a recorded cotinine value of 0 ng/ml.
- B. The 568 with a cotinine value of 0.1 ng/ml up to a maximum of 23.1 ng/ml.
- C. The 9 with a cotinine value ranging from 38.9 ng/ml to 87.8 ng/ml.
- D. The 11 with a cotinine value ranging from 132.2 ng/ml to 473.5 ng/ml.

4.8.1 Spouse smoking habits

The most direct index of passive smoke exposure available in this study is whether or not the spouse is reported to be a smoker or not. <u>Table 12</u> summarizes the main evidence on variation in cotinine by spouse smoking, both comparing the frequency of spouse smoking between the 4 groups of non-users defined above and comparing the median level of cotinine in those married to smokers and in those not married to smokers.

A number of conclusions can be drawn:

- (a) In both sexes, cotinine levels are highly significantly (p<0.001) higher in those married to smokers than in those not married to smokers;
- (b) Even among those married to smokers cotinine levels are still two orders of magnitude lower than in those who smoke or use other nicotine products;
- (c) Among both those married (p<0.001) and not married (p<0.01) to smokers cotinine is significantly higher in men than in women. The variation by sex is, however, rather less than the variation by spouse smoking habits;
- (d) In both sexes, the percentage of those married to smokers is highly significantly (p<0.001) higher in group B than in group A. In men, where only 1 out of 84 in group A was married to a smoker (1.2%) as against 55 out of 256 in group B (21.5%) the difference is particularly obvious;

.

(e) There is no difference in the percentage married to smokers between groups B, C and D. For the sexes combined the percentage in group B is 27.3% (155/558) as against 26.3% (5/19) in groups C and D combined.

These differences seem to be consistent with a number of hypotheses/explanations:

- (i) That passive smoke exposure is the principal discriminant of groups A and B;
- (ii) That smoking by the spouse is only one source of passive smoke exposure and that men are more likely than women to be exposed to these other sources;
- (iii)That more women than men are likely to be fairly unaffected by their spouse's smoking habits, either because non-smoking women are more likely than non-smoking men to insist that their partner only smokes outside the home and/or men are more likely to be away from the home for long periods.

4.8.2 Demographic characteristics

<u>Table 13</u> gives median cotinine level by various demographic characteristics, separately for men and women not married to smokers and for men and women married to smokers. Results of significance tests based on rank methods are also given, both for the separate sex x spouse smoking subgroups and for the whole data (standardised for subgroup). Conclusions to be drawn are as follows:

<u>Age</u>: Among those not married to a smoker the most obvious difference (p<0.001) is the relatively high cotinine level (over 1 ng/ml) seen in both sexes in the 16-24 age group, no doubt reflecting the greater tendency of this age group to be exposed to passive smoke from other sources such as pubs. There is also a higher level in men aged 25-44 than in those aged 45-74 but this pattern is not evident in women.

Among those married to a smoker there is also a relatively high level in the 16-24 year old men. There is also a tendency for 55-74 year olds of both sexes to have higher levels than 25-54 year olds perhaps reflecting a higher proportion of time spent at home. However none of the variations seen are clearly significant, in contrast to the non-users not married to a smoker.

<u>Social class</u>: In all 4 subgroups there is a tendency for cotinine levels to rise with decreasing social class, with median levels in DE being at least twice as high as those in AB in all cases. Overall the trend is very highly significant (p<0.001). Further analysis showed that it was essentially unaffected by standardisation for age.

-27-
<u>Working status</u>: In women not married to a smoker, levels were significantly (p<0.01) related to working status with full-time workers having levels twice as high as part-time workers or those who did not work. In other subgroups no relationship was seen. Again conclusions were unaffected by age standardisation.

Household size: No clear relationship to cotinine level was seen.

<u>Marital status</u>: Among those not married to a smoker, cotinine levels were highly significantly (p<0.001) related to marital status, with levels over twice as high in those who were single as in those who had ever been married. Since the significance disappeared after age standardisation it may be concluded that this result is merely a corollary of the fact that single people tend to be young.

Table 14 gives information on the relative age and social class distribution of the 4 cotinine groups into which the non-users of nicotine containing products have been divided. Group B shows the increased numbers of young and lower social class people compared with group A consistent with the results shown in Table 13. No obvious consistent difference is seen between groups B, C and D in respect of age and social class.

-28-

4.8.3 Possible methodological biassing factors

Some analyses were carried out studying the relationship between cotinine value and

(i) interval between time of interview and time of receipt of sample by HLE,

(ii) number of hours since last main meal,

(iii)whether mouth waters when something appetising is seen.

These guard against the possibility were to that methodological factors such as degradation of cotinine or thickness of saliva might have had a material affect on the results. After taking account of sex and spouse smoking habits no relationship of cotinine to any of these factors was seen.

4.8.4 Presence of other people

Cotinine level was not significantly related to whether or not other people were present (Table 15).

4.8.5 Backcheck on manufactured cigarette smoking habits

Of the 688 non-users for whom backcheck information on manufactured cigarette smoking habits was available 10 reported that, contrary to their original statement, they did smoke manufactured cigarettes. There was no significant difference in frequency between those in group A (1/189 = 0.5%) and those in group B (6/481 = 1.2%). Interestingly, however, of the 18 subjects in groups C and D for whom backcheck data were

available, 3 (16.7%), reported that they had smoked manufactured cigarettes, one of them stating that she did not want her husband to know! The comparison between groups A + B and C + D is, despite the small numbers in groups C + D, quite highly significant (p = 0.003) on an exact test.

4.8.6 <u>Subjects with high cotinine values</u>

Table 16 lists relevant features of those subjects in groups C and D as well as of those subjects in group B with relatively high cotinine values.

4.9 Factors affecting cotinine values among self-reported users of nicotine containing products

Cotinine values were available for:

- (i) 100 men and 71 women who reported they were smokers but had not used any other nicotine containing products,
- (ii) 1 woman (cotinine value 92.8 ng/ml) who reported she was not a smoker but had smoked in the last 7 days and
- (iii)4 men who reported use of other nicotine containing
 products.

4.9.1 Sex

<u>Table 17</u> gives cotinine values, by sex, for smokers of the different types of tobacco product. There was no sex difference in median cotinine value either for the whole group (Males 328.7 ng/ml, Females 311.3 ng.ml) or for smokers of manufactured

cigarettes only (Males 285.6 ng/ml, Females 327.3 ng/ml). Smokers of other products were too few in women for other useful sex comparisons to be made.

4.9.2 Numbers of manufactured cigarettes smoked

Table 18 presents the distribution of cotinine values and the median by sex and number of manufactured cigarettes smoked for smokers of manufactured cigarettes only. In both sexes, there is some tendency for cotinine to rise with number smoked but this is only significant (p<0.01) for females. Significance levels in the table are based on the trend for a rank test relating actual cotinine to grouped number of manufactured Further cigarettes a day. analysis using Spearman rank correlations based on actual (rather than grouped) numbers similar significance levels and correlation smoked gave coefficients of 0.17 for males, 0.36 for females and 0.27 for sexes combined. The correlation for the sexes combined, though significant (p<0.01) was weaker than that seen in the pilot study, 0.65.

4.9.3 Handrolled cigarette only smokers

Table 17 also shows that in men the median cotinine value in the 16 smokers of handrolled cigarettes only (510.6 ng/ml) was greater than that in the 50 smokers of manufactured cigarettes only (285.6 ng/ml). This difference was statistically significant (p<0.01).

-31-

4.9.4 Cigar only smokers

In contrast, the median cotinine value in the 9 male smokers of cigars only (9.9 ng/ml) was significantly (p<0.01) less than in the male smokers of manufactured cigarettes only. 6 out of 9 (66.7%) cigar only smokers had values below 50 ng/ml as compared with 4 out of 50 (8%) of manufactured cigarette smokers. It is noteworthy that of the 8 cigar only smokers who reported consumption, the number reported to be smoked per week was low, with two smoking 1, two smoking 2, one smoking 3, two smoking 4, one smoking 6 and one smoking 10 a week.

4.9.5 Pipe only smokers

Only 3 men were analysed, with values of 20.7, 360.0 and 487.4 ng/ml respectively. No conclusions could be drawn from this small sample.

4.9.6 Users of other nicotine containing products

7 men reported use of other nicotine containing products (Table 19). One refused to provide a sample, one provided an insufficient quantity of saliva for analysis and one was not analysed because HLE was incorrectly informed of the subject's habits. Of the remaining 4, it was interesting to note that there was one snuff taker with a low cotinine value of 1.4 ng/ml. The other 3 all used nicotine gum - one additionally chewing tobacco - and all had levels like typical cigarette smokers, 223.4, 289.9 and 437.0 ng/ml.

4.9.7 Other factors

<u>Table 20</u> gives median cotinine levels for smokers of manufactured cigarettes only by sex and by a range of factors that might conceivably have affected cotinine level:- spouse smoking, age, social class, working status, household size, marital status and presence of other people at the interview.

For the sexes combined no significant relationships were seen at all. In the individual sex analyses, only one marginally significant (p<0.05) finding was seen, a tendency in females for cotinine level to vary by age. As the relationship does not follow any logical pattern it seems likely to be a chance finding.

4.9.8 <u>Subjects with low cotinine values</u>

<u>Table 21</u> gives details of all self-reported users of nicotine-containing products with cotinine values of less than 100 ng/ml. These 24 people contain:

(i) the only non-smoker claiming to nevertheless have smoked in the previous 7 days,

(ii) the only snuff taker,

(iii)9 cigar and pipe smokers generally with low consumption,

(iv) 13 cigarette smokers, only 3 of whom had consumption above10 cigarettes a day.

-33-

For the great majority of people, the low cotinine values appear to be plausibly explained by their stated smoking habits, although it remains a possibility that some were due to inaccurate statements. The only subject who seems obviously aberrant is the 30 a day manufactured cigarette smoker with zero cotinine value. As the original backcheck had been unsuccessful a further attempt to recontact this person was made. This revealed that the person by then had lung cancer but was still claiming to smoke manufactured cigarettes, Conceivably, she might have given up smoking for a short period around the time of the interview.

Only one person in Table 21 gave an inconsistent answer on manufactured cigarette smoking habits when reinterviewed. This was only a marginal difference however - the earlier claim being only that the woman smoked 1 cigarette a day. There were in fact 3 other subjects with cotinine values available who reported smoking manfuactured cigarettes originally and denied it on backcheck. These had cotinine values of 120.2 ng/ml (number smoked not stated originally), 463.1 ng/ml (8 a day) and 565.3 ng/ml (4 a day but also 25 handrolled).

4.10 <u>Misclassification of subjects as users or non-users of nicotine</u> containing products

Cotinine values are available for 176 self-reported users and 808 self-reported non-users of nicotine containing products. A number of statistical methods were tried in an attempt to estimate the rate of misclassification of users as non-users and

-34-

vice versa.

One method was to consider the individual distributions of self-reported users and non-users separately and to look for outliers among them.

A second method was to fit separate normal distributions to the $\log_e(\text{cotinine} + 0.05)$ values for users and non-users and to then study the effect of either

(i) reassigning the user with the lowest cotinine value or(ii) reassigning the non-user with the highest cotinine value

on the total residual sum of squares or the log likelihood of the revised distributions, carrying out the reassignment which had the greatest effect, and continuing to reassign until a further switch had little affect.

A third method took into account the reported smoking habits of the users by fitting a regression equation and studying observations that deviated significantly from the overall line.

There were a number of problems to be taken into account:

(i) the distribution of cotinine values of true non-users was clearly not log-normal due to the large number of zero values. For this reason some of the analyses were repeated omitting all or nearly all self-reported non-users with zero values.

-35-

- (ii) the distribution of true users cotinine values was also not log-normal. Partly this was because there seemed to be some sort of upper ceiling, partly because there was a long lower tail of values which seemed too numerous to ascribe to misclassified non-smokers.
- (iii)it was likely a priori that misclassification rates depended on the extent of smoking, inasmuch as very light smokers are more likely to consider themselves nonsmokers.
- (iv) the exact results depended on the methods used and the assumptions made.

Nevertheless, it was possible to come to some general conclusions.

Misclassification of users as non-users

As will be shown elsewhere, misclassification of smokers as non-smokers is the main source of bias in studies of the relationship of passive smoking and lung cancer with misclassification of non-smokers as smokers of relatively minor We consider the importance. more important type of misclassification first.

Generally the results of the various analyses were consistent in concluding that the 11 self-reported non-users with values above 100 ng/ml were much more likely to be true users than true non-users. For a log-normal distribution based on 808 subjects one would expect only about 1 subject 3 standard deviations above the mean. In practice, based on the distribution fitted to all the self-reported non-users (ignoring almost all subjects with zero cotinine value to improve the fit to a log-normal) there were 11.

The analyses were less clear about the position of self-reported non-users with cotinine values above 30 ng/ml. However, they generally indicated that a substantial proportion of them were also likely to be misclassified users. Thus, after deleting the 11 observations with values above 100 ng/ml, with a consequent reduction in mean and variance, there were still 7 observations more than 3 standard deviations above the new mean.

The analyses were generally consistent with the conclusion that observations below 30 ng/ml formed a fairly continuous distribution with no evidence of outliers. This is reasonably evident both from Table 10 and Table 16. It remains possible that an occasional such subject did in fact fail to report minor use of nicotine containing products.

Misclassification of non-users as users

Here the results were more equivocal. The method based on residual sum of squares only reclassified the 4 self-reported users with cotinine values less than 3 ng/ml as true non-users. The methods based on outliers and maximum likelihood reclassified rather more, up to the 15 self-reported users with values less than 35 ng/ml. When consumption was taken into account the numbers reclassified reduced again, but here the cut-off rule was not straightforward.

From Table 21, it can be seen that many of those with low cotinine values reported relatively light use of nicotine-containing products, particularly of products (cigars, is little other reliable snuff, pipe) for which there information on cotinine value. In this situation one would tend to doubt strongly the conclusion from analyses which suggested all of those people were in fact non-users. It seems much more plausible that the statistical method came up with incorrect results because it assumed falsely that users form a single distribution. The lower estimate of 4 subjects wrongly classified seems more realistic, though it is impossible to justify this formally.

4.11 <u>An interpretation of the data and its use in estimating</u> misclassification rates

Detailed consideration of not only the analyses described in the previous section but also those described earlier suggests a plausible explanation for the pattern of cotinine values seen in self-reported users and non-users of nicotine containing products.

Considering self-reported non-users first, there appear to be 4 main groups of people:

(A) those who do not in fact use nicotine containing products and who are unexposed to passive smoke. These people are not married to smokers (exceptionally they might be if they have little contact with their husband) and form the great

-38-

majority of the 220 subjects with zero cotinine.

- (B) those who do not in fact use nicotine containing products but who are exposed to passive smoke. They tend to be married to smokers and/or have characteristics typical of those who are more liable to be exposed at home, or work or at leisure. They form a fairly smooth log-normal distribution with a mean of about 1 ng/ml with a lower tail going into the zero cotinines and an upper tail going up to about 20 ng/ml.
- (C) those who actually do occasionally smoke but who do not really consider themselves smokers and may tend not to mention or remember it on interview. These probably account for most of the 9 people with cotinine values in the range 38.9-87.8 ng/ml. A justification for regarding B and C as separate distributions is the fact that attempts to fit a common log-normal (deleting 210 non-users with zero cotinine and observations above 87.8 ng/ml) result in a clear excess of extreme high values over expected.
- (D) those who are regular smokers (or users of other nicotine products) but who choose not to admit it on interview. These probably account for the 11 people with cotinine values in the range 132.2-473.5 ng/ml (though C and D may overlap). It is notable that these 11 people have a median value similar to that of smokers, and all cause considerable improvements in fit by treating them as users in the statistical analyses.

-39-

For the purpose of estimating misclassification rates, bearing in mind the possibility that some passively exposed non-smokers might have cotinines above 30 ng/ml and the possibility that some occasional smokers might have cotinines below 30 ng/ml, it seems reasonable to treat all self-reported non-users with cotinines above 30 ng/ml as true users. However since misclassification of occasional smokers as non-smokers will have much less effect on biassing the observed association of passive smoking with lung cancer than misclassification of regular smokers as non-smokers, it remains important to distinguish self-reported non-users with cotinines in the range 30-100 ng/ml and those over 100 ng/ml.

Turning now to self-reported users, we have noted earlier that we are only at all confident that those with cotinine values below 3 ng/ml have really been misclassified. For those in the range 3-30 ng/ml it seems more reasonable to accept their statement and treat them as very occasional users.

Table 22 summarizes the results of the interpretation of the data for both self-reported users and non-users. It is noted that the 97 subjects with cotinine values in the range 3-30 ng/ml have been classified differently according to their own self-reported smoking habits, being treated as passive smokers if they reported no nicotine use (86 subjects) and as very occasional users if they did report nicotine use (11 subjects). Neither of this group are therefore included in the overall estimated percentage who are misclassified. Of the remaining 887 subjects, 24 or 2.71% were misclassified. It may

-40-

be therefore that a similar proportion of these 97 subjects were misclassified. If this were so, this would bring the estimated numbers of non-users misclassified up to 22.3 (2.9%) and the estimated numbers of users misclassified up to 4.3 (2.4%). However it would not affect the estimated proportion of regular smokers among self-reported non-users, who make the major contribution to bias in passive smoking studies, so we shall ignore this minor correction, which in any case is based on an assumption which is unverifiable in this study as cotinine levels cannot distinguish heavy passive smokers from very light smokers.

4.12 <u>Misclassification rates as a proportion of actual users and non-</u> users in the whole sample

Table 22 gives misclassification rates as a proportion of self-reported users and non-users. It is also of value to have estimates of the proportions of actual users and non-users that misclassified. are Based on the observed numbers of self-reported users (775) and non-users (1000) interviewed in the whole study, the data in Table 22, and the assumption that those analysed were representative of those interviewed, one can directly estimate that there were originally 782.1 actual users of which 3.2% failed to report their habits and that there were originally 992.9 actual non-users of which 1.8% claimed to use nicotine containing products. Of actual regular users (those with a cotinine of >100 ng/ml), the percent failing to report that they were users was 2.07%.

4.13 Sources of error in estimates of misclassification rates

It can be seen fairly readily that chemical analytical errors are unlikely to have had any material effect at all on the estimated misclassification rates. We have classified self-reported non-users of nicotine containing products as users if their cotinine exceeded 30 ng/ml and as regular users if their cotinine exceeded 100 ng/ml. From the pilot study, we have shown that for this sort of cotinine value, assays were reproducible to an average \pm 8%. From Table 16 it can be seen that even for the result, 87.8% ng/ml, proportionately closest to one of these cut-off points it would have needed an assay 14% higher to have changed its classification status, and for other results, at least a 24% change would have been needed.

One is on less certain ground as regards misclassification of users where the cut off point used was 3 ng/ml, since the pilot only measured down to 10 ng/ml, so no direct evidence of reproducibility is available. However, taking into account, the low reported consumption of the 4 people between 3 and 7.5 ng/ml, there is no real reason to doubt that the cut-off concealed some misclassified non-users with analytically erroneously high cotinine levels. Indeed, looking at Table 21 one has perhaps more reason to believe that 2 of the 4 self-reported users reclassified as non-users were really true users with an extremely low use.

A more important source of error in misclassification rates is sampling error. As the proportions (p) are small, the variance of log p can be approximated by 1/N where N is the

. ⁵ .

-42-

number misclassified. Based on the data in Table 25 one can then estimate the 95% confidence limits of the proportion of self-reported non-users who are really users as 1.60% - 3.84%, which the corresponding limits for the reverse misclassification are 0.85% - 6.06%.

4.14 <u>Spouse's smoking habits in relation to nicotine use and level of</u> misclassification

As we shall show elsewhere, the level of bias in studies of passive smoking and lung cancer depends not only on the extent of misclassification of smoking habits but also on (a) whether misclassification varies according to spouse's smoking habits and (b) the degree of concordance of the smoking habits of the husband and wife. Although this study was not able to provide any cotinine determinations to validate reports of spouse smoking (and it may be expected that those who misreport their own habits are more likely than others to misreport their spouse's) it can provide some information on both these issues.

Evidence on whether misclassification of users as non-users varies according to spouse's smoking habits is given in <u>Table</u> <u>23</u>, which is a reconstruction of data already provided in Table 12. It can been seen that the percentage misclassified varies little according to whether the subject has a smoking spouse (2.72%) or has not one (2.40%).

As shown in <u>Table 24</u> there is a strong concordance between spouse's smoking habits. The concordance ratio, calculated by the cross-product ratio from the 2 x 2 table, measures the

-43-

relative odds of a smoker marrying a smoker (rather than a non-smoker) to that of a non-smoker marrying a smoker. Whether the subject's habits are as reported or as estimated by his cotinine value, the estimated concordance is somewhat in excess of 3 and is similar for the two sexes.

4.15 <u>Comparison of smoking habits with the 1985 Annual Consumer</u> Survey

Imperial Tobacco were supplied with detailed tables giving the distribution of smoking habits recorded in the salivary cotinine study for comparison with the distribution recorded in the Annual Consumer Survey. Appendix G presents Mr.I.Brown's report on this comparison, As he notes, the results from the two studies were quite close given the different sample sizes and research methodologies. It should be noted that while the current study restricted attention to men and women aged 16-74, the Annual Consumer Survey concerns those aged 16+.

DISCUSSION

-45-

This study has provided a number of pieces of evidence consistent with the hypothesis that passive smoke exposure causes a detectable increase in the uptake of nicotine, as measured by salivary cotinine. One is the very marked increase, non-users of nicotine-containing products, of among the proportion married to smokers according to whether cotinine was or was not detected (27.2% vs. 10.9%). A second is the tendency for cotinine levels among non-users to be higher among those with more likely passive smoke exposure; thus relatively high levels were seen among those in the 16-24 age range (more going out to pubs and social functions), among lower social classes (probably both reasons) and among those aged 55-74 married to a smoker (more time at home in retirement). A third is the fact that all known sources of nicotine from active use were recorded and it is impossible to believe over 70% of reported non-users with non-zero cotinine levels were all actually surreptitious active users.

However, it is abundantly clear that average levels of cotinine from passive smoke exposure are some orders of magnitude lower those active of than from use Thus nicotine-containing products. the median level of even those reported non-users with positive cotinine was only 1 ng/ml, whereas that of reported users was 316 ng/ml. The relatively much larger effect of active than passive use on salivary cotinine levels is also consistent with the fact that

5.

no relationship of cotinine to spouse smoking (or to age, sex or social class) could be seen among self-reported users.

Given that on average passive smokers appear to have much lower levels than active users, how does one explain the observation that 11 of the 808 self-reported non-users had cotinine levels above 100 ng/ml, fully consistent with smokers' levels, and a further 9 had levels above 30 ng/ml? A number of possibilities have to be borne in mind. The one that can be rejected most easily is the possibility of chemical analytical error, since evidence from the pilot study showed that the assays at this level were reproducible to +8%. A second possibility is that a gross error has occurred in data processing or in matching the cotinine result to the interview We believe this possibility has been minimised by the data. complete checking which has been carried out of all the important data. A third possibility lies in variability, either in the extent of exposure to passive smoke or in the extent to which it is metabolised to cotinine. Our original inspection of the distribution of results (Table 10) made this seem unlikely. The main body of non-users with non-zero cotinine form an approximate log-normal distribution and it seemed very unlikely, on this basis, that most of those with cotinine >30 ng/ml formed a true upper tail.

However, there are a number of reasons why it is much more plausible that these self-reported non-users with cotinine values are in fact true users who have been misclassified. One is that it is well-known from other sources (see e.g. Todd,

-46-

1978, Journal of Epidemiology and Community Health, 32, 289-293) that cigarette consumption is underreported in surveys, and it is a priori reasonable to believe some smokers may not wish their habit to be known. A second is that no difference was found between self-reported non-users with cotinine values of 0.1-30 ng/ml and those with cotinine values of >30 ng/ml in the proportion married to a smoker. A third is that, whereas only 7/670 (1%) non-users with cotinine levels of <30 ng/ml were inconsistent on backcheck in their manufactured cigarette smoking habits, 3/18 (17%, p=0.003) of those with cotinine levels of >30 ng/ml were inconsistent. Indeed, one of the latter said at the reinterview that she did not want her husband to know she smokes! A fourth is that purely on statistical grounds, the self-reported non-users with cotinine values above 100 ng/ml fit in with being a true user much better than being as stated.

Based on these arguments and the detailed analyses in Section 4, it seems that by far the most plausible explanation of the distribution of cotinine values for self-reported non-users is that those with cotinine values above 30 ng/ml were in fact all or nearly all true users. Those with values above 100 ng/ml can be classed as true regular users, having levels fully consistent with average active users. Those with values betwen 30 and 100 ng/ml are perhaps more in the nature of true occasional users, having levels rather low for average users. It seems plausible that there are in fact a group of people who do smoke occasionally, but who do not really regard themselves

-47-

Indeed some of this group might have cotinine smokers. as levels lower than 30 ng/ml, where they would be indistinguishable from heavily exposed passive smokers. While, if included, they would add to the misclassification rates, they would have little or no effect on the estimated bias, due to their low exposure.

Evidence on the reverse misclassification from the study of self-reported users of nicotine-containing products is more equivocal. The numbers of subjects studied is smaller, the mix of nicotine-containing products claimed is quite varied and there is quite a long lower tail of users with low cotinine values, many of whom report only very occasional use. One statistical method suggested that 4 used of the 176 self-reported users (those with cotinines less than 3 ng/ml) were in fact true non-users. While 2 of these seemed reasonably certain (a claimed 30 a day cigarette smoker with zero cotinine and a claimed 8 a day cigarette smoker with cotinine 0.4 ng/ml), the others are less so (the only snuff only taker with cotinine 1.4 ng/ml and a l a day cigarette smoker with zero cotinine), and it is likely that the estimated proportion misclassified is unreliable. Furthermore the possibility that a small proportion of smokers might metabolise nicotine unusually with resultant low cotinine values, though perhaps not very plausible, should be borne in mind.

-48-

However, from the point of view of potential bias to the lung cancer/passive smoking association caused by smoking habit misclassification, coupled with husband/wife smoking concordance, having non-smokers claim they are smokers is of much less consequence than having smokers claim they are non-smokers. As will be demonstrated in detail elsewhere in a separate document, what is of most importance in this respect is misclassification of regular smokers as non-smokers. From this study, we estimate that 2.1% of actual regular current users fail to report that they are users. This is of course only part of the misclassification problem, which also involves categorising ex-regular smokers incorrectly as never smokers.

.

Failure to supply sample of saliva

Age group		Male	Female	Total
16-24		18/168 10.7%	11/117 9.4%	29/285 10.2%
25-34		17/178 9.6%	28/238 11.8%	45/416 10.8%
35-44		21/159 13.2%	29/210 13.8%	50/369 13.6%
45-54		11/105 10.5%	16/116 13.8%	27/221 12.2%
55-64		9/100 9.0%	25/156 16.0%	34/256 13.3%
65-74		26/132 19.7%	27/96 28.1%	53/228 23.2%
Trend C	hisq P	3.69 0.055	13.48 <0.001	15.75 <0.001
Total		102/842 12.1%	136/933 14.6%	238/1775 13.4%

. .

Observed and expected numbers of subjects with various characteristics by whether or not saliva sample supplied (standardised for age)

		les		males	****	bined
	Sample	<u>No sample</u>	Sample	<u>No sample</u>	Sample	<u>No sample</u>
Social cl	ass (C2DE	<u>;)</u>				
O E N Chisq P	445 456.4 740	75 63.6 102 5.82 <0.05	463 469.37 797	89 82.63 136 1.31 N.S.	908 925.8 1537	164 146.2 238 6.40 <0.05
Working s	status (Pa	rt-time or	unemploye	<u>d)</u>		
O E N Chisq P	288 289.3 740	48 46.7 102 0.05 N.S.	634 643.0 797	123 114.0 136 4.81 <0.05	922 932.3 1537	171 160.7 238 3.48 <0.1
No childr	en preser	nt in househ	old			
O E N Chisq P	436 439.1 740	67 63.9 102 0.50 N.S.	401 398.5 797	77 79.5 136 0.30 N.S.	837 837.6 1537	144 143.4 238 0.00 N.S.
Household	l size (4	or more)				
O E N Chisq P	286 281.4 740	31 35.6 102 1.00 N.S.	320 324.8 796	52 47.2 136 1.02 N.S.	606 606.3 1536	83 82.7 238 0.00 N.S.
Marital s	status (ev	ver married)	_			
O E N Chisq P	558 554.7 736	75 78.3 100 0.92 N.S.	694 692.0 796	120 122.0 136 0.26 N.S.	1252 1246.8 1532	195 200.2 236 1.34 N.S.

TABLE 2 (continued)

Observed and expected numbers of subjects with various characteristics by whether or not saliva sample supplied (standardised for age)

	<u>M</u> Sample	<u>ales</u> <u>No sample</u>		<u>nales</u> <u>No sample</u>	<u>Com</u> Sample	<u>bined</u> <u>No sample</u>
Smoker of	manufac	tured cigar	ettes			
O E N Chisq P	257 247.0 740	22 32.0 102 4.85 <0.05	312 304.6 797	42 49.4 136 1.81 N.S.	569 551.6 1537	64 81.4 238 6.37 <0.05
Spouse sm	oker of	manufacture	d cigarett	es		
O E N Chisq P	170 164.5 511	15 20.5 70 2.00 N.S.	186 190.9 565	35 30.1 94 1.12 N.S.	356 355.4 1076	50 50.6 164 0.00 N.S.
No other	person p	resent				
O E N Chisq P	404 415.1 710	69 57.9 99 5.48 <0.05	553 539.0 775	81 95.0 132 8.49 <0.01	957 954.2 1485	150 152.8 231 0.13 N.S.

Refusal to supply a sample of saliva by sex, age, manufactured cigarette smoking habits and presence of other person

		16-34	<u>Age</u> 35-54	55-74	Total
Male					
No man cigs	no others present	17/123 13.8%		25/113 22.1%	
	others present	7/75 9.3%	6/75 8.0%	7/62 11.3%	20/212 9.4%
Man cigs	no others present	6/64 9.4%	4/48 8.3%	2/34 5.9%	12/146 8.2%
	others present			1/16 6.3%	
Female					
No man cigs	no others present			27/137 19.7%	
	others present	17/80 21.3%	5/39 12.8%	9/24 37.5%	31/143 21.7%
Man cigs	no others present	4/87 4.6%		9/68 13.2%	
	others present	7/63 11.1%	9/55 16.4%	4/12 33.3%	20/130 15.4%

Self-reported smoking and chewing habits by sex

		<u>N</u>	<u>ale</u> <u>%</u>	<u>Fe</u> <u>N</u>	male <u>%</u>	<u>To</u> <u>N</u>	<u>tal</u> <u>%</u>
Int	erviewed	842	100.0	933	100.0	1775	100.0
Non	-smoker or nicotine user						
	Any	432	51.3	571	61.2	1003	56.5
A.	Did not report smoking in last 7 days	430	51.1	570	61.1	1000	56.3
Β.	Reported smoking in last 7 days	2	0.2	1	0.1	3	0.2
Smc	ker or nicotine user						
	Any	410	48.7	362	38.8	772	43.5
С.	Man cig smoker only	206	24.5	339	36.3	545	30.7
D.	Other product smoker only	127	15.1	8	0.9	135	7.6
E.	Man cig and other product smoker	70	8.3	15	1.6	85	4.8
F.	Nicotine user only	2	0.2	0	0.0	2	0.1
G.	Nicotine user and man cig smoker	2	0.2	0	0.0	2	0.1
H.	Nicotine user and other product smoker	2	0.2	0	0.0	2	0.1
I.	Man cig smoker, other product smoker and nicotine user	1	0.1	0	0.0	1	0.1

N.B. Other products = handrolled, pipe or cigar Nicotine user = user of chewing tobacco, nicotine chewing gum, tobacco "tea bags" or snuff

¢

·

•

Response rates by smoking habits

	<u>N</u>	ale <u>%</u>	<u>Fe</u> N	male %	<u>To</u> N	tal <u>%</u>
No reported smoking or nicotine use at all				_		_
Interviewed Sample provided Attempt to analyse Successful analysis	430 371 367 350	100.0 86.3 85.3 81.4	570 477 469 458	100.0 83.7 82.3 80.4	1000 848 836 808	100.0 84.8 83.6 80.8
Smokers of manufactured cigarettes only						
Interviewed Sample provided Attempt to analyse Successful analysis	206 188 52 50	100.0 91.3 25.2 24.3	339 298 68 66	100.0 87.9 20.1 19.5	545 486 120 116	100.0 89.2 22.0 21.3
Others						
Interviewed Sample provided Attempt to analyse Successful analysis	206 181 56 54	100.0 87.9 27.2 26.2	24 22 6 6	100.0 91.7 25.0 25.0	230 203 62 60	100.0 88.3 27.0 26.1
<u>All who reported smoking</u> or nićotine use at all						
Interviewed Sample provided Attempt to analyse Successful analysis	412 369 108 104	100.0 89.6 26.2 25.2	363 320 74 72	100.0 88.2 20.4 19.8	775 689 182 176	100.0 88.9 23.5 22.7
<u>All who reported use</u> of other nicotine products						
Interviewed Sample provided Attempt to analyse Successful analysis	7 6 4 4	100.0 85.7 57.1 57.1				

.

.

Success of backcheck

	Male		Female		Total	
	N	00	N	8	N	8
Interviewed originally	842	100.0	933	100.0	1775	100.0
Contacted	701	83.3	811	86.9	1512	85.2
Information obtained	698	82.9	801	85.9	1499	84.5
Information obtained from respondent	671	79.7	785	84.1	1456	82.0

۰

Manufactured cigarette smoking habits as originally reported (MCl) and as stated in the backcheck (MC2)

		<u>M</u> a	ale	Fen	nale	Tot	al
		<u>No</u>	<u>1C1</u> Yes	<u>No</u>	<u>IC1</u> Yes	<u>Mo</u>	<u>Yes</u>
Source of information	<u>MC2</u>						
Subject (by phone)	No	336	6	360	12	696	18
	Yes	14	137	9	211	23	348
Subject (personal)	No	96	6	110	4	206	10
	Yes	12	64	5	74	17	138
Subject - total	No	432	12	470	16	902	28
	Yes	26	201	14	285	40	486
Spouse etc	No	16	0	14	0	30	0
	Yes	0	9	0	1	0	10
All sources	No	448	12	484	16	932	28
	Yes	26	210	14	286	40	496

Discrepancy of manufactured cigarette smoking habits on backcheck by spouse manufactured smoking habits

	Male	Female	Total
Spouse man cig smokin	g		-
No	10/340	17/378	27/718
	2.9%	4.5%	3.8%
Yes	12/164	7/195	19/359
	7.3%	3.6%	5.3%
P	<0.05	N.S.	N.S.
Other persons present	at interview		
Spouse	4/163	1/49	5/212
	2.5%	2.0%	2.4%
Other	9/118	9/181	18/299
	7.6%	5.0%	6.0%
No one	25/386	20/548	45/934
	6.5%	3.6%	4.8%
p (Other + no one vs spouse)	<0.05	N.S.	<0.05

.

Salivary	Nicot	ine_user*	Non-	user
Cotinine (ng/ml)	Male	Female	Male	Female
0				
0	0	2	84	136
0.1-0.2	0	0	24	52
0.3-0.5	0	1	36	67
0.6-1.0	0	0	52	64
1.1-2.0	1	0	68	52
2.1-5.0	1	0	50	54
5.1-10.0	5	0	17	18
10.1-20.0	1	· 0	, 9	-4
20.1-50.0	6	1	2	3
50.1-100.0	4	2	2	3
100.1-200.0	9	11	1	0
200.1-500.0	53	44	5	5
>500.0	24	11	0	0
Ν	104	72	350	458
Median p (vs males)	319.2	310.6 N.S.	0.85	0.4 <0.001

Salivary cotinine by nicotine use

* Includes smokers, users of other nicotine containing products or non-smokers who report having smoked in the last 7 days

Frequ <u>%</u>	ency	
30		
29		
28		
27	220 xxx	
26	xxx xxx	
25	xxx xxx	
24	xxx xxx	
23	XXX XXX	
22	xxx	
	XXX XXX	
21	XXX XXX	
20	XXX XXX	
19	xxx xxx	
18	xxx xxx	
17	XXX XXX	
16	XXX XXX	
15	XXX XXX	
14	XXX XXX	
13	XXX XXX	97 96
12	XXX XXX	XXX XXX XXX XXX
11	xxx xxx	84 xxx xxx xxx xxx xxx 82
10	XXX XXX	XXX XXX XXX XXX XXX XXX XXX XXX XXX XX
9	XXX XXX	XXX XXX XXX XXX XXX XXX XXX XXX
8	XXX XXX	xxx 62 xxx xxx xxx xxx xxx xxx xxx
7	XXX XXX	xxx xxx xxx xxx 54 xxx xxx xxx xxx xxx xx
6	XXX XXX	XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX
5	××× ×××	XXX XXX XXX XXX XXX XXX 36
4	XXX	33 xxx xxx xxx xxx xxx xxx xxx xxx xxx
3	XXX XXX	XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX XXX
2	XXX XXX	xxx xxx xxx xxx xxx xxx xxx xxx 16 xxx xxx xxx xxx xxx xxx xxx xxx xxx xx
1	XXX XXX	xxx xxx xxx xxx xxx xxx xxx xxx xxx 7 xxx xxx
0_		
	-3 -2	-2 -1 0 1 2 3 4 5 6 7 2.5 -1.5 -0.5 0.5 1.5 2.5 3.5 4.5 5.5 6.5
		log _e (cotinine + 0.05)

Histogram of $\log_{e}(\text{cotinine} + 0.05)$ values for self-reported non-users of other nicotine containing products

,
TABLE 10 (continued)

Histogram of log_e(cotinine + 0.05) values for self-reported users of nicotine containing products

29 28 27 26 25 24 23 22 21 20 19 31 16 311 15 311 16 311 17 311 18 311 10 311 11 311 12 311 13 311 14 311 15 311 16 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311 3 311	54
29 28 27 26 25 24 23 21 20 19 18 31 17 XXX 18 31 17 XXX 18 31 17 XXX 18 31 17 XXX 18 31 19 XXX 14 XXX 15 XXX 16 XXX 17 XXX 18 31 19 XXX 14 XXX XXX XXX 10 XXX XXX XXX 3 XXX XXX XXX </td <td>XXX</td>	XXX
29 28 27 26 25 24 23 22 21 20 19 31 16 31 15 31 16 31 17 32 18 31 16 31 17 32 18 31 19 3 16 31 3 31 3 32 3 32 3 32 3 32 3 32 3 32 3 32 3 32 3 32 3 32 3 32 3 32 3 32 3 32 3 32 3 32 3 32 3 32 3 32 33 32 3	52 xxx
28 27 26 25 24 23 22 21 20 31 19 31 16 31 17 31 18 31 17 31 18 31 17 31 18 31 17 31 18 31 19 31 10 31 3 31 7 11 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 <	XX XXX XX XXX
27 26 25 24 23 21 20 19 18 17 18 16 21 21 22 21 20 19 18 3 3 3 3 3 3 3 2 2 3 3 3 2 2 2 2 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	XX XXX
27 26 25 24 23 22 21 20 19 31 16 31 15 31 16 31 17 31 18 31 19 31 16 31 17 31 18 31 19 31 10 31 3 31 7 11 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 3 31 <t< td=""><td>XXX XXX XXX XXX</td></t<>	XXX XXX XXX XXX
26 25 24 23 22 21 20 3 19 31 16 31 15 3 14 3 15 3 16 3 17 3 18 31 17 3 18 31 17 3 18 31 19 3 10 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3 20 3	XX XXX
25 24 23 22 21 20 19 31 18 31 17 XXX 16 XXX 15 XXX 14 XXX 15 XXX 16 XXX 17 XXX 18 31 16 XXX XXX XXX 13 XXX 10 XXX XXX XXX 9 XXX 4 XXX 5 XXX 4 XXX 2 3 2 XXX 2	XX XXX
24 23 22 21 20 19 18 16 XXX 15 XXX 14 XXX 13 XXX 10 XXX 7 11 XXX 7 11 XXX	XXX XXX XXX XXX
24 23 22 21 20 19 18 31 16 31 15 31 14 31 15 31 16 32 34 35 36 36 37 37 38 311 32 32 33 34 35 35 36 37 37 38 33 34 35 35 36 37 37 37 38 39 310 311 32 33 34 35 36 37 37 38 39 310 311 32 33 34 34 35 34 35	XX XXX
23 22 21 20 19 18 31 17 XXX 16 XXX 15 XXX 14 XXX 13 XXX 10 XXX 7 11 6 XXX 7 11 6 XXX 7 11 2 XXX 3 XXX 3 XXX 2 XXX 2 XXX	XX XXX XXX XXX
22 21 20 19 18 31 17 xxx 16 xxx 15 xxx 14 xxx 13 xxx 10 xxx 7 11 6 xxx 7 11 6 xxx 7 11 6 xxx 7 11 7 11 2 3 3 xxx 3 xxx <t< td=""><td>xxx xxx</td></t<>	xxx xxx
22 21 20 19 18 311 17 XXX 16 XXX 15 XXX 14 XXX 13 XXX 10 XXX 9 XXX 10 XXX 7 11 6 XXX 7 11 6 XXX 7 11 2 3 XXX XXX 3 XXX 3 XXX 2 XXX	XXX XXX XXX XXX
21 20 19 31 18 31 17 xxx 16 xxx 15 xxx 14 xxx 13 xxx 10 xxx 7 11 6 xxx 7 11 10 xxx xxx xxx 6 xxx 5 xxx 4 xxx 5 xxx 3 xxx 3 xxx 2 3 xxx 2	XX XXX
20 19 18 31 17 XXX 16 XXX 15 XXX 14 XXX 13 XXX 14 XXX 15 XXX 16 XXX 17 XXX 18 XXX 19 XXX 10 XXX XXX XXX 7 11 XXX XXX 7 11 XXX XXX 7 11 XXX XXX 7 11 XXX XXX XXX XXX XXX XXX XXX XXX 4 XXX XXX XXX 3	XXX XXX
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	XX XXX XX XXX
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	XXX XXX
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	(XX XXX (XX XXX
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	XX XXX
16 xxx x 15 xxx x 14 xxx x 13 xxx x 12 xxx x 11 xxx x 10 xxx x 7 11 6 xxx x 7 11 6 xxx x 7 11 6 xxx x 7 11 2 3 2 xx x 3 xxx x 2 xx x 3 xxx 2	XX XXX XX XXX
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	XX XXX
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	
14 xxx x 13 xxx x 12 xxx x 11 xxx x 10 xxx x 9 xxx x 7 111 xxx x 6 xxx x 5 xxx x 4 xxx x 5 xxx x 3 xxx x 2 xxx 2	
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	XXX XXX
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	XX XXX
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	XXX XXX
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	(XX XXX (XX XXX
$\begin{array}{c} 10 \\ 10 \\ 2 \\ 3 \\ 2 \\ 2 \\ 2 \\ 2 \\ 2 \\ 2 \\ 2 \\ 2$	XX XXX
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	XX XXX
9 xxx 8 xxx 7 11 6 xxx 5 xxx 4 xxx 5 xxx 3 xxx 2 xxx 2 xxx	
$\begin{array}{c} & & & & & & & & & & & & & & & & & & &$	XXX XXX
8 xxx x 7 11 xxx x 6 xxx xxx x 5 xxx xxx x 4 xxx xxx x 3 xxx xxx xxx xxx xxx xxx xxx xxx xxx x	(XX XXX (XX XXX
7 11 xxx 6 xxx xxx 5 xxx xxx 4 xxx xxx 3 xxx xxx 2 3 2 xxx 2	(XX XXX
6 XXX XXX X 5 XXX XXX X 4 XXX XXX X 3 XXX XXX X 3 XXX XXX X 2 XXX X XXX X 2 XXX X X XXX XXX XXX XXX XXX XXX XXX X	
5 xxx xxx	
5 xxx xxx xxx xxx xxx xxx xxx xxx xxx x	
4 xxx xxx 5 xxx xxx 3 xxx xxx xxx 2 3 xxx 2 xxx 2 xxx 2 xxx xxx 2 xxx 2 xxx 2 xxx 2 xxx xxx xxx 2 xxx 2 xxx 2 xxx 2 xxx xxx xxx xxx xxx	
5 xxx xxx 3 xxx xxx xxx 2 3 xxx 3 2 xxx 2 xxx xxx	xxx xxx
3 xxx	
2 XXX XXX XXX XXX 2 3 XXX 3 XXX XXX 2 XXX 2 XXX 2 XXX XXX XXX	XXX XXX XXX
2 xxx 2 xxx 2 xxx xxx xxx	XXX XXX XXX
	<pre>xxx xxx xxx xxx xxx xxx</pre>
1 xxx 1 1 1 1 xxx xxx 1 xxx xxx xxx xxx	xxx xxx xxx 1
xxx 0 0 0 xxx 0 xxx 0 xxx xxx xxx xxx x	(XX XXX XXX XXX
-3 -2 -1 0 1 2 3 4 5	6 7 .5 6.5

	<u>N</u>	8			
Cut-off point(ng/ml)	Non-users below	Users below	Non-users above	Users above	* Correctly <u>allocated</u>
0.05	220	2	588	174	58.5
0.95	496	3	312	173	77.5
4.95	737	5	71	171	93.8
10.75	774	10	34	166	95.1
11.25	775	10	33	166	95.2
11.75	776	10	32	166	95.3
11.85	777	10	31	166	95.4
11.95	778	10	30	166	95.4
12.05	779	10	29	166	95.5
12.75	780	10	28	166	95.6
12.85	782	10	26	166	95.7
13.65	783	10	25	166	95.8
14.55	784	10	24	166	95.8
15.55	784	11	24	165	95.6
18.15	785	11	23	165	95.7
19.35	786	11	22	165	95.7
20.65	787	11	21	165	95.8
20.85	787	12	21	164	95.6
23.05	787	13 ·	21	163	95.3
24.55	788	13	20	163	95.4
29.35	788	14	20	162	95.1
32,35	788	15	20	161	94.9
34.75	788	16	20	160	94.6
38.85	788	17	20	159	94.4
40.45	789	17	19	159	94.5
46.25	790	17	18	159	94.5
46.55	791	17	17	159	94.6
47.55	792	17	16	159	94.7
56.35	792	18	16	158	94.4
58.15	793	18	15	158	94.5
63.25	794	. 18	14	158	94.6
71.35	795	' 18 ·	13	158	94.6
80.65	795	20	13	156	94.1
87.75	796	20	12	156	94.2
89.35	797	20	11	156	94.3
99.95	797	24	11	152	93.3
199.95	798	44	10	132	88.4
399.95	806	114	2	62	71.6
799.95	808	174	0	2	56.8

Discriminating nicotine users and non-users by cotinine value

*

Weighted to original distribution of users (775) and non-users (1000).

Cotinine level by spouse smoking habits among self-reported non-users of nicotine containing products

	Group	Range of cotinine (<u>ng/ml</u>)	Numb Total	per of subjects Married to smoker	00
Male	A B C D	0 0.1 - 23.1 38.9 - 87.8 132.2 - 473.3	84 256 4 6	1 55 1 1	1.2 21.5 25.0 16.7
			350	58	16.6
Female	A B C D	0 0.1 - 23.1 38.9 - 87.8 132.2 - 473.3	136 312 5 5 458	23 100 2 1 	16.9 32.1 40.0 20.0 27.5

Median cotinine level

	Not married to smoker	Married to smoker	P
Male	0.6	2.9	<0.001
Female	0.3	1.0	<0.001
Total	0.4	1.5	<0.001
Difference between sexes	p<0.01	p<0.001	

Median cotinine level (ng/ml) by various demographic characteristics among self-reported non-users of nicotine containing products

	Not married	Not married to a smoker		o a smoker	
	Male	Female	Male	Female	Total
Age 16-24 25-34 35-44 45-54 55-64 65-74	1.5 0.6 0.65 0.35 0.25 0.05	1.1 0.2 0.2 0.4 0.3 0.2	4.4 2.3 1.75 1.9 4.0 3.85	0.95 0.55 1.1 1.1 2.95 2.0	
Overall p Trend p		<0.001 <0.01	N.S. N.S.	N.S. <0.1	<0.001 <0.001
<u>Social class</u> AB Cl C2 DE	0.3 0.7 0.7 0.85	0.2 0.3 0.3 0.45	1.05 2.65 2.1 4.4	0.5 0.7 0.95 1.25	
Overall p Trend p		<0.1 <0.05	<0.05 <0.01	N.S. <0.05	<0.001 <0.001
<u>Working stat</u> Full time Part time Non-working	<u>us</u> 0.6 (0.0) 0.5	0.6 0.3 0.2	2.3 - 3.5	0.7 1.4 0.95	·
Overall p Trend p	N.S. N.S.	<0.01 <0.01	N.S. N.S.	N.S. N.S.	N.S. N.S.
<u>Household si</u> One Two Three Four Five or more	1.1 0.3 0.6 0.6	0.5 0.3 0.25 0.2 0.3	4.2 2.5 1.9 3.0	0.7 0.6 1.15 1.35	
Overall p Trend p		N.S. N.S.	N.S. N.S.	N.S. N.S.	N.S. N.S.

TABLE 13 (continued)

Median cotinine level (ng/ml) by various demographic characteristics among self-reported non-users of nicotine containing products

		Not married to a smoker		Married t	Married to a smoker		
		Male	Female	Male	Female	Total	
Marital st Single Married Widowed/ separated or divord	d	1.2 0.4 0.65	0.8 0.2 0.4				
Overall	р	<0.001	<0.01			<0.001	

,

		Cot	inine group	
	A	<u>B</u>	<u><u><u>C</u></u></u>	D
	0 ng/ml	0.1-23.1 	38.9-87.8 ng/ml	132.2-473.3 ng/ml
<u>Male</u> Total	100.0(84)	100.0(235)	100.0(5)	100.0(7)
Age 16-24	8.3(7)	23.0(59)	60.0(3)	14.3(1)
Social class DE AB	23.8(20) 25.0(21)	29.7(76) 14.8(38)	20.0(1) 20.0(1)	28.6(2) 14.3(1)
<u>Female</u> Total	100.0(136)	100.0(312)	100.0(5)	100.0(5)
Age 16-24	2.9(4)	13.5(42)	20.0(1)	0.0(0)
Social class DE AB	17.6(24) 24.3(33)	23.7(74) 16.7(52)	40.0(2) 0.0(0)	40.0(2) 0.0(0)

Percentage (number) with various demographic characteristics by cotinine group among self-reported non-users of nicotine containing products

Percentage (number) with other people present by cotinine group among self-reported non-users of nicotine containing products

	Cotinine group							
	A	<u>B</u>	<u>C</u>	D				
	0 <u>ng/ml</u>	0.1-23.1 ng/ml	38.9-87.8 	132.2-473.3 ng/ml				
Male								
Total	100.0(81)	100.0(241)	100.0(4)	100.0(5)				
Other people present	37.0(30)	41.5(100)	50.0(2)	100.0(5)				
<u>Female</u> Total	100.0(131)	100.0(301)	100.0(5)	100.0(5)				

24.4(32) 24.6(74)

20.0(1)

20.Ó(1)

NP	192	2
Р	13 0	7

Other people

present

S 326 NP 2 106 P

Self-reported non-users of nicotine containing products with high cotinine values

Cotinine (ng/ml)	Sex	Spouse smoked	Other people present	Backcheck on MC	Age	Social <u>class</u>
10.8	М	_	No	-	25-34	DE
11.3	M	No	Spouse	No	65-74	C1
11.8	F	Cigar	Spouse	No	35-44	C1
11.9	M	MC	Spouse .	No	65-74	C2
12.0	F	MC	Spouse	-	25-34	C2
12.1	м М	MC	Other	No	35-44	DE
12.8	M		No	No	16-24	DE
12.8	F	MC+HR	No	-	35-44	C2
12.9	М	MC	No	No	25 - 34	C2
13.7	М	MC	No	No	25-34	C2
15.6	М	-	No	No	25-34	DE
18.2	М	-	-	No	25-34	AB
19.4	F	MC	Spouse	No	35-44	DE
23.1	F	MC	No	No	25-34	C2
	·					
38.9	М	-	Other	-	16-24	DE
40.5	F	No	No	Yes	35-44	DE
46.3	М	-	No	No	16-24	C1
46.6	\mathbf{F}	HR+Cigar	No	No	35-44	DE
56.4	F	MC 😚	Other	No	25-34	C1
58.2	М		Other	No	16-24	AB
63.3	М	MC ·	No	No	55-64	C2
80.7	F	-	No	No	16-24	C2
87.8	F	No	No	No	25-34	C2
132.2	М	_	Other	No	16 - 24	DE
201.8	M	No	-	No	45-54	C1
220.1	M	No	Spouse	Ňo	35-44	C1
239.7	M	No	Other	No	25-34	AB
268.2	F	No	Other	No	25-34	DE
274.5	F	No	No	No	45-54	C1
282.2	F	No	No	Yes	45-54	C2
307.6	M	MC ·	Spouse	No	35-44	C1
361.7	F	MC ·	No		25-34	C1
416.3	F	No	No	Yes	65-74	DE
473.5	Ñ	No	Spouse	No	35-44	DE

Salivary cotinine by type of product smoked (for non-users of other nicotine containing products)

	N	<20		50.1-	inine (100.1- 200.0	200.1-	>500.0	Median
Males	_	<u> </u>						<u></u>
Manufactured cigarette only	s 50	1	3	3	4	32	7	285.6
Other products only Handrolled only Pipe only Cigar only Mixed	33 16 3 9 5	6 0 0 5 1	2 0 1 1 0	1 0 0 1 0	3 2 0 0 1	10 6 2 2 0	11 8 0 0 3	351.7 510.6 360.0 9.9 612.7
Man.cigs + other products Man.cigs + handrolled only Other mixed smokers	17 10 7	0 0 0	1 1 0	0 0 0	2 2 0	8 5 3	6 2 4	389.9 365.7 531.4
A11	100	7	.6	4	9	50	24	328.7
Females								
Manufactured cigarette only	s 66	3	0	1	10	41	11	327.3
Handrolled only	3	0	1	0	0	2.	0	234.9
Man.cigs + handrolled only	2	0	0	0	1	1	0	238.0
A11	71	3	1	1	11	44	11	311.3

N.B. No cotinine determinations were available for female pipe or cigar smokers.

Salivary cotinine by number of cigarettes smoked among smokers of manufactured cigarettes only

Salivary		Number	of man cig	s per day	
Cotinine (ng/ml)	<u>1-12</u>	13-17	<u>18-22</u>	<u>23+</u>	Trend
Male					
20.1-50.0 50.1-100.0 100.1-200.0 200.1-500.0 >500	2 2 7 3	0 0 1 7 1	0 0 1 8 2	1 1 0 7 1	
N Median P	16 249.1	9 239.8	11 396.8	10 292.2	N.S.
Female					
<20 20.1-50.0 50.1-100.0 100.1-200.0 200.1-500.0 >500	2 0 4 12 0	0 0 3 5 1	0 0 1 15 6	1 0 1 7 4	
N Median P	18 290.9	9 258.1	22 431.6	13 386.7	<0.01
Combined					
N Median P	34 282.0	18 240.4	33 416.8	23 318.4	<0.01

,

Dotoile	of	thora	turbo	1100	othor	nigotino	containing	producte
Decalls	ΟL	LIIUSE	WIIO	use	other	TITCOCTUE-	Concarning	produces

Habit	Sex	Salivary cotinine (ng/ml)	Smoking*	Age	Social class
Chewing tobacco Snuff Teabags	M M M		15MC 6HR 30HR	35-44 65-74 25-34	Cl Cl DE
Nicotine gum and chewing tobacco Nicotine gum Nicotine gum Snuff	M M M M	437.0 289.9 223.4 1.4	5MC 20MC+?HR None None	55-64 15-24 25-34 25-34	C2 C2 AB C2

* MC = manufactured cigarttes, HR = handrolled cigarettes, ? = quantity not stated.

,

.

Median cotinine level (ng/ml) by various factors among smokers of manufactured cigarettes only

	Males	Females	Combined	N
<u>Spouse smoking</u> Yes No	277.6 318.4	344.0 317.7	303.4 318.2	53 63
Р	N.S.	N.S.	N.S.	
<u>Age</u> 16-24 25-34 35-44 45-54 55-64 65-74	337.3 300.8 259.3 259.2 539.9 303.0	317.1 311.3 440.3 278.7 170.2 363.7	326.8 311.3 389.7 262.6 171.9 346.8	24 33 28 14 8 9
Overall p Trend p	N.S. N.S.	<0.05 N.S.	N.S. N.S.	·
<u>Social class</u> AB C1 C2 DE Overall p Trend p	318.4 242.7 330.3 293.5 N.S. N.S.	450.7 309.9 336.4 307.4 N.S. N.S.	393.7 306.1 336.4 303.0 N.S. N.S.	13 23 35 45
<u>Working status</u> Full time Part time Non-working Overall p	298.0 (427.1) 249.2 N.S.	301.9 368.8 318.2 N.S.	301.9 368.8 303.4 N.S.	44 21 51
Trend p Household size	N.S.	N.S.	N.S.	
One Two Three Four Five or more	405.6 303.0 239.8 232.6 252.6	302.5 278.7 336.4 312.2 414.6	385.3 290.9 310.6 285.6 389.5	12 18 30 34 22
Overall p Trend p	N.S. N.S.	N.S. N.S.	N . S . N . S .	

TABLE 20 (continued)

Median cotinine level (ng/ml) by various factors among smokers of manufactured cigarettes only

	Males	Females	Combined	N
Marital status				
Single	370.4	309.9	350.6	25
Married	246.6	336.4	303.3	80
Widowed/separated or				
divorced	396.8	329.1	354.9	11
Overall p	N.S.	N.S.	N.S.	
Other people at interview				
Nobody	393.5	317.7	341.6	62
Spouse	239.5	419.1	277.6	21
Other person	293.5	311.3	310.6	30
Overall p	N.S.	N.S.	N.S.	

Cotinine (ng/ml)	Sex	Smoking* habits	Other nicotine	Backcheck on MC
(<u></u>		
0 [,]	F	MC1		No (Inconsistent)
0	F	MC30		Yes
Q.4	F	MC8		Yes
1.4	М		Snuff	-
4.3	М	Cigars 4		No
5:6	М	Cigars 1		No
6.3	М	Cigars 2		No
7.2	М	Cigars 4		No
8.5	М	Pipe 4oz,		No
•		Cigars 10		
9.9	М	Cigars 3		No
14.6	М	MC?		Yes
20:7	М	Pipe 25gr		No
20.9	М	MC10		Yes
24.6	М	MC2,HR2		Yes
29.4	М	MC25		Yes
32.4	М	Cigar?		No
34.8	М	MC5		Yes
47.6	F	HR20		No
71.4	М	MC7		-
71.4	М	MC30		Yes
89.4	М	MC6		Yes
92.8	\mathbf{F}	Non-smoker,31	1C	No
		last 7 days		
93.1	F	MC?		Yes
98.2	М	Cigarl		No

Self-reported users of nicotine-containing products with low cotinine values

* MC = manufactured cigarettes, HR = handrolled cigarettes, ? = amount not stated Quantity per day for cigarette smoking, per week for pipe and cigar smoking.

Self-reported non-users of nicotine containing products who have high cotinine levels by spouse smoking habits

	-	ouse a noker	•	ise not smoker	Unmarried		
True habits	Ν	90	N	S	N	8	
Total	184	100.00	416	100.00	208	100.00	
1. Non-user	179	97.28	406	97.60	203	97.60	
a. No passive exposure	24	13.04	149	35.82	47	22.60	
b. Passive exposure	155	84.24	257	61.78	156	75.00	
2. User	5	2.72	10	2.40	5	2.40	
a. Occasional user	3	1.63	2	0.48	4	1.92	
b. Regular user	2	1.09	8	1.92	1	0.48	

Estimated misclassification rates

Observed habits	<u>True habits/criteria</u>	\underline{N}	%
Non-user of nicotine containing products	Total	808	100.00
0 1	1. Non-user (<30ng/ml)	788	97.52
	a. No passive exposure (Ong/ml)	220	
	b. Passive exposure (0.1-30ng/ml)	568	70.30
	2. User (>30ng/ml)	20	2.48
	a. Occasional user (30-100ng/ml)	9	1.11
	b. Regular user (≥100ng/m1)	11	1.36
User of nicotine	Total	176	100.00
containing products	1. User (>3ng/ml)	172	97.73
	a. Regular user (>100ng/ml)	152	
	b. Occasional user (30-100ng/ml)	9	5.11
	c. Very occasional user (3-30ng/m	1) 11	6.25
	2. Non-user (<3ng/ml)	4	2.27
Total	Total	984	100.00
10041	1. Correctly classified	960	100.00 97.56
	2. Incorrectly classified	24	2.44
	2		,

· · ·

Concordance of spouse's smoking habits with (a) the subject's self-reported smoking habits (b) the subject's cotinine value (Married subjects only)

	Mal Spouse Non Smoker	es Spouse Smoker	Fema Spouse Non Smoker	ales Spouse Smoker	M.	+ l'
<u>Subject's habits</u> Non smoker Smoker	244 144	66 127	270 80	156 157	514 22-e	222 284
Concordance ratio	3.	.26	3	. 40		
Salivary cotinine < 30 ng/ml > 30 ng/ml	192 30	60 31	221 20	124 39		
Concordance ratio	3.	. 31	3	.48		
< 100 ng/ml > 100 ng/ml	193 29	64 27	223 18	127 36		
Concordance ratio	2	.81	3	.51		

APPENDIX A

Sampling points used in main study

UPMINSTER	CANNOCK
CHINGFORD	STRATFORD
PUTNEY	STOKE ON TRENT
BATTERSEA	MACCLESFIELD
EALING	BURY
BRENT	ECCLES
BASINGSTOKE	LIVERPOOL
HAVANT	WALLASEY
BEXHILL & BATTLE	SWANSEA
MAIDSTONE	CARDIFF
FOLKESTONE	SHEFFIELD
BOURNEMOUTH	LEEDS
BEDFORDSHIRE SOUTH WEST	BARNSLEY
BRISTOL	HUDDERSFIELD
DEVIZES	DARLINGTON
SOMERSET & FROME	NEWCASTLE UPON TYNE
GRANTHAM	TAYSIDE
NORWICH	MIDLOTHIAN
NORFOLK NORTH EAST	GLASGOW
BOSWORTH	STRATHKELVIN

APPENDIX B

Dr. Francis J. C. Roe D.M.(Oxon.), D.Sc.(Lond.), F.R.C.Path Consultant in Toxicology and Adviser in Experimental Pathology

VAT Reg. No. 216 7350 73

Office and Home:

19 Marryat Road Wimbledon Common London SW19 5BB Telephone:

> Office (01) 947 9171 Home (01) 946 4518

FJCR/WG

September 1985

Dear Sir or Madam,

Life-style and appetite survey

As its title indicates, this survey is concerned with life-style, well-being and appetite and not with any aspect of health. In the normal way, it would not be necessary for a physician, such as myself, to be involved in the conduct of such a survey. However, it occurred to the scientists who planned the study that some of the 1,000 or so persons to be interviewed might be worried when, at the end of the questioning, the interviewer asks them for a sample of saliva. The purpose of this letter is simply to confirm that the measurements to be made on the sample of saliva relate to life-style and appetite and not to any aspect of health.

The normal procedure with surveys of this kind is to regard both the information provided in answers to questions and the results of the measurements made on the specimen of saliva as strictly confidential. This procedure will be followed in the case of the present survey. Furthermore, as soon as the results of the survey have been analysed, all the records of actual interviews will be destroyed.

Thank you very much for agreeing to take part in the survey and thereby contributing to scientific knowledge.

Yours sincerely,

Vrameis JZ love

Francis J.C. Roe

00

UK Salivary Crhinine Streety

APPENDIX C

Questionnaire used in main study

LIFE-STILE AND APPETITE SURVEY

					OFFI	CE USE (DNLY		
"S NAME SS/MS)			Γ	JN		41	29	(1-4)	
"S "SS				SERIAL NO			•	(5-8)	
· · · · · · · · · · · · · · · · · · ·	<u></u>			CARD NO	1			(9)	
NO. (IF ANY)					•	D _		м	
ITERVIEW				_	(10)	(11)	(12)	
IVIEW STARTED	•								
WIEW ENDED		-	L		<u></u>				
INTERVIEW	<u></u>			(13)		b)			
WRITE IN NUMBER OF MINUTES; IF LESS THAN 10, ENTER LEADIN	IG ZERO					4)	ainu	tes	
IR'S NAME				RVIEWER'S Umber	(15)	(16)	(17)	(18)	(19)
							<u> </u>	<u> </u>	
OF RESPONDENT	(20)	(4)	RESPONDENT	WORKING ST	TATUS				(23)
MALE . Female	1 2				LL TIME (-			1 2
SPONDENT AGE GROUP	(21)						ION-WORX		3
25 - 34	2	(e)	PRESENCE O	F CHILDREN	IN HOUS	HOLD			(24)
35 - 44 45 - 54	3				CHILDRE			1	1
55 - 64 65 - 74	5 6			NO	CHILDRE	N AGED	IS OR UN	IDEX	
TIAL CLASS ITE IN FULL DETAILS OF:- AB	(22) 1	(٢)	HOUSEHOLD How many p	<u>SIZE</u> eople are	there in	your he	ousehold	1,	(25)
) OCCUPATION C1	2		including	yourself a	nd any c	ildren	:	ONE	1
C2	3						T	TWO	2 · 3
DE	14						. 1	FOUR	4
L) INDUSTRY				<u></u>		· F.	IVE OR 1	ICRE	5
WIDOW OR RETIRED CLASSIFY BELOW									
WIDOW WITH WIDOW'S PENSION ONLY	c								
WITH PRIVATE MEANS (E.G. husband's pension) SPECIFY HUSBAND'S FORMER OCCUPATION ABOVE)	D								
RETIRED MAN OR WOMAN WITH STATE RETIREMENT Pension <u>only</u>	ε								
RETIRED MAN OR WOMAN WITH STATE RETIREMENT PENSION AND OCCUPATIONAL PENSION (SPECIFY PREVIOUS OCCUPATION ABOVE)	F								

.

•

w, some questions about your drinking of tea and coffee and other drinks.	CODE	ROUTE
w many cups of tea did you drink yesterday ?	(26)	
NONE	O	
ONE	• 1	
T40	2	
THREE	3	
FOUR	4	
FIVE OR MORE		
nd how many cups of coffee yesterday ?	(27)	
NONE	ر ب	1
ONE	1	
TWO	2	
THREE	-	
FOUR	4	
FIVE OR MORE	5	
		-
ow many pints of milk did you drink yesterday, including milk taken with tea or coffee	(25)	
r with breakfast cereals as well as the amount you drank on its own ?		
NONE AT ALL	0	
LESS THAN 1 PINT	1	
1 PINT, BUT LESS THAN 2	2	
. 2 PINTS OR MORE	3	
an aran times dunted the last 7 days have you double double dutes 0	(20)	
ow many times during the last 7 days have you drunk fruit juice ? NOME AT ALL	(29)	9.5
		-1,,
ONCE	1)
TWICE	2	\ (a)
THREE TIMES OR MORE	3	J
F ONCE OR MORE, ASK		-
a) Was the fruit juice generally natural, generally sweetened, or sometimes natural	(30)	
and sometimes sweetened ?		
GENERALLY NATURAL	1	
•	1	
GENERALLY SWEETENED	2	
GENERALLY SWEETENED SOMETIMES NATURAL AND SOMETIMES SWEETENED	2 3	
SOMETIMES NATURAL AND SOMETIMES SWEETENED		
·	3	
SOMETIMES NATURAL AND SOMETIMES SWEETENED	3	
SOMETIMES NATURAL AND SOMETIMES SWEETENED Now for some questions on various kinds of food. Now many times during the last 7 days have you eaten carrots ? NONE	3 (31) 0	
SOMETIMES NATURAL AND SOMETIMES SWEETENED Now for some questions on various kinds of food. Now many times during the last 7 days have you eaten carrots ? NONE ONCE	3 (31) 0 1	
SOMETIMES NATURAL AND SOMETIMES SWEETENED Now for some questions on various kinds of food. Now many times during the last 7 days have you eaten carrots ? NONE TWICE	3 (31) 0 1 2	
SOMETIMES NATURAL AND SOMETIMES SWEETENED Now for some questions on various kinds of food. Now many times during the last 7 days have you eaten carrots ? NONE ONCE	3 (31) 0 1	
SOMETIMES NATURAL AND SOMETIMES SWEETENED Now for some questions on various kinds of food. Now many times during the last 7 days have you eaten carrots ? NONE ONCE TWICE THREE TIMES OR MORE	3 (31) 0 1 2	-
SOMETIMES NATURAL AND SOMETIMES SWEETENED Now for some questions on various kinds of food. Now many times during the last 7 days have you eaten carrots ? NONE TWICE	3 (31) 0 1 2 3	
SOMETIMES NATURAL AND SOMETIMES SWEETENED Now for some questions on various kinds of food. Now many times during the last 7 days have you eaten carrots ? NONE ONCE TWICE THREE TIMES OR MORE Now many times during the last 7 days have you eaten spinach ?	3 (31) 0 1 2 3 (32)	-
SOMETIMES NATURAL AND SOMETIMES SWEETENED Now for some questions on various kinds of food. Now many times during the last 7 days have you eaten carrots ? NONE THREE TIMES OR MORE Now many times during the last 7 days have you eaten spinach ? NONE	3 (31) 0 1 2 3 (32) 0	-

how many times during the last 7 days have you eaten any other kinds of	CODE	ROUTE
en vegetables ?	(33)	
NONE	υ	{
ONCE OR TWICE	1	
THREE OR FOUR TIMES	2	
FIVE OR SIX TIMES	.3	
SEVEN TIMES OF MORE	· •	:
a many times during the last 7 days have you eaten fish, including shell-fish ?	(34)	—
NONE	э.	
ONCE	3	
TWICE	:	
THREE TIMES OR MORE	٤	
w many times during the last 7 days have you eaten liver, excluding liver pate	(35)	
d liver sausage ? NONE	L.	
ONCE	1	
TWICE	2	
THREE TIMES OR MORE	3	
d how many times during the last 7 days have you eaten any kind of curried food ?	(36)	
NONE	د د	
ONCE	t	
TWICE	2	
THREE TIMES OR MORE	3	Gü

Now I would like to ask you about some things which might leave a taste in the mouth or affect the taste of the food that you eat.

SHOW CARD

Now, thinking of the last 7 days, have you ... READ OUT FOR EACH STATEMENT

DUT FOR EACH STATEMENT	NO	YES
		(37)
Eaten PICKLED ONIONS	N	1
- Eaten OTHER RAW ONIONS	N	2
. Eaten COOKED ONIONS	N	3
Eaten GARLIC	N	4
Eaten MUSTARD	N	5
Eaten HORSERADISH	N	6
Chewed ORDINARY SPEARMINT CHEWING GUM	N	7
Chewed BUBBLEGUM	N	3
Chewed NICOTINE CHEWING GUM	N	Э
Chewed OTHER FLAVOURED CHEWING GUM	N	υ
Chewed CHEWING TOBACCO	ĸ	x
Chewed or sucked TOBACCO "TEA BAGS" (SKOAL BANDITS)	N	A
		(38)
Used MOUTH FRESHENER DROPS SUCH AS GOLD SPOT	N	1
Used MOUTHWASHES SUCH AS LISTERINE	N	2
Taken CHUFF	N	ز

. .

.

• • • •	ho hor groke			•							
	READ OUT		NO	¥56	18	NCCA .	er .				
	(a) manufactured cigarettes ?	(39)	<u>NO</u> 0	<u>YES</u>		"YES" , A			4		
	(a) Banulactured tigarettes ((39)	U	I		папу па	nufactu	: iast (ired cig; smoked j	arette	s on	
					WRI	TE IN -	<u>→</u> .	PER D	 AY	(40-4	1)
	(b) hand-rolled cigarettes ?	(42)	0	1 -	>Thi	nking ab	out the		days,		
							-	smoked			
					WRI	TE IN	\rightarrow .	PER D	AY	(43-4	(4)
	(c) a pipe ?	(45)	0	1	> How hav	-		f tobacc n the la		lays ?	
			RECO	RD ANSWER	IN OUNCES	<u>→.</u> .		•••••	(46-4	17)	
				OR	IN GRAMS	→	LAST 7	DAYS	(48-5	;0)	
• .		(DEPENDIN	GON		THE RESPO						
	(d) as much as 1 cigar or										
	<pre>! miniature cigar a week ?</pre>	(51)	0	۱				nd minia n the la		-	
					WRI	TE IN -	→ .	LAST 7		• (52-)	53)
	IF RESPONDENT DOES SMOKE ANY OF THE ABOVE	4 TYPES, GO TO 0.13.							JRIJ		
	IF SMOKES NONE OF THESE TYPES, CARRY OUT F	URTHER CHECK BY ASKI	NG (e):-							•
	(e) Have you smoked any of these at all,	in the last 7 days	?	_							
			NO	TES				On which TATE TYP		iid yo	u
					MON	TUE	WED	THUR	FRI	SAT	SUN
	manufactured cigarettes ?	(54)	0	1	<u>→ 2</u>	3	4	5	6	7	8
	hand-rolled cigarettes ?	(55)	0	1	<u>→</u> 2	3	4 :	5	6	7	8
	a pipe ?	(56)	0	1	→ 2	3	4	5	6	7	8
	a cigar or miniature cigar ?	(57)	0	1	> 2	3	4	5	6	7	8
1. 13	RESPONDENT MARITAL STATUS: Are you							CO	DE	7	OUTE
								(58	3)		•
						S	INGLE		1	9	• 15
	· ·		٠			MA	RRIED		2	1 9	.14
	IF MARRIED, ASX Q.14	•		WIDO	WED/DIVOR	CED/SEPA	RATED		3	9	. 15
. 14	Does your husband (wife) smoke REAR	TUD									
	- La restructura		NO	YES						•	
	(a) Manufactured cigarettes ?		0	1	(59)						
	(b) Hand-rolled cigarettes ?		0	1	(60)						
	(c) Cigars or miniature cigars ?		0	1	(61)						
	(d) A pipe 7		0	1	(62)						
	RECORD Q.15 FROM OBSERVATION ONLY										
1.15	Is anybody else present in the room at thi	.3			(63)						
	point in the interview ?	YES, SPOUSE	ALSO	PRESENT	(63) 1						
	,	ES, OTHER PERSON(S)	ALSO	PRESENT	2						
		NO, NOBODY	ELSE	PRESENT	3						

. 1. 20. 34

Now some questions about travelling. By travelling, we mean all kinds of	CODE
journeys outside the home, like going shopping, visiting people, going to	
work, going on special trips or holidays, going for a walk, and so on.	
Compared with other men (women) of your age, do you feel that	(64)
you travel READ OUT	
MORE THAN AVERAGE	1
ABOUT AVERAGE	2
or LESS THAN AVERAGE	3
For roughly how many hours have you been outside the house today, either to	(65)
the shops, or to work, or visiting, or any other reason ?	
WRITE IN NUMBER OF HOURS	• • • • • • • •
Different people eat at different times of the day. It is now about	1000
(LOOK AT WATCH, AND QUOTE THE APPROXIMATE TIME). Roughly how long ago did	(66)
you have a meal - I mean a main meal or snack meal or sandwiches, not just	
a biscuit or piece of cake ?	
WRITE IN APPROXIMATE NUMBER OF HOURS AGO	•••••
Would you say your mouth waters when you see something appetising ?	(67)
YES	1
NO/NOT PARTICULARLY	2
DON'T KNOW	3
NOW REQUEST RESPONDENT TO SUPPLY A SAMPLE OF SALIVA IN THE SPECIAL BOTTLE.	
AT THE SAME TIME, GIVE RESPONDENT THE LETTER OF RE-ASSURANCE SIGNED BY	(68)
DR. ROE.	
SALIVA SAMPLE OBTAINED	ENTE 1→SERI
	NUME
RESPONDENT REFUSED TO GIVE SALIVA SAMPLE	2
	I
IF SAMPLE OBTAINED:- (69 - 72)	
WRITE IN THE SERIAL NUMBER SHOWN ON GLASS TUBE	¥~
LEAVE LETTER FROM DR. ROE WITH RESPONDENT	
FINALLY. THANK RESPONDENT AND CLOSE INTERVIEW	

. . .

·

APPENDIX D

Interview Instructions
RSGB LTD, RESEARCH CENTRE, WEST GATE, LONDON W5 IEL TEL NO (01) 997-5555

JN 4129

LIFE-STYLE AND APPETITE SURVEY INTERVIEWER INSTRUCTIONS

1. INTRODUCTION

This survey is unusual in one respect - at the end of the interview, we wish you to obtain a sample of saliva from each respondent. (You will be receiving special containers for the collection of these samples - 'see Sections 2(i) and 6, below).

We want to emphasise that there is absolutely no cause for concern either for you or for the respondent - about this request. The survey is simply about certain aspects of appetite and life-style, and the saliva sample is required for analysis purposes in the light of the different consumption patterns revealed by respondents in respect of the items on the questionnaire. The survey is <u>not</u> conducted to check on any illnesses or diseases the respondent may or may not have; the results of the saliva test will certainly not be used in any way which will involve the respondent with any further contact.

All respondents supplying a saliva sample will be given a letter of reassurance from a doctor (your materials include 40 copies of this letter).

If you as an interviewer are asked for further explanation, please do not be drawn into inventing additional answers - it is sufficient (and it is true!) for you to say that your job is to ask the questions on the questionnaire and record the replies, and that you do not possess specialised scientific or medical knowledge.

The survey was piloted with considerable success - we achieved a success rate of almost 90% of respondents supplying the sample.

2. MATERIALS

For this survey, you will receive materials from 2 sources:-

(1) From the Hazelton Laboratory, Harrogate

A carton will be sent to you containing 40 individually-packed glass tubes, for the saliva samples.

Each glass tube will be in a hygienically-sealed wrapper, marked "STERILE". The transparent wrapper is not easy to tear open if you only use your hands - the laboratory suggest that you take with you a pair of scissors to cut the plastic wrapper around the glass tube. This worked very satisfactorily on the pilot, and we hope you will be able to take your own scissors with you without too much inconvenience.

The wrapper and glass tube are packed in a plastic "cradle" for protection - please simply lever the cradle open (it might prove a bit stiff!) to get at the wrapped bottle.

Each plastic cradle is itself in a jiffy bag, for further protection when posting back. Each jiffy bag has a postage-paid label on it, and is pre-addressed to the Hazleton Laboratory in Harrogate.

Each glass tube has a label with a unique number on it. The number and label are both very important - see Section 6 later.

(ii) From RSGB

. Your pack will contain:-

- . 60 questionnaires, plus 1 spare for any notes you may wish to make
- . 60 AMSO leaflets
- . 40 letters of reassurance (signed by Dr.Roe)
- This set of Interviewer Instructions
- . 1 Contract Note
- . 2 Show Cards
- . 1 Quota Card
- 6 Respondent Address lists (Saliva Sample Obtained)
- . 6 Respondent Address lists (Sample Not Obtained)
- 5 RSGB Reply-paid Envelopes
- . 1 Freepost Envelope
- . 1 Interviewer Invoice
- . 1 Roll of sellotape

3. WHO TO INTERVIEW

You will working to a straightforward quota, set according to the UK adult population aged 16-74.

Please interview in the area advised by your Regional Organiser.

4. WHEN TO INTERVIEW

You may interview <u>only</u> on Monday, Tuesday and Wednesday. This is because saliva samples must be posted as soon as possible after they are obtained, and <u>no later than Thursday</u> to ensure they arrive by the week-end.

Males under 65 may only be interviewed after 5.00p.m.

5. QUESTIONNAIRE

The questionnaire should prove entirely straightforward, but please take note of the following:-

<u>Q.1 - Q.3</u>. These 3 questions are asked in terms of "yesterday" behaviour.

<u>Q.4 - Q.11</u>. These questions relate to behaviour over "the last 7 days".

<u>0.11</u>. We require information on usage of 15 products, and for convenience have listed these on a Show Card. Please hand the card to the respondent, and read out each of the 15 in turn; remind the respondent from time to time that we only want their usage in the last <u>7 days</u>.

<u>Q.12(a) and (b)</u>. These relate to the number of cigarettes and handrolled cigarettes smoked <u>per day</u>, on average, over the last 7 days.

<u>Q.12(c) and (d)</u>. These relate to ounces of tobacco and number of cigars/miniature cigars smoked in the last 7 days altogether.

Q.13 Marital Status. Include as "Married" any respondent in a commonlaw marriage, i.e. living with a person of the opposite sex who is regarded as a spouse.

Q.11-15 (General Point). Please take care in recording answers to Q's.11-15. The "NO" answers are to be recorded in the left-hand column, and "YES" in the right.

<u>Q.16</u>. If the respondent asks you what is "average", you should simply reply "whatever you feel is average".

Q.18. When asking this question, you will need to quote the time of day. Please wear a wrist watch, or have some other means available for being able (roughly) to tell the time. Please note that breakfast counts as a main meal.

6. COLLECTION OF THE SALIVA SAMPLE

- (a) Only after Q.19 in the interview should you introduce the request for the saliva sample.
- (b) At the same time as making the request, hand the respondent Dr.Roe's letter.
- (c) Respondents supplying a sample may keep the letter of reassurance; however, please take the letter back from any respondent declining to provide a sample.
- (d) The amount of saliva we need is not large, but you must be prepared to allow respondents several minutes to produce the required amount. In the pilot, some respondents needed 7 or 8 minutes - so please do not hurry them! The level of saliva should reach the <u>lower</u> edge of the label on the bottle, after any bubbles have settled.

.

- (e) There are no particular techniques to help generate saliva. It does <u>not</u> actually help if respondents take a drink of water, so please do not encourage them to do so. Nor does it help to suck a sweet. Respondents should simply introduce the saliva at a steady wate into the tube, without allowing the bouth to becase any. The final point - there may be one or two respondents who are not absolutely sure what saliva is (they may form the wrong idea when they hear the word "sample"!). If necessary, casually mention that saliva is the "liquid which forms naturally in the mouth". Please make a note on the questionnaire if you feel there were any peculiar circumstances regarding the supply of a particular sample.
- (f) Allow the respondent to remove the glass tube from the wrapper. The "STERILE" marking which is clearly visible will provide assurance that the tube has been hygienically packed.
- (g) Once the respondent has dribbled the required saliva into the tube, please screw the cap <u>securely</u> on the bottle, and then WRITE INTO BOX 69-72 ON THE QUESTIONNAIRE THE NUMBER WHICH IS SHOWN ON THE LABEL. <u>This is absolutely essential</u>, since we cannot otherwise link the laboratory's sample analysis with the answers recorded by you on the questionnaire.
- (h) Then lay the glass tube in the plastic cradle (the transparent wrapper can be discarded), and put the cradle into the jiffy bag.
- (i) Seal the jiffy bag with the sellotape provided, and post it at the earliest convenient moment. If it is too late to catch the post the same day, it would be appreciated if you would store the jiffy bag(s) in your fridge overnight, before posting the next morning.

Remember:-

- . Post same day as interview, if possible
- . Otherwise post next morning
- Post no later than Thursday (with interviewing not later than Wednesday)

(j) Finally, record the respondent name and address on your special Respondent Address List, against the relevant Sample Bottle No. (If the respondent declines to supply a sample, the name and address must be recorded on the other Respondent Address List provided on this survey). <u>Please return these address lists along</u> with your final day's interviewing; you should retain a copy for your own records.

7. RETURN OF COMPLETED QUESTIONNAIRES TO RSGB

Please return your questionnaires <u>daily</u>. 5 Return Envelopes are provided.

Please contact your Regional Organiser with any queries. If your Regional Organiser is not available to deal with problems, then telephone the office and ask for Trevor Richards (Ext.242) or Neil Russell (Ext.260).

APPENDIX E

Follow-up (backcheck) questionnaire

		OFFICE USE ONLY
ESPONDENT'S NAME		JN 4020 (1
ESPONDENT'S	·	JN , (1
······································		SERIAL NO (5
		CARD NO 1 (9
		i
LEPHONE NO. (IF ANY)	····	р н
TE OF INTERVIEW		(10) (11) (12)
ME INTERVIEW STARTED		
HE INTERVIEW ENDED		
NGTH OF INTERVIEW		(13) (14)
WRITE IN NUMBER OF MINU	•	
IF LESS THAN 10, ENTER	LEADING ZERO	ainutes
		INTERVIEWER'S (15) (16) (17) (1
TERVIEVER'S NAME		NUMBER
-		
SEX OF RESPONDENT	(20)	(d) RESPONDENT WORKING STATUS
н	ULE 1	
FEM	IALE 2	FULL TIME (30+ HRS PER VEEK) PART TIME (8-29 HRS PER VEEK)
RESPONDENT AGE GROUP	(21)	NON-VORKING
16 -	24 1	
		BACK-CHECK EXTRA DETAILS
•• •	- 1	Finally, just ê other questions:-
65 -		Q.1 Compared with other men (women) of your age,
	<u> </u>	do you feel that you travel READ OUT
SNIAL CLASS	1 2 2 2 3	
SOCIAL CLASS WRITE IN FULL DETAILS OF:-	(22 '	
WRITE IN FULL DETAILS OF :-	AB 1	MORE THAN AVERAGE
	AB 1	MORE THAN AVERAGE About Average or LESS Than Average
WRITE IN FULL DETAILS OF:-	AB 1	ABOUT AVERAGE OF LESS THAN AVERAGE
WRITE IN FULL DETAILS OF:- (1) OCCUPATION	A5 1 C1 2	ABOUT AVERAGE or LESS THAN AVERAGE Q.2 Do you shoke manufactured signrettes ?
WRITE IN FULL DETAILS OF:- (1) OCCUPATION	A5 1 C1 2 C2 3	ABOUT AVERAGE OF LESS THAN AVERAGE
WRITE IN FULL DETAILS OF:- (1) OCCUPATION	A5 1 C1 2 C2 3 DE -	ABOUT AVERAGE or LESS THAN AVERAGE Q.2 Do you shoke manufactured signrettes ? YES
VRITE IN FULL DETAILS OF:- (1) OCCUPATION	AB 1 C1 2 C2 3 DE -	ABOUT AVERAGE or LESS THAN AVERAGE Q.2 Do you smoke manufactured stgarettes ? YES NO OUTCOME OF HACK-CHECK:-
VRITE IN FULL DETAILS OF:- (1) OCCUPATION	AB 1 C1 2 C2 3 DE - (23) UI C	ABOUT AVERAGE or LESS THAN AVERAGE Q.2 Do you shoke manufactured stgarettes ? YES NO
VRITE IN FULL DETAILS OF:- (1) OCCUPATION	AE 1 C1 2 C2 3 DE - (23) ULT C in - D E D	ABOUT AVERAGE or LESS THAN AVERAGE Q.2 Do you smoke manufactured signrettes ? YES NO OUTCOME OF MACK-CHECK:- SUCCESSFULLY INDUCTED (PHONE)
VRITE IN FULL DETAILS OF:- (1) OCCUPATION	AB 1 C1 2 C2 3 DE - (23) (23) (11) C1 2 (23) (11) C1 2 (23) (11) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12) (12)	ABOUT AVERAGE or LESS THAN AVERAGE Q.2 Do you shoke manufactured signrettes ? YES NO OUTCOME OF BACK-CHECK:- SUCCERSFULLY SNDUCTED (PHONE) OUTCOME OF BACK-CHECK:- SUCCERSFULLY SNDUCTED (PHONE)

. . . .

ţ

Salivary Cotinine Study Summary Incidence Table

<u>Interview</u>

	no sample	not analysed	nicotine user	non- user
bottle serial number				
no data	238	0	0	0
2001 to 3000	0	327	110	513
3001 to 4000	0	192	72	323
questionnaire serial number				
1 to 1000	0	355	98	543
1001 to 2000	Õ	164	84	292
2001 to 3000	238	0	0	. 0
9001 to 9999	0	0	0	1
day of interview				
1 to 4	54	117	28	157
5 to 8	38	95	46	146
9 to 12	34	41	32	94
13 to 16	19	35	10	65
17 to 20	34	97	12	85
21 to 24	31	66	27	138
25 to 28	12	24	15	41
29 to 31	16	44		110
month of interview				
September	108	243	70	399
October	130	276	112	437
interview length in minutes	,			
1 to 5	42	4	0	4
6 to 10	118	59	36	120
11 to 15	54	225	59	314
16 to 20	20	145	52	274
21 to 25	2	55	17	77
26 to 30	1	24	15	33
31 to 35	0	4	0	9
36 to 40	· 1	2	3	1
41 to 45	0	1	0	3
46 to 50	0	0	0	1

· · ·

Salivary Cotinine Study Summary Frequency Table

Interview

	no sample	not analysed	nicotine user	non-
	Sembre	anaryseu	user	user
bottle serial number				
no data	238	0	0	0
2001 to 3000	0	327	110	513
3001 to 4000	. 0	192	72	323
questionnaire serial number				
1 to 1000	0	355	98	543
1001 to 2000	Ő	164	84	292
.2001 to 3000	238	104	0	292
9001 to 9999	250	Ő	0	1
day of interview				
1 to 4	54	117	0.0	1 - 7
5 to 8	38	95	28	157
9 to 12 .	36		46	146
13 to 16	34 19	41	32	94
17 to 20		35	10	65
21 to 24	34	97	12	85
25 to 28	31	66	27	138
29 to 31	12	24	15	41
29 60 51	16	44	12	110
month of interview				-
September	108	243	70	399
October	130	276	112	437
interview length in minutes				
1 to 5	42	4	0	4
6 to 10	118	59	36	120
11 to 15	54	225	59	314
16 to 20	20	145	52	274
21 to 25	2	55	17	77
26 to 30	1	. 24	15	33
31 to 35	Ō	4	19	9
36 to 40	1	2	3	, 1
41 to 45	0 0	1	0	3
46 to 50	0	Ó	Ő	1
	Ū	J	Ŭ	7

•

Salivary Cotinine Study Summary Frequency Table

Demographic details

	no sample	not	nicotine	non-
	sampre	analysed	user	user
age group				
16-24	29	94	41	121
25-34	45	117	46	208
35-44	50	107	41	171
45-54	· 27	64	24	106
55-64	34	81	13	128
65-74	53	56	17	102
social class				
AB	24	55	21	150
C1	50	121	36	246
C2	82	142	58	232
DE .	82	201	67	208
respondent working status				
full time	67	207	80	328
part time	37	65	22	139
non-working	134	247	80	369
presence of children in				
household				
children aged 15 or under	94	242	94	364
no children aged 15 or under	144	277	88	472
				•
household size				
no data	0	0	0	1
one	30	53	18	84
two	. 76	144	40	245
three	49	131	40	175
four	54	129	53	215
five or more	29	62	31	116
marital status				
no data	2	3	1	1
single	41	96	42	142
married	164	340	121	619
widowed/divorced/separated	31	80	18	74

. .

• • •

.

Salivary Cotinine Study Summary Frequency Table

Respondent's smoking habits

	no sample	not analysed	nicotine user	non- user
respondent code				
no data	238	519	0	0
smoker	0	0	178	0
user of other nicotine	õ	Ő	2	0
product	v	v	2	Ŭ
smoker and nicotine user	0	0	2	0
non-smoker or nicotine	õ	ŏ	0	836
user	Ŭ	Ŭ	Ŭ	010
smoker of manufactured				
cigarettes				
no	174	92	40	836
yes	64	427	142	0
number of manufactured				
cigarettes per day				
no data	180	127	49	836
1 to 5	8	55	9	0
6 to 10	16	89	28	0
11 to 15	· 7	75	24	0
16 to 20	15	121	43	0
21 to 25	3	10	9	0
26 to 30	8	25	13	0
31 to 35	0	3	0	0
36 to 40	1	11	5	0
41 to 45	0	1	0	0
46 to 50	0	2	2	0
smoker of hand-rolled				
cigarettes				
no	226	437	145	836
yes	12	82	37	0
number of handrolled				
cigarettes per day				
no data	226	452	155	836
1 to 6	3	23	8	0
7 to 12	2	11	5	ő
13 to 18	2	10	6	0
19 to 24	2	10	5	0
25 to 30	2 2 3		1	0
37 to 42	0	ว ว	1 2	0
43 to 48	0	8 3 1	0	0
55 to 60	0 0	1	0	0
	5	4	Ű	Ŭ

Salivary Cotinine Study Summary Frequency Table

Respondent's smoking habits (continued)

	no sample	not analysed	nicotine user	non- user
pipe smoker				
no	228	490	174	836
yes	10	29	8	0
ounces of pipe tobacco in previous 7 days				
no data	233	500	175	836
1 to 6	0	2	0	0
7 to 12	1	7	1	0
19 to 24	2 1	3 5 0	3 2	0
25 to 30	1	5	2	0
37 to 42	0	0	1	0
43 to 48	0	1	- 0	0
49 to 54	1	0	0	0
55 to 60	0	1	` 0	0
grams of pipe tobacco in last 7 days				
no data	236	516	181	836
1 to 20	0	1	0	0
21 to 40	1	Ō	1	0
81 to 100	1	1	ō	0
121 to 140	0	1	0	Ō
smoker of l cigar or miniature cigar a week				•
no	230	467	163	836
yes	8	52	105	0
number of cigars or miniature cigars last 7 days				
no data	230	481	167	836
1 to 10	4	31	15	0
11 to 20			0	0
21 to 30	3 1	311	0	0
31 to 40	Ō	1	0	0
51 to 60	0	1	0	0
91 to 99	0	1	0	0
smoked manufactured				-
cigarettes in last 7 days				
not recorded	41	3	1	139
no data	86	506	178	0
no	111	10	2	697
Tuesday	0	0	1	0

·

Salivary Cotinine Study Summary Frequency Table

Respondent's smoking habits (continued/2)

	no sample	not analysed	nicotine user	non- user
smoked handrolled cigarettes in last 7 days				
not recorded	41	3	1	139
no data	86	506	178	0
no	111	10	3	697
smoked pipe in last 7 days				
not recorded	41	3	1	139
no data	86	506	178	0
no	111	10	3	697
smoked cigar/miniature cigar in last 7 days				
not recorded	41	2	-	1 2 0
no data	86	506	· 178	139
no	111	9		0
Friday	0	9	2 1	697
Saturday	0	1	0	0 0

· · · · ·

Salivary Cotinine Study Summary Frequency Table

Chewing/snuff taking

	no sample	not analysed	nicotine user	non- user
chews nicotine chewing gum				
no yes	238 0	519 0	179 3	836 0
chews chewing tobacco				
no	238	518	181	836
yes	0	1	1	0
chews or sucks tobacco 'tea bags'				
no	237	519	182	836
yes	1	0	0	0
takes snuff				
no	238	518	181	836
yes	0	1	1	0

•

Salivary Cotinine Study Summary Frequency Table

Spouse smoking habits

	no sample	not analysed	nicotine user	non- user
spouse smokes manufactured cigarettes				
no data no yes	74 114 50	181 188 150	61 57 64	219 475 142
spouse smokes handrolled cigarettes				
no data no	75 152	182 300	64 104	226 574
yes	11	37	104	36
spouse smokes cigar/miniature cigar				
no data	76	185	64	227
no yes	154 8	302 32	111 7	565 44
spouse smokes pipe .				
no data no	76 158	185 323	64 116	230 589
yes	4	11	2	17
other persons present				
no data	7	12	5	35
spouse yes other person present	28 53	66 126	35 45	114 142
nobody else present	150	315	97	545

Salivary Cotinine Study Summary Frequency Table

Results of backcheck

	no sample	not analysed	nicotine user	non- user
smokes manufactured				
cigarettes				
no data	45	81	31	122
Yes	50	355	121	10
No	143	83	30	704
outcome of backcheck				
successful (by phone)	123	306	105	551
successful (personal)	64	126	40	141
information from spouse etc.	6	8	7	22
refused further information	6	1	0	6
no contact made	39	68	27	110
moved/no longer at address	0	10	3	6

.

.

Salivary Cotinine Study Summary Frequency Table

<u>Sample</u>

	no sample	not analysed	nicotine user	non- user
day of sample receipt				
no data	238	519	7	20
1 to 4	0	0	39	20 261
5 to 8	Ō	Õ	4	16
9 to 12	Ō	õ	68	213
13 to 16	Ō	Ō	0	213
17 to 20	Ő	Ō	22	125
21 to 24	0	Ō		36
25 to 28	0	Ō	34	141
29 to 31	0	0	0	2
month of sample receipt				
no data	238	519	0	0
September	0	0	56	279
October	0	0	126	556
November	0	0	0	1
cotinine value (in tenths of ng/m	1)			
no data	238	519	6	28
0 to 999	0	0	24	797
1000 to 1999	0	0	20	1
2000 to 2999	0	· 0	32	6
3000 to 3999	0	0	38	2
4000 to 4999	0	0	27	2
5000 to 5999	0	0	22	0
6000 to 6999 7000 to 7999	0	0	22 6 5	0
8000 to 8999	0	0	´ 5	0
9000 or more	0	0	1	0
Sood of more	0	0	ļ	0
cotinine (grouped) (in ng/ml) no data				
	238	519	6	28
0.1-0.2	0	0	2	220
0.3-0.5	0	0	0	76
0.6-1.0	0	0	1	103
1.1-2.0	0	0	0	116
2.1-5.0	0	0	1	120
5.1-10.0	0	0	1	104
10.1-20.0	0	0	5	35
20.1-50.0	0 0	0	1 7	. 13
50.1-100.0	0	0		5
100.1-200.0	0	0 0	6	5 5 1
200.1-500.0	0	0	20	
>500.0	0	0	97	10
	v	U	35	0
APPENDIX F

Salivary Cotinine Study Summary Frequency Table

Drinks

	no sample	not analysed	nicotine user	non- user
cups of tea drunk yesterday				
none	36	89	45	138
one	10	47	8	65
two	18	42	26	88
three	29	61	19	131
four	44	62	13	134
five or more	101	218	71	280
cups of coffee drunk				
yesterday				
no data	0	2	1	1
none	97	178	52	262
one ·	43	76	14	153
two	38	66	29	127
three	17	46	20	100
four	. 8	44	21	73
five or more	35	107	45	120
pints of milk drunk yesterday				
no data	0	0	0	3
none	29	40	17	75
less than 1 pint	164	329	115	572
1 pint, not less than 2	40	130	39	166
2 pints or more	5	20	11	20
times fruit juice drunk in				
last 7 days				
not at all	136	307	120	378
once	15	46	12	80
twice	18	30	11	79
three times or more	69	136	39	299
nature of the fruit juice				
no data	137	310	121	380
generally natural	75	155	44	364
generally sweetened	20	40	13	70
sometimes natural or sweetened	6	14	4	22

APPENDIX F

Salivary Cotinine Study Summary Frequency Table

Food

times carrots eaten in last 7 days not at all 64 153 43 175 once 61 128 65 198 twice 53 100 33 216 three times or more 60 138 41 247 times spinach eaten in last 7 days no data 0 3 0 1 not at all 234 498 178 785 once 3 12 0 41 twice 1 5 3 8 three times or more 0 1 1 1		no sample	not analysed	nicotine user	non- user
not at all 64 153 43 175 once 61 128 65 198 twice 53 100 33 216 three times or more 60 138 41 247 times spinach eaten in last 7 60 138 41 247 times spinach eaten in last 7 60 138 41 247 times at all 0 3 0 1 not at all 234 498 178 785 once 3 12 0 41 twice 1 5 3 8 three times or more 0 1 1 1 times other green vegetables 5 1 1 1					
once 61 128 65 198 twice 53 100 33 216 three times or more 60 138 41 247 times spinach eaten in last 7 60 138 41 247 times spinach eaten in last 7 60 138 41 247 times spinach eaten in last 7 60 138 41 247 times at all 0 3 0 1 not at all 234 498 178 785 once 3 12 0 41 twice 1 5 3 8 three times or more 0 1 1 1 times other green vegetables 1 1 1	•	64	153	43	175
twice 53 100 33 216 three times or more 60 138 41 247 times spinach eaten in last 7 60 3 0 1 no data 0 3 0 1 not at all 234 498 178 785 once 3 12 0 41 twice 1 5 3 8 three times or more 0 1 1 1 times other green vegetables 5 5 5 5					
three times or more 60 138 41 247 times spinach eaten in last 7 days no data 0 3 0 1 not at all 234 498 178 785 once 3 12 0 41 twice 1 5 3 8 three times or more 0 1 1 1 times other green vegetables	twice				
days 0 3 0 1 not at all 234 498 178 785 once 3 12 0 41 twice 1 5 3 8 three times or more 0 1 1 1 times other green vegetables 1 1 1 1	three times or more	60	138	41	
no data 0 3 0 1 not at all 234 498 178 785 once 3 12 0 41 twice 1 5 3 8 three times or more 0 1 1 1 times other green vegetables 5 5 5 5					
not at all 234 498 178 785 once 3 12 0 41 twice 1 5 3 8 three times or more 0 1 1 1 times other green vegetables 1 1 1 1	•	•	2	•	•
once312041twice1538three times or more0111times other green vegetables		-		•	
twice1538three times or more0111times other green vegetables					
three times or more 0 1 1 1 times other green vegetables					
times other green vegetables					
		Ŭ	-	±	-
ealen in iast / davs	times other green vegetables eaten in last 7 days				
no data $0 1 0 0$		0	1	0	0
not at all 9 31 12 16	not at all				
once or twice 50 98 42 121	once or twice	50			
three or four times 68 161 50 258	three or four times	68	161	50	
five or six times 44 100 31 190	five or six times	44	100	31	190
seven times or more 67 128 47 251	seven times or more	67	128	47	251
times shellfish eaten in last					
7 days no data 1 3 2 5		•	2	•	
			-		
not at all 91 171 69 250 once 83 223 64 336					
twice 48 77 33 168					
three times or more 15 45 14 77					
	chice cimes of mole	10	40	74	17
times liver eaten during the last 7 days	times liver eaten during the last 7 days				
no data 1 1 0 1		1	1	0	1
not at all 186 408 149 661	not at all				
once 44 99 27 164	once	44	99	27	164
twice 6 9 5 8	twice	6	9	5	8
three times or more 1 2 1 2	three times or more	1	2	1	2
times curried food eaten in last 7 days					
no data $3 2 0 11$	•	3	2	0	11
not at all 180 370 130 596		-			
once 39 117 34 165					
twice 11 16 14 37				14	
three times or more 5 14 4 27	three times or more	5	14	4	27

APPENDIX F

Salivary Cotinine Study Summary Frequency Table

Travel

.

· · · · · · · · · · · · · · · · · · ·	no sample	not analysed	nicotíne user	non- user
frequency of travel		-		
no data	-			
more than average	1	2	0	1
about average	64	178	69	311
less than average	110	216	78	. 383
ress chan average	63	123	35	141
number of hours outside				
no data	4	3	1	4
no	53	82	24	129
one	· 27	63	17	105
two	25	71	20	103
three	31	44	18	66
four	18	46	19	70
five	15	52	12	64
six	14	• 28	13	53
seven	5	12	5	19
eight	13	38	9	59
nine	7	40	22	65
ten	21	24		63
more than 10	5	16	15	37
hours since last main meal				
no data	•	•		
no	2	2	2	4
one	16	53	14	69
two	51	108	37	163
three	38	76	30	156
four	34 39	73	19	123
five	21	62	32	124
six	12	39	13	77
seven	3	26	5	48
eight	3	12 7	5 2	15
nine	0	3	-	14
ten	1		1	3
more than 10	18	4 54	2	4
	10	54	20	36
whether mouth waters		•		
no data	0	3	0	2
yes	109	285	103	530
no/not particularly	124	226	79	298
don't know	5	5	Ő	290 6
	-	-	~	0

,

APPENDIX G

Comparison of Smoking Habits from the Salivary Cotinine Study and the 1985 Annual Consumer Survey

Overall the results from the two studies were quite close given the different sample sizes and research methodologies.

The main differences between the studies was in the proportion of female cigarette smokers at 38% from the salivary study and 34.5% from the A.C.S.

A breakdown of cigarette smokers from the salivary study by age and class showed there was a higher proportion of 16-24 year old and DE females and a lower proportion of C2 males, than there were from the ACS. However, the overall age and class profiles of the cigarette smokers were in main similar.

A comparison of the studies indicated that the average weekly cigarette consumption was similar for females, but lower in the case of the salivary study for men (i.e.118 of 133). The average consumption for males was lower among the 35-54 year olds and all but the DE social groups.

I Brown Marketing Services 12th May 1986 MRSH.rep

PROPORTION OF ADULTS SMOKING DIFFERENT PRODUCTS

	SAL	IVARY COFI	SALIVARY COTININE STUDY	1985	ANNUAL CON	1985 ANNUAL CONSUMER SURVEY
	MEN	WOMEN	MEN & WOMEN	MEN	WOMEN	MEN & WOMEN
	۶۹	સ્ટ	22	8	8	8
SMOKING HABITS						
SMOKER OF MANUFACTURED CIGARETTES	33	38	35 }	34\$	34 } ≁	34 }
SMOKER OF HANDROLLED CIGARETTES	13	2	7}	10}	13	9
PIPE SMOKER	ŝ	-4-1	2}	5 }	Neg.	2
CIGAR SMOKER (AT LEAST WEEKLY)	ი	· · ·	4 }	7	Neg.	3}
ALL SMOKERS	49	39	43 }	46 }	35	40 }
NON-SMOKER	51	61	563	53 }	65	59 }
BASE:	842	933	1,775	4,292	4,565	8,857

,

ï

1985 ANNUAL CONSUMER SURVEY	MEN + WOMEN Z		41	40 1	36 }	26 }		24 }	32	37	39 1	341
985 ANNUAL C	WOMEN X		394	41 1	37	264		241	33	36 }	384	34}
51	MEN X		42 1	40	35	26 1		244	30 }	37 }	41	34
INE STUDY	MEN + WOMEN	·	474	37	35 1	27 1		26	32	35	43 1	35 }
SALIVARY CONTININE STUDY	WOMEN		54	374	37	32 }		29	33 }	37 }	474	38
SAL	<u>X</u>		43	36 }	34	22 }		22	30 }	32 1	39 1	33
		AGE	16-24	25-34	35-54	55+	CLASS	AB	CI	C2	DE	TOTAL

PROPORTION OF CIGARETTE SMOKERS

ļ

MRSTATS.REP

TABLE 2

•

Ŧ . . `

PROFILE OF CIGARETTE SMOKERS

1

1985 ANNUAL CONSUMER SURVEY	$\frac{MEN + WOMEN}{2}$	t	22	20	32	25			11	21	31	37	100	
1985 ANNUAL	WOMEN		20	20	32	28	100		11	23	28	38	100	
	MEN		24	21	32	23	100		12	19	34	35	100	
ININE STUDY	MEN + WOMEN Z		21	24	33	21	100		10	23	29	38	100	
SALIVARY CONTININE STUDY	WOMEN X	·	18	25	34	23	001		11	23	30	36	100	
	MEN X		26	23	32	19	100		6	23	27	41	100	
		AGE	16-24	25-34	35-54	55+	TOTAL	CLASS	AB	C1	C2	DE	TOTAL	MDCTATC DED

.

TABLE 3

MRSTATS. REP



	1985 ANNUAL CONSUMER SURVEY	Manori T NAM	NO ¹ S.		111	123	136	100			115	118	125	121	171	121	3172
CIGARETTES)	985 ANNUAL CC	WOMEN	No's.	001	001	711	122	98		č	44	102	112	116		109	1620
ON (NUMBER OF	1		No'B.	120	761	+C1	150	122		261	001	139	137	126		133	1552
AVERAGE WEEKLY CIGARETTE CONSUMPTION (NUMBER OF CIGARETTES)	INE STUDY	MEN + WOMEN	No's.	97	122		171	109		107	108		115	118		114	583
VERAGE WEEKLY C	SALIVARY CONTININE STUDY	WOMEN	.00 8	101	113	121	8 9 1	. 98		105	111			111		110	327
41	·	MEN NO ' O	•	120	134	122	10.	127		109	105	120		125			256
			AGE	1624	25-34	35-54	554	100	CLASS	AB	CI	C2	r 4	IJĽ	All Cigarette	Smokers	BASE; MRSTATS. REP

TABLE 4

AVERAGE WEEKLY CICARETTE CONSUMPTION (NUMBER C

. .

I