A survey carried out on behalf of the Department of Health



National Diet and Nutrition Survey - Assessment of dietary sodium in adults (aged 19 to 64 years) in England, 2011

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Executive Summary

This survey was designed to provide data to establish progress towards meeting the Department of Health's target to reduce the population average of dietary salt intakes to no more than 6g per day.¹ The aim was to collect useable 24-hour urine samples from 600 respondents, representative of the population aged 19 to 64 years living in England in the second half of 2011. Urinary sodium excretion was used to estimate salt intake. Salt intake was calculated using the equation: 17.1 mmol of sodium = 1g salt and assumes all of the sodium was derived from salt.² Urine collections were deemed complete by either 70% recovery of para-amino benzoic acid (PABA) or where individuals chose not to take PABA but recorded a complete 24-hour collection. The analysis of urinary sodium excretion was carried out at MRC Human Nutrition Research, Cambridge (HNR).

Key findings

- The mean estimated salt intake, derived from urinary sodium excretion, for adults aged 19 to 64 years was 8.1g per day, with men having a mean estimated intake of 9.3g per day and women having a mean estimated intake of 6.8g per day
- Overall, 70% of participants had a daily intake of salt higher than the recommended maximum of no more than 6g per day; 80% of men and 58% of women exceeded this recommendation
- An analysis of trends in estimated salt intake (g per day), taking into account the previous six sodium excretion surveys carried out in UK countries between 2000/01 and 2009, and the current survey carried out in England in 2011, showed a significant downwards trend in mean estimated salt intake both overall from 9.5g in 2000/01 to 8.1g in 2011 and for men and women separately. Statistical analysis showed there has been a significant reduction in mean estimated salt intake between 2000/01 and 2011
- The drop in estimated salt intake in 2011 compared with the previous estimate in 2008 was not statistically significant

1 Introduction

This survey provides data to establish progress towards meeting the Department of Health (DH)'s target to reduce the average population salt intakes in England to 6g per day.¹ This survey builds on the series of previous urinary sodium excretion surveys reporting salt intakes in the general adult population in United Kingdom (UK) countries.

Dietary salt intake can be assessed by measuring sodium excretion in urine. A 24-hour urine collection method was used, as this was consistent with previous surveys. Since the level of sodium in urine fluctuates according to what was eaten at the last meal and how much fluid an individual has drunk, and because salt is the predominant source of sodium in the UK diet, a urine collection over 24 hours is accepted as being the most reliable method for assessing salt intake in the population.¹ To be usable in the final analysis the 24-hour collection has to be complete, which can be measured by analysis of para-aminobenzoic acid (PABA) excretion.

A sample size of 600 usable urine samples, representative of the population aged 19 to 64 living in England, was required to be able to detect a difference of 0.5g of salt intake compared with the previous UK survey in 2008 (calculated from the standard error in that survey).³ These samples were generated from the National Diet and Nutrition Survey (NDNS) rolling programme,⁴ with additional samples generated via a "sodium boost" add-on study to the NDNS, This allowed an estimate of salt intake at a defined point in time.

2 Background

There is an established relationship between salt intake and health, in particular cardiovascular disease (CVD).^{1,5} CVD remains a major cause of morbidity and mortality in the UK and worldwide. The British Heart Foundation estimates that CVD costs the UK economy 30 billion pounds each year and, in 2010, caused 50,000 premature deaths in the UK.⁶ Diet is a major component in the preventative strategy to reduce the risk of CVD. High blood pressure (hypertension) is a risk factor for CVD, and scientific evidence suggests that a high salt intake contributes to the development of high blood pressure.⁷

Since the early 1990's the UK government has recommended a reduction in salt consumption in the interest of public health. In 1991, the Committee on Medical Aspects of Food and Nutrition Policy's (COMA) panel on dietary reference values set the reference nutrient intake of sodium at 1.6g per day (or 4.2g of salt) for men and women.⁸ Following this, COMA's cardiovascular review group

recommended that population average salt intakes should be reduced from the then average of 9g per day to 6g per day for adults.⁹ The 2000/01 NDNS found that the mean estimated salt intake in adults in GB was 9.5g per day.¹⁰ COMA's recommendations on salt reduction were later endorsed by the Chief Medical Officer of England¹¹ as well as by the Scientific Advisory Committee on Nutrition (SACN), who in their report on salt and health highlighted that a reduction in the salt content of processed foods and drinks was necessary to achieve the recommended levels of salt intake.¹

In 2003 the DH and Food Standards Agency (FSA) committed to a nationwide salt reduction initiative to reduce the UK population average salt intake to 6g per day. In order to achieve this target by 2010, in 2006 the FSA introduced voluntary salt reduction targets for the food industry for 85 categories of food.¹² Publication of the UK dietary sodium excretion survey (2008) showed that the average estimated salt intake for adults in the UK was 8.6g per day,³ which was a 10% reduction compared with 2000/01. In May 2009 the FSA set revised targets for the industry to be achieved by 2012.¹³ Salt reduction is a key element of the DH's Public Health Responsibility Deal, which was launched in 2011 and which outlines a series of pledges to which businesses have been asked to commit that will help to improve public health.¹⁴ The salt reduction pledge sets targets for salt reduction in 80 categories of food for businesses to meet in 2012, and has the potential to deliver a 1g reduction in salt intakes (based on 2007 salt levels in food).

Furthermore, there have been targeted salt reduction campaigns that aim to inform the population about health risks associated with salt consumption. For example, the FSA's 'Sid the slug', 'check the label' and 'Is your food full of it?' campaigns.¹⁵ More recently the national Change 4 Life¹⁶ campaign has a focus on healthy lifestyles, including salt reduction. Large supermarkets have also introduced front-of pack labelling providing information about salt content to help consumers make informed choices.

3 Aims of the study

- To achieve 600 useable 24-hour urine samples over a 4-6 month period using samples collected in the NDNS rolling programme, supplemented by additional samples collected in a sodium boost study,
- Urine samples were to be obtained from a representative sample of the population of England, aged 19 to 64 years
- To estimate dietary salt intakes (g per day) from urinary sodium excretion
- To conduct an analysis of trends in salt intake (g per day) for the sodium surveys carried out between 2000/01 and 2011

Ethical approval for the study was granted by the MREC as a substantial amendment to the main NDNS study (Ref. No. 07/H0604/113).

4 Methodology

4.1 Sample design

The aim of the study was to collect useable 24-hour urine samples from 600 participants, representative of the population aged 19 to 64 years living in private households in England. The participants were recruited from two sources:

- the core England NDNS sample interviewed by nurses in the first five months of Year 4 nurse fieldwork (visits carried out between 07/07/11 and 14/12/11). It was estimated that 48 participants would be generated from the core England NDNS sample
- a "sodium boost" study that ran separately to, but using the same protocols as NDNS. The boost fieldwork ran between 05/09/11 and 14/12/11 and was designed to generate an additional 552 cases

Together these two studies form the Sodium Survey England 2011 (called the "Diet and Health Study 2011" in field). A random sample of 43 postcode sectors was selected from the Postcode Address File for the boost study. The boost sample used the same stratifiers as the main NDNS sample; the file was initially sorted by Government Office Region, then within each region the file was stratified into five equal bands based on the Index of Multiple Deprivation. Within each band the file was then sorted by population density.

Within the 43 postcode sectors a random sample of telephone numbers was drawn using Random Digit Dialling (RDD). RDD is a method where a representative sample of telephone numbers is generated at random from a frame of all possible telephone numbers. As well as including ex-directory numbers, RDD samples include disconnected numbers but as many non-working numbers as possible were removed before the sample for the boost study was drawn.

The RDD sample covered all eligible telephone area codes located in the 43 selected postcode sectors. The database lists the first seven digits of all telephone numbers, including ex-directory numbers, which have been allocated to telephone companies for land lines (e.g. 01234 56XXXX). For each selected area code, the last four digits were randomly generated. 11,529 telephone numbers were issued (after removing non-working numbers).

A maximum of two people aged 19 to 64 years within each household were eligible to take part in the study. Where there were more than two eligible adults in a household, two adults were randomly selected. Females who were pregnant or breastfeeding were not eligible to take part. The sample from the previous (2007/08) UK Sodium Study³ was skewed towards women (398 women and 294 men); the smaller sample size for male participants reduced the scope of the analysis that could be carried out on this group. To increase the number of male participants in this current study, male household members were given a higher chance of being selected (see section 5.4 for further detail).

4.2 Participant recruitment

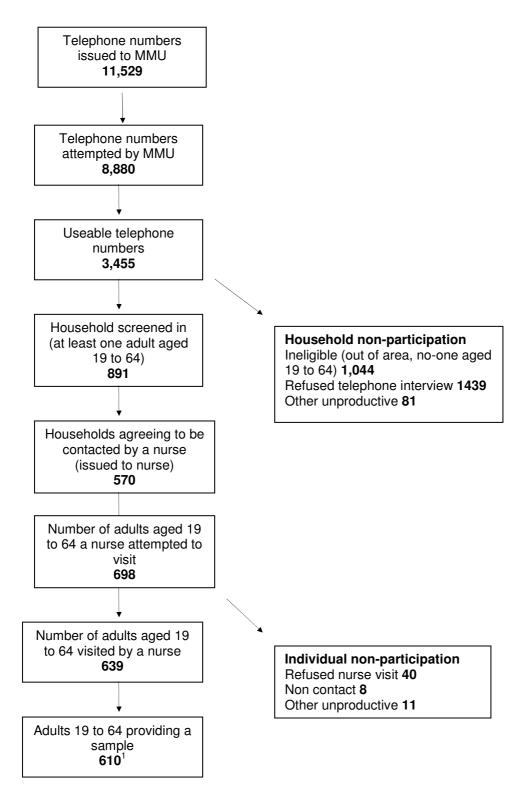
Participants for the boost study were recruited by NatCen's Multi-mode Unit (MMU) interviewers. Prior to starting work on the study, MMU interviewers attended a half-day training session which covered the background and purpose of the study and their role in recruiting individuals to the study. Interviewers were also given detailed written project instructions covering the aims of the study, methodology and fieldwork procedures.

The telephone numbers were issued to the MMU in four batches. The MMU interviewers attempted to make contact with the generated telephone numbers and when successful followed a Computer Assisted Telephone Interviewing (CATI) script to introduce the study and check the eligibility of household members. Within each household, up to two adults, aged between 19 and 64 years, were eligible to take part in the study. If there were three or more eligible adults, two were selected at random within the CATI programme.

The MMU interviewer then conducted a short telephone interview with eligible households to collect contact and household information and basic contextual information, e.g. economic circumstances, shopping and diet habits (recent consumption of general food items such as fruit, cereal, meat and oily fish) within the household. The interviewer then sought agreement for the nurse to visit the selected participant(s).

Each household that agreed to take part in the nurse visit stage received a letter thanking them for their agreement to take part in the study and informing them that the nurse would be in touch shortly to arrange a visit. They were also sent a leaflet outlining the study in more detail. The details of those agreeing to be visited were passed on to the assigned nurse, who then arranged an appointment at a time convenient to the participant(s).

Recruitment of participants to the sodium boost study: flow diagram



¹ A further 108 samples were collected from NDNS participants

4.3 Urine collection procedures

4.3.1 Nurse training

Nurses new to urine collection procedures were briefed in person by the project researchers. The faceto-face briefings lasted one day and covered all elements of the study process. They included the study aims, background and methodology, documentation and paperwork, a practise of the CAPI (computer-assisted personal interview) programme, a practical demonstration of the equipment used to collect urine and the despatch procedures. Nurses were also given detailed written project instructions.

If the nurse had recently worked on NDNS (and was therefore familiar with the procedures and urine protocols) they completed a self-briefing. This involved reading the project instructions, completing a quiz, practical exercises of labelling and form completion and CAPI practise. The practical exercises and quiz were marked in the office and feedback given to each nurse.

4.3.2 Nurse contact and first nurse visit

The nurse made initial contact with the participant(s) via telephone, after which they sent a letter confirming details of the appointment date and time to the participant(s). They then visited participating households at least twice. The purpose of the first nurse visit was to encourage the participant(s) to take part, check eligibility, provide the participant(s) with detailed leaflets about PABA (see Appendix A) and the urine collection instructions, obtain written consent and deliver the equipment. The nurse also agreed a date with the participant(s) for when they would carry out the 24-hour urine collection, assigned a serial ID for labelling and booked an appointment for the second visit (usually the day, or the day after, the 24-hour urine collection finished). The nurse completed an appointment card for the participant to serve as a reminder of when the nurse would return to pick up the urine sample(s).

4.3.3 Urine collection protocol

After obtaining written consent (see Appendix B), participants were asked to collect all urine they passed during a 24-hour period starting from the second morning urine pass of the 24-hour collection day, and ending with the first urine passed the following morning. The nurse discussed with the participant on which day of the week to make the collection. In order to maximise response participants were allowed to make the collection on a day of their choice and the majority preferred to collect their sample at the weekend (or on another non-work / college day). However, in recognition that diet often differs between weekdays and weekend days, nurses encouraged participants to collect their sample on a weekday where possible. Females were instructed to collect their urine on non-period days.

To do the 24-hour collection, participants were provided with the following equipment:

- 5 litre capacity screw cap (or jerry can) container to serve as the collection container for urine. This contained a small amount of the preservative boric acid (powder)
- 2 litre capacity screw cap container for collections made away from the home. This was also used as an overflow container should the participant fill the 5 litre jerry can
- 1 litre plastic jug, kept inside a re-sealable plastic bag when not used
- Funnel kept inside a re-sealable plastic bag when not used
- Plastic carrier bags for transporting the equipment away from home
- An aide-memoire safety pin for the participant to pin the under- and outer garments together during the period of the collection to remind that the specimen of urine about to be passed should be collected
- Three PABA tablets to be taken to verify completeness of the 24-hour collection

Participants were instructed to pass urine into the 1 litre plastic jug, and then pour the sample into the 5 litre collection container using the funnel provided. Plastic bags were provided to carry the equipment (including a smaller 2 litre collection container) if participants were not at home for some of the collection period.

Participants were also asked to take three PABA tablets at evenly spaced intervals throughout the day of the collection (the first tablet in the morning at 8am (no later than 12noon), the second at 12 noon (no later than 4pm) and the last tablet at 6pm (no later than 10pm)). Analysis of PABA excretion provided a measure of the completeness of the 24-hour urine sample (see section 4.4). However unlike previous sodium excretion surveys, participants were still eligible to take part if they did not want to take PABA but were willing to carry out the 24-hour urine collection. Likewise, those who could not take PABA because of an allergy to vitamin preparations, hair dyes or sunscreen lotions and those who were taking sulphonamide antibiotics, but were willing to carry out the collection, were eligible.

Before leaving the household the nurse completed the participant details, agreed start date of the 24hour collection and whether the participant had consented to take PABA tablets on a Urine Collection Sheet (see Appendix C). This sheet was then completed by the participant during the collection period. They recorded the time they took the PABA tablets, the start and finish times of their collection, any missed urine passes, and any medication or supplements taken during the collection period.

4.3.4 Second nurse visit

At the second nurse visit the nurse collected two sub-samples from the 24-hour urine sample and disposed of the remaining urine and equipment. To do this the nurse was supplied with the following equipment:

- Scales for weighing the urine collection container.
- 2 x 10ml Sarstedt Urine syringe, 2 x quills, 1 small beaker.
- Disposable gloves, apron, disposable work mat, postal container and packing material for despatching the samples and despatch note.
- Labels for the urine samples.

The container with the 24-hour collection was weighed twice by the nurse and the weight recorded on the despatch sheet and in the CAPI. The nurse then carried out the sub-sampling procedure, and discarded the remainder of the 24-hour collection, labelled the samples and checked that the Urine Collection Sheet was complete, in particular the start and end time, report of any missed collections or missed PABA tablets and any medications/supplements taken during the collection period. This information was entered into CAPI. The nurse then packaged and sent the samples, Urine Collection Sheet, PABA blister pack and despatch paperwork to the laboratory at HNR.

Finally, each participant was given a £15 promissory note for their participation in the study (a £15 High Street voucher was subsequently sent out from the office).

4.4 Urine analysis (HNR) Lab procedure

After the second nurse visit, all samples were labelled and despatched to HNR, where the analysis of sodium was carried out using an ion selective electrode on the Siemens Dimension® Xpand clinical chemistry system with the QuikLYTE® module. Completeness of 24-hour urine collections was assessed using the para-amino-benzoic acid (PABA) recovery method.¹⁷

4.5 Assessment of completeness of collection

In brief, for those who consented to taking PABA and reported taking each of the three 80mg PABA tablets spaced at 8-hour intervals, urinary recovery over 24-hours was considered complete if the collections had a PABA recovery between 70% and 104%¹⁸ analysed by a HPLC method.¹⁹ Further details are provided in Appendix D. A recent methodological study (unpublished data) conducted at HNR showed that for our current analytical HPLC method, the appropriate cut-off for completeness in healthy adults is 70% (mean - 2SD) which incorporates both biological and methodological variation. This is a different assay method to those used in previous sodium surveys (see Appendix F).

Urine samples with a PABA recovery under 70% were considered incomplete, whilst samples with a PABA recovery greater than 104% were considered unfeasibly high and therefore unreliable. No

adjustment formulae were applied to the 24-hour sodium excretion for any of the samples in the current survey.

As on the main NDNS, individuals who elected not to take PABA but recorded they had completed a 24-hour urine collection were also included. Such individuals who recorded start and finish times within 1 hour of a 24-hour collection period (i.e. recorded urine collected between 23-25 hours) were deemed to have a complete 24-hour collection. In addition participants who elected to take PABA but reported that they did not take all three PABA tablets yet still recorded they had completed a 24-hour urine collection were also included. Excluding the results from these individuals did not materially alter the results.

4.6 Methodological differences: comparisons with previous surveys

The protocol for analysing PABA in this current survey using a specific HPLC method, is a more secure way of determining the completeness of a urine collection than the less specific colorimetric methods used in the past (see Appendix F). The move to HPLC reflects improvements in analytical methods over time, and results in a more straightforward criterion for interpreting PABA recovery in terms of the completeness of 24-hour urine collections. HNR has built on the experience of methods used in the previous surveys, all of which used different protocols for excluding urine samples on the basis of the likelihood that the 24- hour collection was incomplete. If the more specific (HPLC) analytical method and revised exclusion criteria from the current survey had been applied to previous survey data the estimated impact would be a reduction in published estimates of mean salt intake in the region of 1 to 3%, or about 0.1 to 0.3g of salt. Median values would have been less affected and closer to the published values.

5 Response and Weighting

Response at the two stages of the sodium boost study, the usability (i.e. whether the participant was eligible, the sample was received by the lab and whether it was complete) and collection days of the sodium boost and NDNS samples is presented below.

5.1 RDD and nurse response (boost study)

Of 8,880 telephone numbers attempted by NatCen's telephone interviewers 39% (3,455) were useable. Of these, 26% (891) were households that had at least one eligible adult and agreed to the telephone interview (30% were ineligible, 42% refused the telephone interview and 2% were unproductive for another reason).

During the telephone interview 64% (573 / 891) agreed a nurse visit, although three households gave incorrect or incomplete contact details meaning 570 households were issued to the nurses.

(Table 1)

In total 1,001 individual cases were issued to nurses, of which nurses attempted to visit 70% (698) (303 (30%) were not attempted due to low nurse capacity during the fieldwork period). Of these, 92% (639) of individuals had a nurse visit (6% refused and 3% were returned as a non-contact or other unproductive) and 87% (610) provided a 24-hour urine sample. Table 2 shows this individual response at the nurse stage by sex.

(Table 2)

5.2 Number of useable samples (boost study and NDNS)

In total, 718 urine samples were collected (610 from the boost study and 108 from NDNS). However, four samples were collected from participants who were outside the 19 to 64 age range and one sample was not received by the laboratory.

Therefore, 713 urine samples, from 309 men and 404 women, were processed by the laboratory. Of these, 77% (547) were classified as 'complete' and 23% (166) were classified as 'incomplete or unreliable'.

(Table 3)

The majority of urine samples that were classified as 'incomplete or unreliable' (162) were excluded from the dataset on the basis of PABA excretion being outside the range of 70-104% where three PABA tablets had been taken, or on the basis of the participant's record where three PABA tablets

were not taken. Four samples were excluded because of an incomplete or missing urine collection form. See details in Table 4.

(Table 4)

The sex of participants included in the analysis was significantly different (p<0.05) from the participants excluded from the analysis; urine samples from 19% of men (59 / 309) and 26% of women (107 / 404) were excluded. Of those included in the analysis, 46% were men and 54% were women. However, the age of participants was not significantly different between the included and excluded sample. The mean age for men was 47.6 years in the included sample and 46.5 years in the excluded sample. For women the mean age in the included sample was 48.1 years, and 46.6 years in the excluded sample. This was similar to previous urinary sodium surveys.

(Table 5)

5.3 Urine collection days

As described in section 4.3.3, where possible nurses encouraged participants to collect their urine sample on a weekday, so that the collection timings were not concentrated at the weekend when diet may differ.

Overall, 46% of samples were collected from Monday to Friday, and 54% were collected at the weekend. Table 6 shows day of 24-hour urine collection by day of the week broken down by age group and sex.

(Table 6)

5.4 Weighting

There were two stages to the weighting. The first step was to generate a set of weights to correct for unequal selection probabilities of individuals within households. The second stage was to make an adjustment for different levels of non-response.

Selection weights

A set of selection weights were generated to adjust the sample for selection of individuals within eligible households. Selection probabilities varied depending on the sample source. For the sodium boost sample up to two adults aged 19 to 64 years were selected from each household, with male household members having a higher chance of being selected. Men in households with three or more eligible individuals were weighted by a factor of 1.56, whilst women within the households were given a weight of 1.00. A factor of 1.56 was chosen as it was estimated that this would increase young males in the responding sample by around 30% (as previous studies had shown that men had lower

response rates). Two household members were then selected at random with probability proportional to this weight. For NDNS, one eligible adult aged 19 years or over was selected, although selected adults aged 65 or over were not included in this sodium survey.

Selection weights are equal to the inverse of the selection probabilities:

- The selection weights for boost sample members in households with up to two eligible household members are equal to 1, since all eligible individuals were selected
- The selection probabilities for boost sample members in households with more than two eligible household members are equal to: 2 X weighting factor / total weighting factor, where the weighting factor is 1.56 if the individual was male and 1.00 if the individual was female, and the total weighting factor is the sum of the weighting factors of all eligible household members. The selection weights are then equal to the inverse of this selection probability
- Within each NDNS household one eligible adult was selected at random with equal probability. The selection weights are therefore equal to the number of eligible NDNS individuals (aged 19+) within the household ²⁰

Calibration of the selection weights

The selection weights were then adjusted to create a final set of weights for analysis. All individuals who provided a useable sample were given an analysis weight. The analysis weights were generated using calibration methods. The aim was to reduce bias resulting from sampling error and differential non-response by sex and age and Government Office Region (GOR). An iterative procedure was used to adjust the selection weight until the distribution of the (weighted) sample matched that of the English population by age, sex and GOR. The adjustment keeps the values of the final weights as close as possible to those of the initial weights to ensure the properties of the initial weights are retained in the final calibrated weights. Population information about individuals aged 19 to 64 and living in England was taken from the 2010 mid-year population estimates.²¹ The distributions of the population and weighted and unweighted samples are shown in Table 7.

(Table 7)

6 Results

6.1 Estimated salt intakes

The aims of the 24-hour urine collection analysis were to estimate the mean and population distribution of 24-hour salt intake (g per day) in England among those aged 19 to 64 years.²² In line with the 2000/01 NDNS of Adults aged 19 to 64 years¹⁰ and the previous urinary sodium surveys in England (2006),²³ Scotland (2006),²⁴ Wales (2007),²⁵ UK (2008)³ and Scotland (2009)²⁶ salt intake was calculated using the equation: 17.1 mmol of sodium = 1 g of salt. This assumes that dietary intake of sodium is equal to the 24-hour sodium output in urine, and that all sodium in the diet comes from salt.²

Table 8 provides mean urinary sodium excretion by sex and age group expressed as mmol/24hr and table 9 shows the percentage distribution of urinary sodium excretion. Table 10 provides mean estimated salt intake by sex and age group expressed as g per day and table 11 shows the percentage distribution of estimated salt intake. Mean urinary sodium excretion was 159mmol/24hr for men and 117mmol/24hr for women aged 19 to 64 years.

The mean estimated salt intake for adults aged 19 to 64 years was 8.1g per day, with men having a mean daily intake of 9.3g per day and women having a mean daily intake of 6.8g per day. Table 10 shows that there was a downward trend in mean estimated salt intake in women with increasing age; however the same pattern was not seen in men.

(Table 10)

Overall, 70% of the participants had a daily intake of salt higher than the recommendation of no more than 6g per day. Among men 80% exceeded 6g per day compared with 58% of women.

(Table 11)

7 Salt intake Trend Analysis (2000/01 to 2011)

This section of the report describes an analysis of trends in estimated salt intake (g per day, calculated from 24-hour sodium excretion) for the seven sodium surveys carried out in UK countries between 2000/01 and 2011: NDNS 2000/01 (GB),¹⁰ England Sodium Survey 2006,²³ Scottish Health Survey Sodium Survey 2006,²⁴ Wales Sodium Survey 2007,²⁵ UK Sodium Survey 2008,³ Scottish Health Survey Sodium Survey 2009²⁶ and the NDNS England Sodium Survey 2011. For the trend analysis, each survey has been treated as a separate time point. This means that results from different countries are compared over time. Sodium intake in different UK countries will be affected by a range of factors. However we consider that there are enough similarities between UK countries to make this a valid comparison. The key details of these surveys are shown below.

Survey	Year	Useable urine sample size	Age-range (years)	PABA
Great Britain	July 2000 - June 2001	1,152	19-64	None
England	October 2005 – July 2006	515	19-64	Required
Scotland	March – November 2006	564	19-64	Required
Wales	May – November 2006	533	19-64	Required
United Kingdom	January – May 2008	692	19-64	Required
Scotland	January 2009 – February 2010	702	19-64	Required
England	July - December 2011	547	19-64	Optional
	(majority in September,			(although
	October and November)			encouraged)

7.1 Trend analysis methodology

In some surveys, an adjustment was made to the sodium excretion in a proportion of urine samples to compensate for incomplete 24-hour collections. The sodium content of these incomplete samples was adjusted according to the amount of PABA that had been recovered. Further discussion of this adjustment and the formula used to make the adjustment can be found in Appendix F and the 2009 Scottish Health Survey sodium report.²⁶

Estimated salt intake (g per day) was then calculated using the equation: 17.1 mmol of sodium = 1 g salt.

No adjustments were made to samples from the NDNS 2000/01 sodium survey (PABA was not used in this survey) or to samples from the NDNS England 2011 sodium survey (as different inclusion criteria were applied). The impact of these methodological and analytical differences is described in Section

4.6 and Appendix F. In summary if the more specific HPLC method and revised exclusion criteria used in the NDNS England 2011 survey were applied to previous survey data it would be likely to slightly reduce previous published mean salt intake values by approximately 1 to 3%, or about 0.1 to 0.3g of salt.

The data were weighted and clustered. The appropriate survey weights were used for each of the surveys included in the analysis. The analysis incorporated information about clustering as each survey had been geographically clustered for practical reasons. The analysis was run using the complex surveys module in SPSS, which allows information about weights and clusters to be correctly taken into account when generating estimates and standard errors. Any stratification was ignored however, since this information was not available for all surveys. Stratification generally improves survey precision slightly, ignoring it in the analysis makes the estimated standard errors (and therefore confidence intervals) slightly larger than they would otherwise be, although the impact will be small.

7.2 Trend analysis results

Table 12 shows the mean estimated salt intake (g per day, calculated from 24-hour sodium excretion) for each sodium survey carried out between 2000/01 and 2011. Figures 1 and 2 plot the mean estimated salt intakes and 95 per cent confidence intervals for the different survey years. Figure 1 shows mean estimated salt intake overall and Figure 2 shows separate means for men and women. The focus of this analysis is the trend in salt intake between 2000/01 and 2011 (i.e. the slope).

The table and plots show a downward trend in the mean estimated salt intake (g per day) both overall and for men and women. Overall, mean estimated salt intake decreased by 1.4g per day, from 9.5g per day in 2000/01 to 8.1g per day in 2011. Across the same period, mean estimated salt intake decreased by 1.7g per day for men (from 11.0g per day to 9.3g per day) and by 1.3g per day for women (from 8.1g per day to 6.8g per day).

(Table 12, Figures 1 and 2)

Linear regression was used to test the trend in mean estimated salt intake across survey years. The regression model was used to fit a trend line through the data and test the gradient of this trend. There was a significant downward trend in mean estimated salt intake across the period between 2000/01 and 2011. The decline across survey years was significant (p<0.05).

The same finding held when looking at men and women separately.

7.3 Comparisons between estimated salt intakes in the current and previous sodium surveys

The means and percentages for the 2011 survey discussed in this section are presented in Tables 8-11 of this report and are for stratified data. Means and percentages for the previous England 2006 and Wales 2007 survey datasets are un-stratified whilst the UK 2008 survey dataset is stratified using Standard Statistical Region, population density, socio-economic group and car ownership. In addition the adjustment formulae detailed in Appendix F were applied to marginally incomplete collections in these datasets. As previously mentioned, the application of the current survey's analytical methods and exclusion criteria to previous survey data would be likely to reduce the published mean salt intake values by approximately 1 to 3%, or about 0.1 to 0.3g of salt (see Section 4.6 and Appendix F). These small differences do not substantially affect the overall downward trend in salt intake over time.

In the period between 2008 and 2011, the mean estimated salt intake for persons aged 19 to 64 years decreased by 0.3g per day in men and 0.9g per day in women. However, this decrease in salt intake was not significant.

Eighty-nine per cent of men and 70% of women aged 19 to 64 years exceeded the 6.0g per day daily salt target in the 2006 England sodium survey. These figures were compared with the findings presented in Table 11 and Appendix F, which shows that in 2011 80% of men and 58% of women aged 19 to 64 years exceeded this salt target. In the 2008 UK sodium survey, 82% of men and 66% of women aged 19 to 64 years exceeded this salt target, whilst the 2007 Wales sodium survey showed 82% of men and 55% of women exceeded the 6.0g per day salt target.

8 Discussion

This report presents the results of a 24-hour urine sample study that was designed to provide an estimate of salt intake towards the end of 2011 using sodium excretion in urine. The study was carried out in a representative sample of adults aged 19 to 64 years in England from July to December 2011. The estimated daily salt intake was 9.3g for men and 6.8g for women (8.1g per day for men and women aged 19 to 64 years combined).

There was a drop between 2008 and 2011 in the estimated daily salt intake of adults aged 19 to 64 living in England. A comparison of salt intakes from the two years showed that this decrease was not statistically significant, due in part to the smaller than expected achieved sample size in 2011 (i.e. 549 rather than 600). However, the drop forms part of a wider downward trend and should be viewed in that context. A number of sodium studies have been carried out since the 2000/01 NDNS. A trend analysis using these studies showed a significant downward trend in salt intake across this period

The current and previous studies have resulted in a low number of useable samples in the younger age groups; most notably the 19 to 34 age categories, which highlights the continued challenges of involving younger adults in 24-hour urine studies.

Ongoing surveys enable the monitoring of progress made towards the UK population target of a mean intake of no more than 6g per day. It informs progress made by manufacturers in reducing the salt content of products and public health salt reduction campaigns. This report shows the overall downward trend in estimated salt intakes in similar surveys carried out over the past decade. It demonstrates positive progress towards the long term programme of salt reduction in the UK. However, a notable proportion of participants still have a daily salt intake greater than the recommendation of no more than 6g per day.





MRC Human Nutrition Research

The Diet and Health Study 2011 Information about PABA

If you have agreed to collect the 24-hour urine sample, our nurse will ask you to take 3 PABA tablets during the day. The tablets can be taken with food if you wish. This leaflet tells you about what PABA is and how it works.

• What is PABA?

PABA is short for **p**ara-**a**mino**b**enzoic **a**cid. It is a naturally occurring substance which is part of the B vitamin folic acid.

Small amounts of PABA are found in foods such as liver, kidney, brewer's yeast, molasses, whole grains, mushrooms and spinach. Larger amounts are included in some vitamin tablets, so we need to know if you are taking any vitamin tablets while you are providing the urine sample.



• Why are we asking you to take PABA?

We can tell how complete your sample is by measuring the level of PABA in the urine.

• Can PABA be used by anyone?

PABA is very safe. Substances like PABA are sometimes used in some hair dyes and PABA is sometimes used as a sunscreen. If you are allergic to sunscreen lotions, vitamin preparations or hair dyes you will **not** be given PABA. PABA is suitable for vegetarians as it does not contain any meat products. PABA is gluten free, however it does contain lactose (milk sugar). The nurse will check that it is safe for you to take the tablets before giving them to you.

PABA is safe but if you are pregnant, or think you might be pregnant, please be reminded that you should not take part in any aspect of this survey.

Some medicines and supplements interfere with the test we use for PABA in the urine, so we also need to ask you about the medicines and supplements you may be taking. We will not ask you to stop taking your medicines and supplements; we only need to know about them.

PABA should not be taken at the same time as one specific type of antibiotic. The nurse will check that it is safe for you to take tablets before giving them to you.

Please keep your PABA tablets safe and remember to take them during the day and to record when you take them on your Urine Collection Sheet!



If you have any questions about PABA, or if you are worried about any aspect of the urine collection, please speak to the nurse.







(BLOCK

Diet and Health Study 2011

CONSENT FORM

Affix serial ID label:

Respondent's name_

LETTERS)

- S I have received the information leaflets which explain the nature and purpose of the study. I have read and understood these leaflets.
- § I am satisfied with any enquiries I have made regarding the study.
- S I have been informed that the results will be kept confidential and presented in a way that protects my identity.
- S I understand that I may withdraw my consent to any or all of the survey elements at any time without needing to give a reason.

I hereby consent to the following aspects of the study:

24 HOUR URINE CONSENTS:

Please initial box if consent given

Taking PABA tablets to support the 24-hour urine collection.

Laboratory analysis of my 24-hour urine collection, to help assess my diet.

Storage of any remaining urine for tests in the future relating to nutrition and health, provided that the tests are approved by an NHS ethics committee. I understand that I can withdraw my consent to store my urine at any time, without giving any reason, by asking the investigators in writing for my urine to be removed from storage and destroyed. I understand that my data is being used in anonymised form only.

Signature:Date

Appendix C Urine Collection Sheet







Diet and Health Study 2011

24-hour Urine Collection Sheet

SECTION A: NURSE TO COMPLETE

	Nurse name
Please affix serial number label here Label UCOLL	Nurse Number
Respondent initials:	Respondent Sex: M
Respondent DOB:	/ / Age: Years
Start date of 24-hour collection	
Respondent consented to take F	PABA tablets? Yes No

SECTION B: RESPONDENT TO COMPLETE

1. DATE / TIME OF COLLECTION PERIOD

	Date	Time (24-hour clock)
24 hour collection: Start	/ /	:
24 hour collection: End	/ /	:

2. DATE / TIME OF PABA TABLETS

PABA tablet	PABA tablet taken? (Y / N)	Date	Time(24-hour clock)
* 1 st tablet – take at 8am		1 1	:
* 2 nd tablet – take at 12noon		/ /	:
* 3 rd tablet – take at 6pm		/ /	:

* Please see 24 hour urine collection information leaflet for detailed instructions.

If you forget to take a tablet please take it as soon as you remember and no later than 4 hours after the time stated above.

IMPORTANT: Please turn over and complete the rest of your collection sheet..

3. MISSED URINE

It is very important that you collect all the urine you produce in the 24 hour period.

However, if you have MISSED any urine collections, please make a note of the date and time in the table below:

	Date	Time (24-hour clock)
1	/ /	:
2	/ /	:
3	/ /	:
4	/ /	:

4. MEDICINES AND DIETARY SUPPLEMENTS

We also need to know about any medicines and dietary supplements you have taken over the 24 hour period. Please enter the names of these in the table below:

1	
2	
3	
4	
5	
6	

Please give this form to the nurse, along with your urine sample. The nurse may ask you to confirm some of the details you have recorded.

Many thanks for taking part in this study.

As a token of our appreciation we will send you £15 in High Street vouchers for completing this study.

Appendix D HNR analytical procedures

This appendix describes the methods used to analyse sodium and PABA in the Sodium Survey, England 2011 and details regarding the quality control procedures for these assays are described in Appendix E.

Sodium measurement

The sodium method on the Siemens Dimension® Xpand clinical chemistry system with the QuikLYTE® module is an established *in vitro* diagnostic test intended for the quantitative measurement of sodium and potassium in urine. An ion-specific electrode is used to develop an electrical potential proportional to the activity of each specific ion in the sample. The electrical potential generated by a sample is compared to the electrical potential generated by a calibrator solution, and the concentration of the desired ions is calculated (in mmol/litre) by use of the Nernst equation. Sampling, reagent delivery, mixing, processing, calculation and printing of results are automatically performed by the Dimension® system. Samples are identified with bar codes; the instrument automatically uploads barcode and concentration information to a results spreadsheet, thus eliminating transcription errors.

PABA Analysis by HPLC

HPLC was used to analyse PABA in the 2011 sodium survey. PABA metabolites in urine are hydrolysed under alkaline conditions, the solution is then neutralised and the resultant PABA determined by HPLC. The HPLC method is a reverse–phase method using an internal standard to compensate for volume losses during hydrolysis. The PABA HPLC method used at HNR is based upon that previously used at the MRC Dunn Nutrition Unit which in turn is based upon the method described by Jakobsen *et al.*,(1997).¹⁹ The PABA HPLC method was then modified at HNR to replace the acetonitrile in the mobile phase with methanol because of the unavailability of acetonitrile.

Completeness of hydrolysis is monitored by including a sample containing PAHA (para amino hippuric acid) with each batch. This is hydrolysed to PABA which is then quantitated by HPLC.

Appendix E HNR Laboratory quality control procedures

The quality of the laboratory analyses is assured by rigorous instrument maintenance, staff training, adherence to standard operating procedures and good laboratory practice. The quality control and assessment practices used at HNR are all standard procedures for the type of assay used and HNR is ISO accredited (BS EN ISO 9001:2008).

An aliquot of a urine sample containing PABA is included in every chromatographic run, treated in exactly the same way as the respondents' samples. This was frozen when fresh as several hundred single-use aliquots, one of which was thawed and used each day. The running mean and standard deviation of the PABA concentration in this sample obtained on each occasion is recorded in 'JMP', a laboratory QC program (www.jmpdesign.com). Each result for this QA sample is compared with this mean and assay results for the batch are accepted if the QA results lie between -2SD and +2 SD of the mean. The data for this running control are also examined for evidence of drift and for evidence of any changes when new calibrators are prepared. Sample results are reported if these checks indicate that the assay is in control, and repeated if not.

Additionally the following controls are included:

- An internal standard (prepared in-house; meta hydroxybenzoic acid) is used to ascertain that recovery is within acceptable limits and to correct for any minor discrepancies in extraction recovery
- A solution of PAHA (para aminohippuric acid) at known concentration is subjected to the hydrolysis procedure as described in Appendix D and included in the assay, to ensure that this part of the analysis has proceeded fully

There is no external quality assessment scheme for PABA.

Urine electrolytes (Siemens Dimension Xpand analyser)

Internal commercially-prepared quality control samples (Biorad Liquichek) are run on the analyser to check for proper calibration and function before the samples are analysed, and included in every batch. The results are recorded (mean, sd, %cv) and for each quality control (QC) sample a check is made that the result obtained is within the manufacturer's specified range and also within our more stringent criteria, i.e. within 2SD of the mean and standard deviation, both determined at HNR.

The HNR Nutritional Biomarker Analysis Laboratory is a member of NEQAS (National External Quality Assessment Scheme) - this scheme sends samples "blind" to all hospital and similar labs

in the UK and compares results, therefore providing regular accuracy checks against hundreds of peer laboratories and against target concentrations. The laboratory's performance in this scheme is consistently good.

Appendix F PABA adjustment formula – comparison with the previous survey analysis

In previous surveys, where PABA excretion indicated that the collection was marginally incomplete, the measured sodium content was adjusted to estimate the sodium content had all the urine passed during the 24-hours been collected. An adjustment was carried out when the PABA recovered in the urine was between 70% and 85% by the less specific colorimetric method and between 75 to 78% for those samples additionally analysed by HPLC in some surveys.¹⁷ Such an adjustment was unnecessary in the present survey because of the revised exclusion criteria.

The method used to compensate for incomplete 24-hour collections in the Scotland Sodium Survey 2009 is described in Johannsson et al 1999.²⁷

Adjusted 24-hour Sodium = Sodium + 0.82 X (93 - Percentage PABA recovery)

This published formula was used in the 2004 Health Survey for England sodium survey.²⁸ In recent UK sodium surveys including the England Sodium Survey 2006,²³ Wales Sodium Survey 2007²⁵ and the UK Sodium Survey 2008³ a different formula was used. As there was no published reference for this formula, the original adjustment formula taken from Johannsson et al 1999²⁷ has been used where compensation for incomplete urine collections was required.

Adjusted 24-hour Sodium = Sodium X (93 / Percentage PABA recovery)

Data from the previous England Sodium Survey 2006,²³ Wales Sodium Survey 2007²⁵ and the UK Sodium Survey 2008³ have been reanalysed using the referenced PABA adjustment formula taken from Johannsson et al 1999,²⁷ to allow direct comparison with the current survey.

The effect of reanalysing the 2006 to 2008 data using the formula described in Johannsson et al 1999²⁷ on mean sodium output and mean estimated salt intakes overall was small, although differences in individual intakes where adjustment was required were more marked. These corrected values have been used in the trend analysis and are shown in Table 12.

In previous surveys a colorimetric method was the primary assay method for the measurement of PABA in 24-hour urine samples. Any samples with high values that suggested gross interference were repeated using HPLC. Interference arises because the colorimetric assay cannot discriminate between PABA and other aromatic amines which may originate from drugs, most commonly paracetamol. HPLC is now used for all samples at HNR instead of the traditional colorimetric method as such interference can also occur at lower levels and may not produce a colour signal sufficient to trigger re-analysis by HPLC. This may make incomplete collections

appear complete and therefore lead to them being included inappropriately in the dataset. The move to HPLC reflects improvements in analytical methods over time, and results in a more straightforward criterion for interpreting PABA recovery in terms of the completeness of 24-hour urine collections. Applying the more specific HPLC method and revised exclusion criteria for completeness to previous survey data would result in lower estimates of mean salt intakes than previously published values in the region of 1 to 3%, or about 0.1 to 0.3g of salt. Median values would have been less affected and closer to the published values.

9 References and Notes

1 Scientific Advisory Committee on Nutrition (2003). Salt and Health. The Stationery Office. <u>http://www.sacn.gov.uk/pdfs/sacn_salt_final.pdf</u>. (The recommendation is for no more than 6.0g of salt per day.)

2 Salt (sodium chloride) is the major source of dietary sodium, however, there are other forms of sodium present in foods. For example, sodium citrate, monosodium glutamate, sodium cyclamate, sodium bicarbonate, sodium nitrate.

3 National Centre for Social Research. An assessment of dietary sodium levels among adults (aged 19–64) in the UK general population in 2008, based on analysis of dietary sodium in 24-hour urine samples. 2008. <u>http://www.food.gov.uk/multimedia/pdfs/08sodiumreport.pdf</u>

4 National Diet and Nutrition Survey. Department of Health. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsStatistics/DH_12816

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7 National Institute for Health and Clinical Excellence (2010). Guidance on the prevention of cardiovascular disease at the population level. http://guidance.nice.org.uk/PH25/Guidance/pdf/English

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http://www.food.gov.uk/science/dietarysurveys/ndnsdocuments/ndnsprevioussurveyreports/ndnsv 303

11 Department of Health (2001) The Annual Report of the Chief Medical Officer of the Department of Health.

12 http://www.food.gov.uk/multimedia/pdfs/salttargetsapril06.pdf

- 13 http://www.food.gov.uk/scotland/scotnut/salt/saltreduction
- 14 http://responsibilitydeal.dh.gov.uk/
- 15 http://tna.europarchive.org/20090810121540/http://salt.gov.uk/index.html

16 http://www.nhs.uk/Change4Life/Pages/change-for-life.aspx

17 Bingham S and Cummings J H. The use of 4-aminobenzoic acid as a marker to validate the completeness of 24h urine collections in man. Clin Sci (Lond) 1983; 64(6):629-35.

18 Recoveries slightly greater than 100% reflect the fact that there is inevitably some error in both the measurement of the volume (weight) of the 24 hour urine collection and the measurement of the concentration of PABA in the urine.

19 Jakobsen J, Ovesen L, Fagt S, et al. Para-aminobenzoic acid used as a marker for completeness of 24-hour urine: Assessment of control limits for a specific HPLC method. Eur J Clin Nutr 1997; 5: 514.

20 The selection weights for NDNS sample members are based on the chance an individual had of being selected for the NDNS, where one person was selected out of all those in the household aged 19 or over. Although we later drop selected individuals aged 65 or over, these individuals would have been involved in the selection process for younger household members, so should be included in the weight.

21 Office for National Statistics. *Mid 2010 Population Estimates*. [Online] Available: <u>http://www.ons.gov.uk/ons/rel/pop-estimate/population-estimates-for-uk--england-and-wales--</u> <u>scotland-and-northern-ireland/mid-2010-population-estimates/index.html</u> (accessed 26/04/2012).

22 Analysis of the results in this section and table 10 were done using Stata whereas the trend analysis in section 7 was done using SPSS. The two packages calculate standard errors and standard deviations slightly differently.

23 National Centre for Social Research. An assessment of dietary sodium levels among adults (aged 19–64) in the general population in England, based on analysis of dietary sodium in 24-hour urine samples. 2006. <u>http://www.food.gov.uk/multimedia/pdfs/englandsodiumreport.pdf</u>

24 National Centre for Social Research. A survey of 24-hour and spot urinary sodium and potassium excretion in a representative sample of the Scottish population. 2006. <u>http://www.food.gov.uk/multimedia/pdfs/scotlandsodiumreport.pdf</u>

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