safefood

Salt: Hard to Shake

Dietary salt intake and related risk factors in the Irish population

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Cite as: Perry IJ, Browne G, Loughrey M, Harrington J, Lutomski J, Fitzgerald AP (2010). Dietary salt intake and related risk factors in the Irish population. A report for ***safe*food**.
ISBN: 978-1-905767-13-7

Foreword

Dietary salt intakes greatly exceed nutritional requirements in almost all populations worldwide. High salt intake is associated with high blood pressure, heart disease, stroke and a number of other conditions. Internationally there is now scientific and policy consensus on the need to decrease dietary salt intake in order to reduce the burden of suffering and death. During the past decade governments and statutory agencies worldwide have set targets for reductions in salt intake in their populations. In 2005, the Food Safety Authority of Ireland (FSAI) estimated that Irish adults were consuming an average of 10 grams of salt per day and recommended a target of 6 grams or less. This target has been actively supported by all of the relevant stakeholders including the Department of Health & Children. The Food Safety Authority of Ireland has taken a leading role in working with the food sector to reduce the salt content of processed food. ***safe*food**, a North-South body responsible for the promotion of food safety on the island of Ireland, has coordinated public education initiatives. ***safe*food** commissioned this research on salt intakes in Irish adults in order to assess the impact of these initiatives to date and to contribute to ongoing strategy development. The study was led by Professor Ivan Perry and Dr Gemma Browne, working with colleagues in the Department of Epidemiology and Public Health, University College Cork, and the Health Research Board Centre for Health and Diet Research.

Publication date: October 2010

ISBN: 978-1-905767-13-7

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Glossary of Acronyms

AI: Adequate Intake

BMI: Body Mass Index

BP: Blood Pressure

CI: Confidence Intervals

CVD: Cardiovascular Disease

DASH: Dietary Approaches to Stop Hypertension trial

EPIC: European Prospective Investigation of Cancer

ESRI: Economic and Social Research Institute

EU: European Union

EURONUT: European Community Concerted Action on Nutrition and Health

FDA: Food and Drug Administration

FFQ: Food Frequency Questionnaire

FSAI: Food Safety Authority of Ireland

g/day: Grams per day

GP: General Practitioner

GRAS: Generally recognised as safe

kcal/day: Kilocalories per day

mg: Milligrams

mmHg: Millimetres of Mercury

mmol: Millimole

NHANES: National Health and Nutritional Examination Surveys

PABA: Para-aminobenzoic acid

IQR: Inter Quartile Range

RCSI: Royal College of Surgeons in Ireland

RDA: Recommended Daily Allowance

SD: Standard Deviation

SLÁN: Survey of Lifestyle, Attitudes and Nutrition

UCC: University College Cork

UK: United Kingdom

UL: Tolerable Upper Limit

WHO: World Health Organisation

Acknowledgements

The principal investigators and research team at University College Cork (UCC) gratefully acknowledge the funding received by ***safe*food** and the support and advice from Dr Cliodhna-Foley Nolan, Director of Human Health and Nutrition at ***safe*food**. The research group are also supported by the Health Research Board and the Department of Agriculture and Food under the aegis of the HRB Centre for Health and Diet Research. We would also like to thank the following scientists, medical personnel and organisations who contributed to the study:

- SLÁN 2007 consortium (Survey of Lifestyle, Attitudes and Nutrition) led by Prof Hannah McGee at the Royal College of Surgeons (RCSI) in collaboration with the Economic and Social Research Institute (ESRI), NUI Galway (Department of Health Promotion) and UCC (Department of Epidemiology & Public Health).
- Ms Lorna Cox and Ms Shirley Runswick, MRC Human Nutrition Research, The Elsie Widdowson Laboratory, Cambridge, United Kingdom.
- Professor Kevin Cashman, UCC.
- Dr Stephen Byrne, Dr Laura Sahm and Mr Dónal Óg O'Donovan, College of Medicine and Health, School of Pharmacy, UCC.
- Dr Joseph A Eustace, Consultant Nephrologist, Cork University Hospital.
- Professor Barbara Livingstone, University of Ulster.
- Dr Carl Vaughan, Mercy University Hospital, Cork.

Finally, we would like to thank everyone who participated in this research study and the support of the management and staff at the occupational setting who granted permission for the sample study to be conducted at their place of work.


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Executive Summary

Introduction

Dietary salt intakes are well in excess of nutritional requirements in most countries worldwide (1). There is now an overwhelming scientific consensus, based on observational studies and clinical trials over the past 40 years, that salt intake in excess of physiological requirements plays a critical causal role in the rise in blood pressure with age and the development of essential hypertension (1-3).

Hypertension is the dominant risk factor for heart disease, stroke and related cardiovascular disease (CVD) in all populations. CVD, including heart disease, stroke and related diseases, is the major cause of death in Ireland, accounting for almost 40 per cent of all deaths. A relatively modest reduction in salt intake has the potential to prevent a significant number of heart attacks and strokes annually (4). In a recent study, based on data from the United States, it was estimated that a population-wide reduction in dietary salt of three grams per day (g/day) would decrease the annual number of new cases of Coronary Heart Disease in the US by a third to 120,000, stroke by a third to 66,000, and myocardial infarction by 54 per cent to 99,000 (4). It was further estimated that a regulatory intervention designed to achieve a reduction in salt intake of three grams per day would save 194,000 to 392,000 quality-adjusted life-years and between $10 billion and $24 billion in US health care costs annually (4).

In 2003, the Scientific Advisory Committee on Nutrition in the United Kingdom (UK), considering the extensive evidence for a direct link between salt intake and high blood pressure, recommended that the average consumption of nine grams of salt per day in adults in the UK should be decreased to six grams per day to reduce high blood pressure and lower the burden of cardiovascular disease (2). These recommendations were echoed in the Irish report published by the Food Safety Authority of Ireland (FSAI) in 2005 (3) which highlighted that Irish people are consuming salt at levels well in excess of tolerable upper limits (UL)[1].

1 Tolerable Upper limit (UL): the highest average daily nutrient intake level that is likely to pose no risk of adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects may increase.

The FSAI report recommended a similar target to that set in the UK: a fall in average salt intake from an estimated ten to six g/day by 2010. This target was set as a potentially achievable population level objective, not a recommended daily allowance (RDA)[2]. It should be noted that in 2005 the US Institute of Medicine proposed an adequate intake (AI) of 3.8 grams (g) and a tolerable upper limit (UL) of 5.8 g of salt daily[3] (5).

The Irish and UK authorities set the 6g salt per day target, while the World Health Organization (WHO) has set a lower target of 5g (6). Current data from EU member states indicates that salt intakes are exceeding this WHO maximum limit. The EU white paper *'A Strategy for Europe on Nutrition, Overweight and Obesity Related Health Issues'* urges member states to prioritise salt reduction. The EU Framework for National Salt Initiatives (2008) aims to reduce salt intake and member states are urged to carry out 24-hour urinary sodium excretion surveys, the gold standard method for estimating dietary salt intakes, to accurately assess the magnitude of the problem.

A relatively modest reduction in salt intake has the potential to prevent a significant number of heart attacks and strokes annually.

The FSAI report called for greater engagement with the food industry to reduce the salt content of foods on the Irish market. It recommended further research and regular population surveys to accurately assess salt intake in the population and monitor the prevalence of hypertension. It also recommended public awareness and health promotion campaigns aimed at reducing salt intakes.

Health promotion initiatives to highlight the health consequences of excess salt intakes and to support consumers in reducing consumption have been undertaken widely, with ***safe*food** and the Irish Heart Foundation leading them in Ireland.

In 2007 ***safe*food** commissioned this study to accurately assess dietary salt intake in the Irish population and its association with relevant lifestyle-related risk factors. The research project was led by Professor Ivan Perry and Dr Gemma Browne, working with a research team in the Department of Epidemiology and Public Health, UCC and the Health Research Board (HRB) Centre for Health and Diet Research.

2 Recommended daily allowance (RDA): the average daily nutrient intake level sufficient to meet the nutrient requirement of nearly all (97 to 98 per cent) of healthy individuals in a particular life stage and gender group.

3 Adequate Intake (AI): the recommended average daily intake level, based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate- used when an RDA cannot be determined.

Aims and Objectives

The overall aim of this study was to provide accurate and well validated estimates of dietary salt intake in the Irish population to support the ongoing evaluation of policy initiatives over the past decade designed to reduce it. The specific objectives were as follows:

To estimate dietary salt intake in the Irish population based on

1. (i) analyses of the existing SLÁN-07 nutritional dataset (7-8) and linked random ('spot') urine samples from this national health and lifestyle survey (Phase I study)
   (ii) studies of additional samples of adults with estimates of salt intake based on 24-hour urinary sodium excretion (Phase II study)
2. To describe variation in salt intake by age, sex, and measures of obesity.
3. To assess the dietary sources of salt.
4. To estimate potassium intakes based on 24-hour urine collection and describe the distribution of sodium to potassium ratio in the population.

Methods

The above objectives were addressed in two studies: SLÁN-07 (Phase I study) and the Phase II study.

Phase I study

The Phase I study was based on further analysis of SLÁN-07 data. SLÁN is a national health and lifestyle study funded by the Department of Health and Children. SLÁN-07 was based on a nationally representative household sample of 10,364 adults (62 per cent response rate) aged 18 years and over, recruited in 2007 (7-8). The study was conducted by a national research consortium led by Professor Hannah McGee at the Royal College of Surgeons (RCSI), in collaboration with the Economic and Social Research Institute (ESRI), NUI Galway (Department of Health Promotion) and UCC (Department of Epidemiology & Public Health). Food Frequency Questionnaire (FFQ) data was available from 9,223 subjects and 'spot' urine samples from 1,207 men and women aged 45 years and older who underwent physical measurements of height, weight, abdominal circumference and blood pressure.

Phase II study

Dietary data from the FFQ, physical measurements (height, weight, abdominal circumference and blood pressure) and 24-hour urine collections were obtained from a total of 599 adults aged 18 to 81 years based on three sub-samples. These were as follows:

- A general population sample drawn from participants on the SLÁN-07 survey who agreed to re-screening in 2008-09 (n=54) and participants of the 1998 Cork and Kerry Diabetes and Heart Disease Study (n=65) who were re-screened in 2007.
- A group of student volunteers (n=169) from two large academic institutions in the Republic of Ireland.
- An occupational group, sampled from an occupational setting (n=311) from a total staff of approximately 1600 workers.

24-hour urinary sodium excretion is considered the gold standard method to estimate dietary salt intake. In non-sweating individuals living in temperate climates and in steady state sodium and fluid balance, it is estimated that between 90 per cent and 95 per cent of dietary salt intake is excreted in urine. Up to three 24-hour urinary sodium collections are required to adequately characterise salt intake at the individual level. A single measurement, however, is adequate for group-level estimates of salt intake in nutritional surveillance studies.

24-hour urinary sodium excretion is considered the gold standard method to estimate dietary salt intake.

In this study we collected and assayed 24-hour urinary samples from the 599 participants in the Phase II study. Para-aminobenzoic acid (PABA), a biologically inert substance which is rapidly excreted in urine, was administered to all participants on the day of urine collection to validate the completeness of the 24-hour collection sample. The PABA-validated estimates of salt intake are based on 488 subjects who had taken PABA and had a measured percentage dose excretion of >70 per cent. The findings on salt intake are expressed as grams per day, mean (sd) and median.

To estimate total sodium excretion in the spot urines, the sodium content was corrected for total 24-hour urine volumes calculated from the validated 24-hour urine samples collected in the Phase II study by gender.

Table 1 provides an overview of the urinary analysis components of the Phase I and II studies.

Table 1 Urinary Analysis Studies

Study	Numbers	Urinalysis	Population
Phase I	1,207	Spot Urine	SLÁN- Irish householders
	Total 1,207		
Phase II	54	24 hour Urine +	SLÁN
	65	24 hour Urine +	Cork and Kerry Diabetes Cohort
	169	24 hour Urine +	Students
	311	24 hour Urine +	Occupational setting
	Total – 599		

Main findings

The results are organised into six main sub-sections. Dietary intake of salt was estimated using three different methodologies: self-reported food frequency questionnaires; spot urine analysis and 24-hour urine analysis, (see Table 2). Results from the three techniques are reported and compared, together with variation in these estimates by age, gender, blood pressure and obesity.

Table 2 Dietary salt intake estimates

Method	Sample size Age Range (years)	Mean g/d	Std. Dev. g/d	Median g/d
FFQ	SLÁN n= 9,223 (18-90)	8.1 (M) 7.6 (F)	3.9 (M) 3.5 (F)	7.4 (M) 7.0 (F)
Spot Urine	SLÁN n= 1,207 (36-90)	10.3 (M) 7.4 (F)	5.0 (M) 4.2 (F)	9.7 (M) 7.1 (F)
24 Hr Urine	n= 599 (18-81)	10.4 (M) 7.4 (F)	4.3 (M) 2.7 (F)	9.7 (M) 7.1 (F)

1. Estimates of salt intake derived from self-reported dietary intakes and level of agreement with estimates derived from 24-hour urine collection

   Self-reported dietary salt intake levels (mean (sd), median) estimated using the SLÁN-07 FFQ in n=9,223 individuals were 8.1g (3.9), 7.4 g/day for men and 7.6g (3.5), 7.0 g/day per day for women. These estimates do not include salt added during cooking or at the table.

   When salt intake estimated from 24-hour urine collections from the Phase II study were compared to FFQ estimates it was found that FFQ underestimates salt intake in men by approximately 15 per cent whereas estimates for women are accurate with an error of less than one per cent.

2. Dietary sources of salt

   The food groups contributing most to salt intake based on the food frequency questionnaires in SLÁN-07 and the Phase II study are cereals, breads and potatoes followed by meat, fish and poultry products, which together account for over 50 per cent of the salt in our diet, **Table 3**.

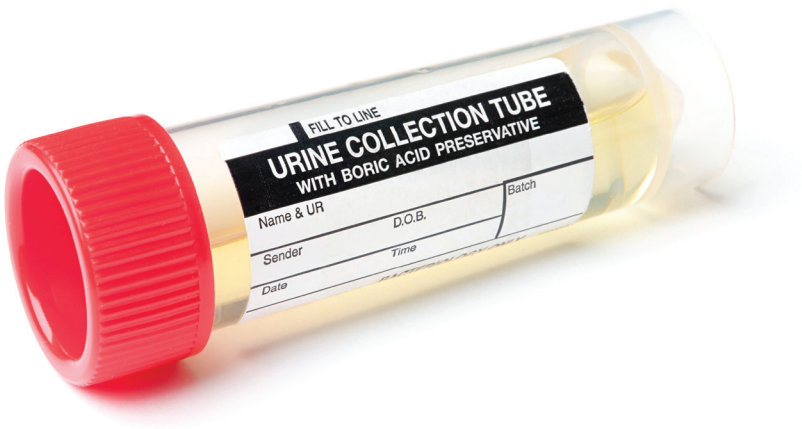


Table 3 SLÁN-07 study: Food groups contributing to salt intake based on Food Frequency Questionnaire data

	Salt (g)	Contribution to overall salt intake (%)
Cereals, breads, and potatoes	2.7	34
Meat, fish and poultry	1.8	22
Soups, sauces, spreads	1.1	14
Vegetables	0.9	11
Dairy products and fats	0.8	10
Sweets, savoury snacks	0.6	8
Drinks	0.1	1
Fruits	0.0	0
Milk	0.0	0

3. Dietary sodium intake density

   In the recent (2010) US Institute of Medicine report *Strategies to Reduce Dietary Sodium Intake in the United States* dietary sodium intake density (mg of sodium per 1000 calories consumed) is used to analyse secular trends in salt intake based on dietary recall (9-10). In this report we present estimates of dietary sodium intake density for Ireland using both the SLÁN-07 and the Phase II study FFQ data and we compare the findings with recent US data.

   In the SLÁN-07 data, the mean (sd) sodium intake density was similar in men and women (1,501 mg /1000 kcal (392) and 1,500 mg/1000 kcal (376)). The findings were similar in the Phase II study. These findings are also broadly consistent with data from the US based on 24-hour diet recall data from the National Health and Nutritional Examination Surveys (NHANES).

   In multivariate analyses, sodium intake density increases significantly with age but not with obesity.

4. Estimates of salt intake derived from spot urine samples and associations with blood pressure

   Using SLÁN-07 spot urine samples corrected for urine volume, the estimates (mean (sd), median) for salt intake per day in adults aged over 45 years were as follows: men, 10.3 grams (5.0), 9.7 grams and women, 7.4 grams (4.2), 7.1 grams.

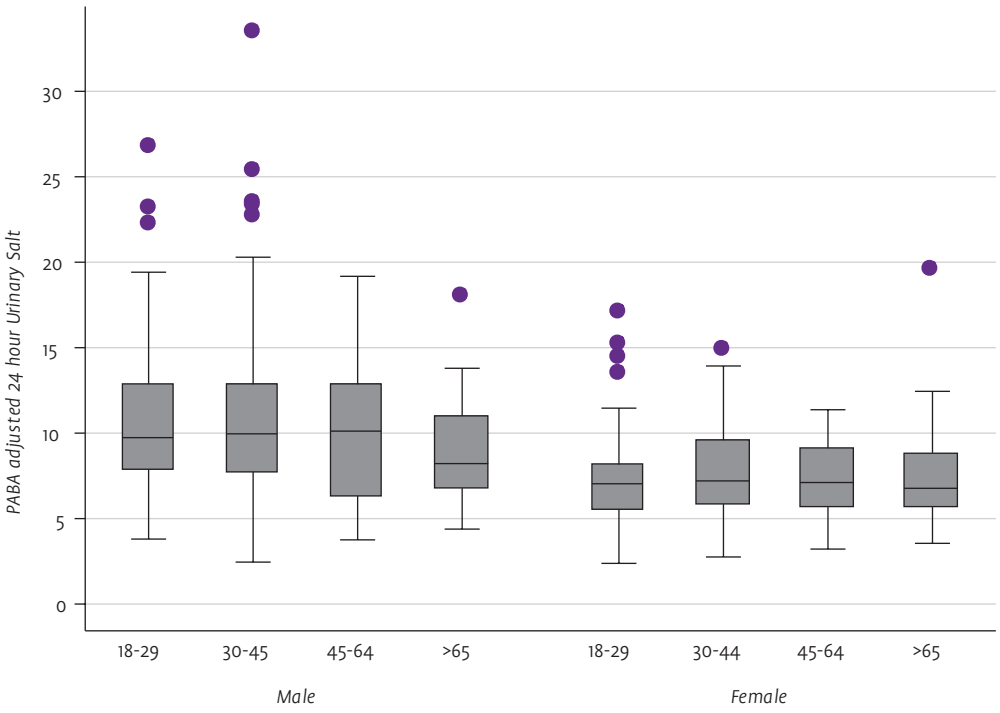
   The association between estimated salt intake and blood pressure in the 1,093 subjects who completed the SLÁN-07 physical examination and provided a urine specimen was examined. Following exclusion of those on anti-hypertensive treatment, including diuretics (four per cent of men and three per cent of women in this sample), positive associations with both systolic and diastolic blood pressure were observed.

5. Estimates of salt intake derived from 24-hour urine collection by age, gender and obesity measures

   Estimated dietary salt intake (mean (sd), median) based on PABA validated 24-hour urine collections was 9.3 g/day (4.1), 8.5 g/day with higher intakes in men 10.4 g/day (4.3), 9.7 g/day than in women, 7.4 g/day (2.7), 7.1 g/day.

   It was found that 86 per cent of Irish men (95 per cent CI 82 – 90 per cent) and 67 per cent of Irish women (95 per cent CI 60 – 74 per cent) consume more than six grams salt per day with only 1.3 per cent and 11.5 per cent consuming less than four grams per day. Significant variation in salt intake with age was not detected. However, there were relatively few participants in the older age categories, (see **Figure 1**).

Figure 1 Phase II study: Distribution of PABA-validated salt intake (g/day) by gender and age



Dietary salt intake was strongly associated with increased general and central obesity in both men and women in analyses adjusted for calorie intake (see **Figure 2 and Figure 3**).

Figure 2 Phase II study: Distribution of PABA-validated salt intake (g/day) by gender and general obesity

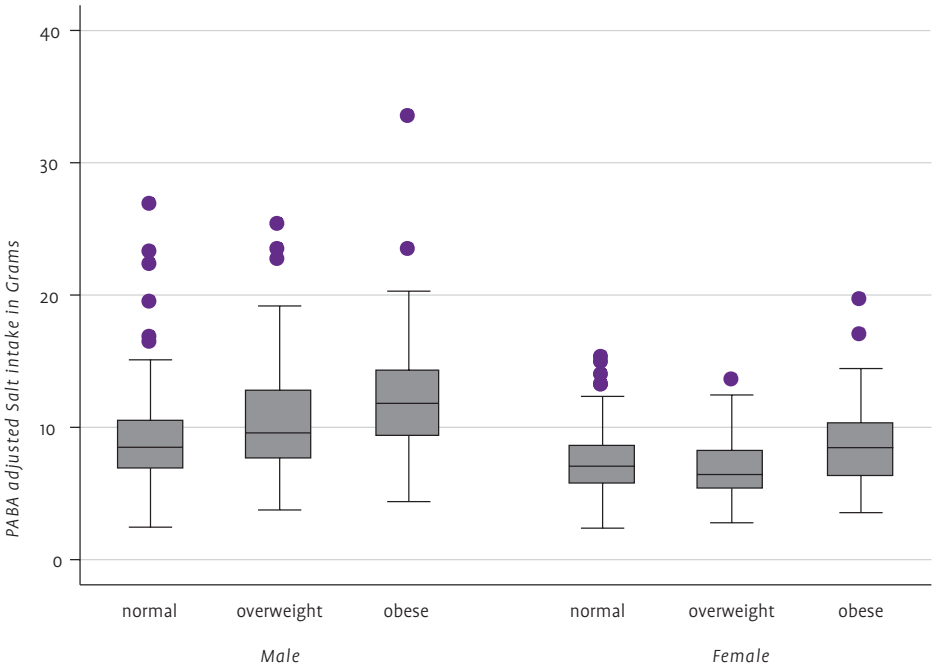
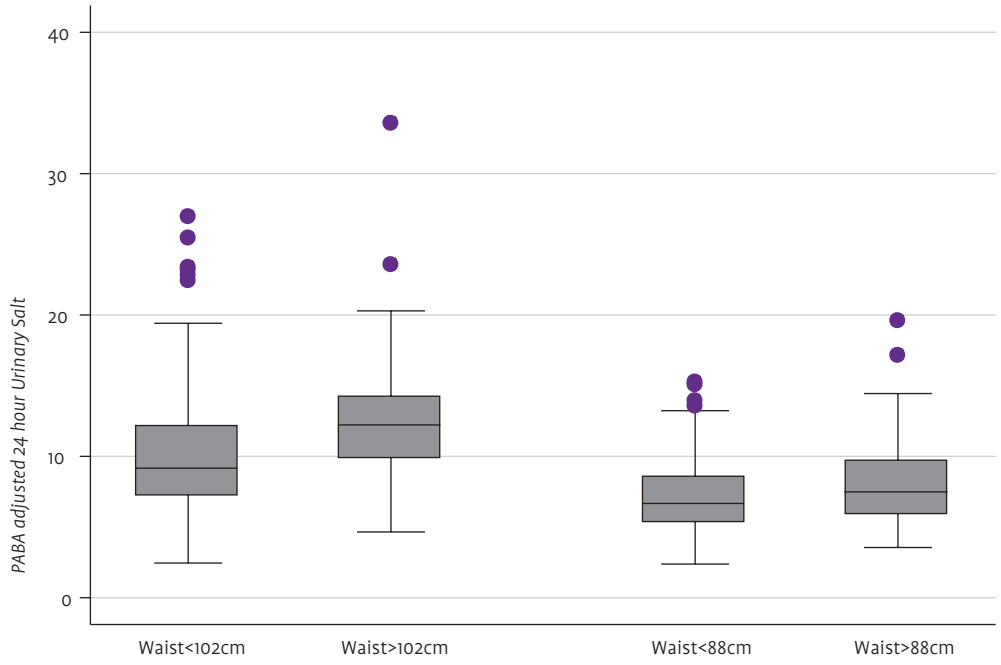


Figure 3 Phase II study: Distribution of PABA-validated salt intake (g/day) by gender and central obesity



6. Estimates of potassium intakes and sodium to potassium ratios derived from PABA validated 24-hour urine collections
   The Recommended Daily Allowance (RDA) for potassium is 3,100 mg/day. Estimated intakes (mean (sd), median) for men were 3630 mg/day (1180), 3560 mg/day and for women, 2780 mg/day (1050), 2620 mg/day. Sodium to potassium ratio (mean (sd)) was similar in men 2.0 (0.81) and women 1.93 (0.88) but varied inconsistently with age.

Conclusions

The findings from this study provide relevant data for the effective planning and evaluation of public health initiatives which are focused on reducing dietary salt intake in the population. The results highlight gender differences in dietary salt intake, a positive association between dietary salt intake and markers of obesity, and the potential use of spot urines in estimating population dietary salt intakes.

Dietary salt intakes in the Irish population remain high with the overwhelming majority of the population (86 per cent men and 67 per cent women) consuming salt at levels well in excess of the current target of six grams per day. Average (mean) salt intake based on 24-hour urinary collections in the study (Phase II) was 9.3 g/day, with substantially higher rates in men at 10.4 g/day than in women at 7.4 g/day, highlighting a significant gender difference.

The poor response rate for the studies involving 24-hour urine collections (Phase II), which require considerable commitment from volunteers, highlights the challenges we face in monitoring salt intake in the population. It is noteworthy that estimates of salt intake based on random ("spot") urine samples from the SLÁN-07 study, adjusted appropriately for 24-hour urine volume, provide group level estimates of intakes that are similar to those derived from PABA validated 24-hour urine collections. This observation, if replicated, has important practical implications for population level nutritional surveillance of salt intakes.

Dietary salt intake was strongly associated with general and central obesity in both men and women. This finding has implications for targeting future health promotion initiatives.

It is likely that we are underestimating average salt intakes in the population, given the potentially significant volunteer biases in both the SLÁN-07 and the Phase II study samples – due to declining response rates for health and nutritional surveys and the particular difficulty of recruitment for studies involving 24-hour urine collections.

There is no clear evidence from this research that salt intakes have declined over the past two decades. It is probable that increasing calorie intakes, reflected in rising levels of overweight and obesity, are now an important factor contributing to high salt intake and may be cancelling the impact of recent modest changes in the salt content of processed food. The findings suggest that current efforts to reduce salt intake in the population through engagement with the food industry need to continue and to be intensified.

Key recommendations from this study include the following

As most salt is added to food during processing, the relevant statutory agencies should engage more intensively with the food sector to ensure that further reductions in the salt content of processed food are achieved within a reasonable time scale.

Health promotion initiatives that highlight the health consequences of excess salt intakes and promote lower salt products and the use of less discretionary salt should be adopted to support the work of the food industry and the regulatory food agencies.

In keeping with international best practice, the findings support the need for a multifaceted approach with an emphasis on focused health promotion initiatives.

A key part of the equation are campaigns that raise awareness and promote choosing lower salt products, increasing consumer demand for them and for using less discretionary salt.

The findings also identify specific at risk groups in the Irish population (males and overweight individuals) at whom interventions should be targeted.

The issue of clear and accurate labelling of the salt content of processed food, using simple formats such as the traffic lights system, should be reviewed as a high priority. In particular, the practice within the food industry of referring to a salt intake of six grams per day as a 'guideline daily amount' is misleading, and should be discontinued.

Given the accumulating evidence on the health and economic costs of high salt intake the government, in collaboration with our EU partners should consider, the statutory regulation of the salt content of processed food. As suggested in the (2010) US Institute of Medicine report, *Strategies to Reduce Dietary Sodium Intake in the United States* (9), mandatory changes in permissible salt concentrations in processed food could be phased in over a reasonable time scale to allow consumers and the food industry to adapt.

There is a need for ongoing population monitoring for salt intake as part of national nutrition surveillance systems. In particular, we need reliable data on salt intake in children and adolescents.

Given the difficulties associated with obtaining 24-hour urine collections from representative samples of adults and children, the group level reliability of alternative methods of surveillance of dietary salt intake, such as random ("spot") samples corrected for urinary volume and dietary sodium intake density, should be further assessed.

The annual health and economic costs of excessive salt intake should be modelled for the Republic of Ireland using this data and relevant additional data on morbidity, mortality and costs.

Dietary salt intakes in the Irish population remain high with the overwhelming majority of the population consuming salt at levels well in excess of the current target of six grams per day.

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1

Introduction and Background

Salt[1] is a compound of sodium (1g salt = 0.4g sodium or 17.1mmol sodium) and chloride. Humans, like all other mammals, consumed less than 0.25 grams (g) of salt per day (g/day) during several million years of evolution.

About 5,000 years ago, the Chinese discovered that salt could be used to preserve foods. Salt then became of great economic importance and a factor in the development of settled communities. Roman soldiers received a part of their wage in salt – hence the term 'salary'. Salt was the most taxed and traded commodity in the world, with intake reaching a peak around the 1870s.

However, with the invention of the deep freezer and the refrigerator, salt was no longer required as a preservative. Salt intake had been declining, but with the recent large increase in the consumption of highly salted processed foods, salt intake is now increasing worldwide [11]. Unfortunately salt has a number of additional properties as a food additive beyond its role as a food preservative. For example in baking it controls the consistency of the dough and extends shelf life and in cheese and meats it increases the water content [12]. The presence of salt in processed foods has become ubiquitous and an estimated 75 per cent of our salt intake is now derived from processed food [13].

1 The terms salt and sodium are often used synonymously. However, on a weight basis, salt comprises 40 per cent sodium and 60 per cent chloride. The conversion of different units for sodium and salt is as follows: one g sodium = 2.5 g salt; 1 mmol sodium= 23 mg sodium; 1 g salt = 0.4 g sodium; and one g salt = 17.1 mmol sodium. Salt is the major source of sodium in the diet (approximately 90 per cent). In this report we use the term salt for simplicity.

Salt and health: overview

Public policies to protect and promote the health of the population are of necessity based on the balance of currently available evidence. The balance or totality of the evidence on salt and blood pressure (BP), is now overwhelmingly on the side of action to reduce population exposure to this dietary additive [11]. The case for action on salt is based primarily on the association with elevated blood pressure including the rise in blood pressure from childhood to adult life [14]. However it should be noted that we also have evidence that high salt intake directly increases the risk of stroke and heart attack [15-17], left ventricular hypertrophy [18] and renal disease [19]. Salt intake is also incriminated in the development of renal stones and osteoporosis [20]; it is linked to the severity of asthma [21] and is probably a major cause of stomach cancer [22]. Salt intake is also a factor in the obesity epidemic through soft drink consumption [11].

High salt intake directly increases the risk of stroke and heart attack.

The evidence on salt and blood pressure has been well and comprehensively reviewed by He and Macgregor [11]. Consistent findings have emerged from diverse research settings and designs, including:

- observational epidemiological studies (ecological, cross-sectional and migration studies),
- animal and genetic models,
- clinical trials in normotensives and hypertensive individuals,
- clinical trials involving middle-aged and elderly population samples,
- a trial in infants with long-term follow-up, and
- a Portuguese community intervention study.

In addition to the overwhelming body of evidence linking salt intake with hypertension, the evidence that links high salt intake with increased risk of cardiovascular events (heart attack and stroke) is accumulating. This issue was recently addressed by Strazzullo and colleagues (2009) in a meta-analysis of all observational studies published to-date) [17]. They identified 13 relevant and suitable studies published from 1996 to 2008 which provided evidence from 170,000 people contributing overall more than 10,000 vascular events. The pooled relative risk indicated a 23 per cent greater risk of stroke for an average difference in sodium intake of approximately five grams (g) of salt a day. A smaller but significantly increased risk of coronary heart disease associated with higher salt intake was also observed in this meta-analysis. Because of imprecision in the measurement of salt intake, these estimates of the effect of high salt intake on (CVD) events are likely to be underestimated.

DASH study

Observational epidemiological studies and meta-analyses of clinical trials of varying methodological rigour in different populations and patient groups have unfortunately provided fertile ground for the salt industry and others who wish to sustain the controversy on salt and blood pressure [23]. In this context, the findings from the DASH-sodium study (dietary approaches to stop hypertension) are particularly important [24-25]. The DASH study, an extremely well controlled, randomised crossover feeding study, conducted over 12 weeks and involving 412 participants, has demonstrated substantial falls in blood pressure associated with reducing salt intake in both hypertensives and normotensives, with a clear dose response. Among non-hypertensives on the control diet (those with allegedly little to gain from sodium restriction), lower salt intake (50 (mmol) sodium per day) vs higher (150 mmol sodium per day) decreased blood pressure by 7.0/3.8 (mmHg) in those older than 45 years of age and by 3.7/1.5 mmHg in those aged 45 years or younger. Of particular importance in this study was the finding that the combination of salt restriction with the DASH study diet (characterised by increased consumption of fruit and vegetables and reduced saturated fat) produced additive effects on blood pressure in both hypertensives and normotensives. Compared with the control diet with a high sodium level, the DASH diet with a low sodium level led to a mean systolic blood pressure that was 7.1 mmHg lower in participants without hypertension, and 11.5 mmHg lower in participants with hypertension [24-25].

The importance of hypertension and the rationale for a population based strategy on salt

Cardiovascular diseases including ischemic heart disease and stroke are the most common causes of death in Ireland [26]. The World Health Organization (WHO) estimates that 22% of deaths worldwide are due to ischemic heart disease or stroke [27]. Cardiovascular disease and stroke also cause significant disability and a reduction in quality of life. Hypertension is thought to be implicated in 62 per cent of strokes and 49 per cent of ischemic heart disease events worldwide [28]. Hypertension is at epidemic levels in middle-aged men and women in developed and an increasing number of developing countries worldwide. The prevalence of hypertension is particularly high in Ireland. In the SLÁN-07 study, approximately six in ten respondents aged 45 years and over (60 per cent) had high blood pressure. Of these, approximately six in ten (57 per cent) were not on medication for blood pressure. Of those on medication, about seven in ten (70 per cent) were not controlled to blood pressure levels below 140/90mmHg [7].

The association between blood pressure and the risk of heart attack and stroke is graded, linear and continuous across virtually the entire distribution of blood pressure in the population. The majority of cases of cardiovascular disease in the population arise in the largest group at risk, i.e. those with BP that is considered within the high normal or slightly elevated range as opposed to the minority of individuals with extremely high blood pressure [29]. Thus small changes in mean BP which achieve a small downwards shift in the population distribution of blood pressure have the potential to save a substantial number of lives each year [30-32]. This provides the scientific basis for public health (population level) policy on salt and blood pressure which is designed to reduce average salt intakes and thereby achieve a fall in average blood pressure across the entire population.

The potential impact of a successful population based strategy has been modelled in a recent study [4]. In this study which is based on data from the United States, it was estimated that a population wide reduction in dietary salt of three grams per day would reduce (in the US population), the annual number of new cases of Coronary Heart Disease to between 60,000 and 120,000 cases, stroke between 32,000 and 66,000 cases and myocardial infarction between 54,000 and 99,000 cases. It would reduce the annual number of deaths from any cause by 44,000 to 92,000. It was further estimated that a regulatory intervention designed to achieve a reduction in salt intake of 3 g/per day would save between 194,000 and 392,000 quality-adjusted life-years and between $10 billion to $24 billion in health care costs annually [3]. Based on these data it is likely that modest reduction in salt intake in the population achieved by regulation is one of the most cost effective intervention currently available to policy makers.

Salt Intake worldwide

Substantial variations in salt intakes has been documented in different countries worldwide ranging from an estimated intake of 0.2 g/day in the Yanomamo Indians in Brazil [33] to an average intake well in excess of 12 g/day in Japan. It is clear that throughout the world salt intakes are well in excess of nutritional requirements, with average intakes in most countries of between nine g/day and 12 g/day, with many Asian countries with intakes in excess of 12 g/day [11]. Indeed the available evidence suggests that despite numerous advances in food science and technology, our salt intake today is the same as it was in the late 1800's [11].

In 2005-2006 an assessment of dietary salt intakes among adults (aged 19-64) in the UK general population was carried out. This work was based on the analysis of dietary sodium in 24-hour urine collections from a national sample of 780 adults (341 men, 439 women) of whom 692 individuals provided data suitable for analysis. The overall weighted mean salt intake in the sample was 8.7 g/day with higher intakes in men (9.7 g/day) than in women (7.7 g/day) [34]. As expected cereals, bread, meat and meat products were the main contributors of salt in the diet. These findings are seen as representing an improvement or at least a reversal of earlier adverse trends based on comparison with UK data from 2003-2004, when mean salt intake was estimated at 9.5 g/day [11]

Salt intake in children is a particular concern, although it is not well documented. MacGregor cites a 1984 study in the United Kingdom (UK) in which two consecutive 24-hour urine samples were collected from 34 school children aged four to five years in which it was found that the average sodium excretion was four grams of salt per day. [35]. If this is expressed for adults on a weight basis, it is equivalent to approximately 15 to 20 grams/day. This work was conducted at a time when the consumption of processed foods by children was not high. Since then, salt intake in children in developed countries has increased due to the increasing consumption of processed foods which now account for approximately 80 per cent of total salt intake. Surveys in the United States showed that the proportion of foods that children consumed from restaurants and fast-food outlets increased by nearly 300 per cent between 1977 and 1996, and it is very likely to have increased even further in more recent years. Snack food consumption showed a similar trend in this period. As processed, restaurant, fast foods, and snacks are generally very high in salt, fat, and sugar, it is possible that children from the age of three to four up now consume as much salt as adults [11].

Current data from (EU) Member States are indicates that salt intakes in Member States are exceeding the WHO maximum limit. The EU White Paper *'A Strategy for Europe on Nutrition, Overweight and Obesity Related Health Issues'* urges Member States to prioritise salt reduction. The EU Framework for National Salt Initiatives (2008) aims to reduce population salt intakes and Member States are urged to carry out 24-hour urinary sodium excretion surveys to accurately assess the magnitude of the problem.

Salt Intake in Ireland

Connolly et al [36] used a three day weighed food diaries to estimate mean dietary salt intake in Irish adults at 8.9 g/day, 9.5 g/day in men and 7.8 g/day in women. Madden et al [37] estimated salt intake among students at ten grams/day, 12.2 g/day in men and 7.9 g/day in women. In a subsequent study, published in 1987, Short and colleagues obtained twenty-four hour urine samples from 70 male and 62 female selected residents of Cork City (army personnel, nurses and civil service and laboratory workers, aged 19-60 years) which were analysed for sodium, potassium and creatinine content. Self-reporting and the creatinine index were used to assess 24-hour urine sample completeness. Of the total 132 urine collections, 94 were adjudged complete. The average 24-hour excretion of Na in complete collections was 9.7 g/day for males (n=46) and 7.8 g/day for females (n=48), respectively [38]. In the North/South Ireland Food Consumption Survey published in 2001 [39] showed a mean salt intake in adults was estimated at 8.3 g/day based on seven-day diet diaries, similar to estimates of 8.2 to 8.3 g/day from SLÁN national surveys (Table 1 below). This estimate as with the SLÁN estimates excluded discretionary salt added at the table and during cooking. Given that 15-20 per cent of total salt intake is discretionary, the authors of the North/South Ireland Food Consumption Survey estimated actual intake at about ten g/day. In 1999-2000, MacLeod et al studied a sample of 114 adult hospital outpatients (77 males and 37 females) with Type 2 diabetes in Cork who had received specific dietary counselling on salt restriction [39]. Mean daily sodium intake in the sample as a whole, estimated from 24-hour urinary output (without PABA validation) was 9.7 g/day. As expected, mean salt intakes were significantly lower in females, 8.4 g/day compared to males 10.4 g/day salt [40].

Table 1 Salt intake (g/day) based on food frequency questionnaire data from SLÁN surveys: SLÁN 1998 and SLÁN 02

SLÁN Survey	Mean g/day	Mean Salt Intake by Gender g/day	Standard Deviation	10th centile g/day	50th centile g/day	90th centile g/day
1998	8.3	Men 8.7 Women 8.0	3.8	4.2	7.6	13.1
2002	8.2	Men 8.6 Women 8.0	5.9	3.6	7.2	13.2

Public policy on salt and health

In 2003, the Scientific Advisory Committee on Nutrition in the UK [2], considering the extensive evidence for a direct link between salt intake and high blood pressure, recommended that the average UK consumption of nine grams of salt per day in adults should be reduced to six grams per day to reduce high blood pressure and lower the burden of cardiovascular disease. These recommendations were echoed in the Food Safety Authority of Ireland (FSAI) report in 2005 [3] which set a mean salt intake of six grams/ daily as an "achievable" target for the adult Irish population. In the FSAI report it was indicated that "while six g/day is considered to be an achievable goal for the population at this time, it should not be regarded as an optimal or ideal level of consumption". It was also recommended that as distinct from the achievable population target, advice targeted at individual adults should reflect the recommended daily allowance (RDA) for sodium of four grams salt per adult per day. The distinction between an achievable population target of six g/day and an "RDA" of four g/day is a source of confusion and in this context it should be noted that in 2005, the US and Canadian panel on *Dietary Reference Intakes for Electrolytes and Water* [5] suggested an "adequate intake" of 3.8 g/ day and a "tolerable upper limit of 5.8 grams of salt daily. Adding to the confusion on this issue, the World Health Organization (WHO) has set a lower target for dietary salt intake at five grams salt per day [6]

There is broad agreement particular on the vulnerability of children and the elderly to the adverse effects of high salt intake and in the FSAI 2005 report it was recommended that this issue "needs to be highlighted in discussion with the food industry regarding new product development and the reformulation of existing products. This should also be considered in health promotion campaigns mounted by public and private bodies." The FSAI report also called for greater engagement with the food industry to reduce the salt content of foods on the Irish market. It recommended further research and regular population surveys to accurately assess salt intake in the population and monitor the prevalence of hypertension [3].

2

Research Objectives and Methods

Aims and Objectives

The overall aim of this study is to provide accurate and well validated estimates of dietary salt intake in the Irish population to support the ongoing evaluation of policy initiatives over the past decade designed to reduce it. The specific objectives were as follows:

1. To estimate dietary salt intake in the Irish population based on
    i. analyses of the existing SLÁN-07 nutritional dataset set and linked random ("spot") urine samples from this national health and lifestyle survey [7-8],
    ii. studies of additional samples of adults with estimates of salt intake based on 24-hour urinary sodium excretion.
2. To describe variation in salt intake by age, sex and measures of obesity.
3. To assess the dietary sources of salt.
4. To estimate potassium intakes based on 24-hour urine collection and describe the distribution of sodium to potassium ratio in the population.

Methods

The objectives were addressed in two studies: SLÁN-07 (Phase I study) and Phase II.

SLÁN-07 (Phase I study)

The SLÁN-07 (Phase I study) was conducted by a national research consortium led by Professor Hannah McGee at the Royal College of Surgeons (RCSI) in collaboration with the Economic and Social Research Institute (ESRI), NUI Galway (Department of Health Promotion) and University College Cork (UCC) (Department of Epidemiology & Public Health) [7-8]. The study was funded by the Department of Health & Children with a contribution from ***safe*food** to meet the costs of the urinary sodium excretion sub-study. Details of the sampling and field survey methods for SLÁN-07 have been described in detail [7-8]. The 2007 survey involved a nationally representative sample of 10,364 adults aged 18 and over (62 per cent response rate) of whom 9,223 (89 per cent) completed a standard Food Frequency Questionnaire (FFQ). The SLÁN-2007 survey included a physical examination of a sub-sample of older adults, 45 years of age and older (n=1,207). All respondents aged 45 and over who took part in the main survey were invited to take part in the physical examination study. Overall, 67 per cent of adults aged 45 to 64 years and 33 per cent of adults aged 65 years and older agreed to undergo the physical examination. The physical examination was carried

out at a separate time, usually in an occupational health setting, in 2007 and early 2008. Data on height, weight, waist circumference, blood pressure, together with non fasting blood samples and random ("spot") urine samples were collected from this sub-sample. All physical measurement data and biological samples on this group were obtained by trained nurses who operated to a standardised protocol.

SLÁN-07 Food Frequency Questionnaire

The main macronutrient and micronutrient intakes were estimated using data from the Food Frequency Questionnaire (FFQ). The FFQ used in the study was an adapted version of the European Prospective Investigation of Cancer (EPIC) study [41] FFQ. The FFQ is designed to assess the whole diet and includes 150 food items arranged into the main food groups consumed in the Irish diet. Respondents were asked to complete the FFQ after their main SLÁN survey interview. Some completed the questionnaire while the interviewer waited; others chose to complete it at a later stage and returned it by mail. Other forms were collected by the interviewer after appointment. The interviewer assisted in completion in cases where this was preferred or where the respondent had difficulties filling in the FFQ on their own. A large print version was available to those with reading difficulties. Subjects were asked to indicate their average use of each food item over the previous year. Frequency of consumption of a medium serving or common household unit, such as a slice or a teaspoon, was elicited for each item. Typical weights, portion sizes and nutrient intake were based on recommendations established by the Food Standards Agency in conjunction with McCance and Widdowson's Food Composition Tables:

The frequency categories were as follows:

- 'never or less than once a month',
- '1-3 times per month'
- 'once a week',
- '2-4 per week',
- '5-6 per week',
- 'once a day',
- '2-3 per day',
- '4-5 per day', and
- '6+ per day'

The FFQ data were used to assess sources of salt intake and to estimate intakes of sodium, potassium, energy and nutrients. Estimates of salt intake were based on reported dietary intake and excluded discretionary salt added during cooking and at the table. The FFQ dietary data were converted to food quantities and subsequently to food nutrient values by Ms Janas Harrington, Department of Epidemiology & Public Health, UCC, using a dedicated nutritional analysis software programme – FFQ Software Version 1.0, developed by Mr Juzer Lotya, of the National Nutritional Surveillance Centre, School of Public Health and Population Science, University College Dublin. Estimates were derived using the McCance and Widdowson's Food Composition Tables [42]. No adjustments were made for salt reductions in foods achieved by the food industry since the publication of these tables. Thus, although it is possible that reported daily salt intake may be underestimated in this analysis due to the exclusion of discretionary salt, this effect may be nullified in part by the recent reductions in the salt content of processed foods. As the FFQ is not a reliable instrument to assess alcohol consumption, caloric intake from alcohol was excluded from the energy intake estimates.

Urinary analyses in the SLÁN-07 (Phase I study)

Urinary electrolyte/protein levels were measured using standard reagents and methods by Claymon Biomnis Laboratories – a commercial accredited laboratory based in Dublin, Ireland.

Urine samples were assayed for:

- Sodium
- Potassium
- Chloride
- Urea
- Creatinine
- Microalbumin

The findings from SLÁN -07 on sodium excretion, sodium to potassium ratio and sodium to creatinine ratio in random urine samples are presented in this report. The sodium to creatinine ratio measure provides a measure of sodium excretion that is adjusted for fluid intake and urinary concentration. Sodium to creatinine ratios have been used in large scale studies as an estimate of dietary sodium intake at population level [41]. In further analyses, the sodium concentration in the spot urine samples (mmol/Litre) was converted to grams per litre and to estimated grams per 24 hours using gender specific validated 24-hour urine volume estimations derived from the Phase II study.

Phase II study

In the Phase II study we obtained dietary data (FFQ), physical measurements (height, weight, abdominal circumference and blood pressure) and 24-hour urine collections in a total of 599 adults aged 18 to 81 years. The Phase II study was based on three sub-samples as follows:

- A general population sample drawn from participants of the SLÁN -2007 survey who agreed to re-screening in 2008-09 (n=54) and participants of the 1998 Cork and Kerry Diabetes and Heart Disease Study (n=65) who were re-screened in 2007.
- A group of student volunteers (n=169) from two large academic institutions in the south of Ireland.
- An occupational group, sampled from an occupational setting (n=311), from a total staff of approximately 1600 workers

Sampling

General population sample

A random sample of 511 respondents who had completed the SLÁN-07 study and had indicated an interest in taking part in further research were contacted by post and invited to take part. All resided in Munster, specifically counties Clare, Limerick, Tipperary, Waterford, Kerry and Cork. These respondents had not undergone physical measurements as part of the SLÁN study [7, 8]. Twenty one invitation letters were returned unopened as the respondents were no longer residing at the addresses used. One respondent had died. In total, 192 people out of a possible 489 people returned response slips indicating their interest in taking part in the study. All 297 non-responders were followed up by phone but this did not increase the response rate significantly. Ultimately, 54 completed a physical examination and a 24 -hour urine collection. Data were collected from this group between December 2008 and September 2009.

A further sample of older adults was recruited from participants in the Cork and Kerry Diabetes and Heart Disease re-screening Study [43]. This study was running concurrently in the same academic department as the Phase II study. The study was originally carried out in 1998, and in 2009 the surviving members of that cohort were invited to be rescreened (n=639). A total of 362 subjects (57 per cent), aged over 65 years accepted the invitation for rescreening. In the course of rescreening, 217 participants were asked if they would like to take part in the Phase II study. While 113 participants expressed an interest in the study only 65 people from this older cohort provided a 24-hour urine sample. The physical examination and sample collection on the Cork & Kerry Study participants was performed in their primary care centre and included anthropometric and BP measurements, fasting blood samples and a 24-hour urine collection. These data were collected between December 2008 and April 2009.

Student samples

We recruited a convenience sample of students from two academic institutions in the south of Ireland, (UCC) and Cork Institute of Technology (CIT).UCC has a student population of approximately 17,500 students (30 per cent postgraduate) and CIT has approximately 11,000 students (four per cent postgraduate). The research team liaised with the student health physician in each institution prior to sampling and the physical examinations were carried out in the Student Health Centre at UCC and at the Health Sciences Building, UCC.

Students were invited to participate by means of presentation from members of the research team before and after lectures and through notices outlining the study which were placed prominently in the areas of both academic institutions most frequented by students (cafeterias, libraries, sports facilities, student union facilities and shops). Invitations to participate in the study were also placed on the student union electronic web based notice board. A total of 233 students expressed an interest in taking part of whom 169 completed the physical examination and returned a 24-hour urine collection. 149 of these were based in UCC and 20 at the Institute of Technology. In order to encourage students to take part in the study a sum of €25 was offered to participants who returned a 24-hour urine sample. Data were collected from this group between February and April 2009. Participating students were drawn from a wide range of academic disciplines including medicine, nursing, public health, science, engineering, computer science, law and the humanities.

Occupational sample

In April 2009 a large data management company comprising a manufacturing, software development and support remit was approached and invited to take part in the study. The company employs 1,600 people across two campuses in Ireland. Initially, a synopsis of the study was communicated to the company by the research team. This was followed by a site visit and presentation, during which the research team outlined the study in more detail to human resources, occupational health and managerial staff in the company.

The management of the company asked us to ensure that all employees and contract staff would have the opportunity to take part in the study. So a group e-mail was sent to all of the company's employees in September 2009 inviting them to take part in the study and informing them that the proposed study would include a detailed health check. In addition, an information desk was set up in the company's two campuses, and, over a three day period, employees met the research team to ask any questions they had concerning the study. Those who expressed an interest in taking part were given free ***safe*food** branded promotional materials such as shopping bags and pens in order to heighten the visibility of the study and further increase interest levels in the study. All health checks and urine sample returns took place in the workplace.

To broaden the scope of the health check and encourage participation, all respondents in this phase were offered a fasting cholesterol and glucose profile. This was undertaken by a research pharmacist from UCC. The health checks took place over a five week period. In total, 396 employees agreed to take part (one quarter of the organisation's employees). However, only 311 employees underwent the health check *and* returned a 24-hour urine sample. Employees signed an amended consent form which included their permission that their employer receives a general and completely anonymised report on the findings from the health check in the organisation. Data were collected from this group in October and November 2009.

Exclusion criteria

People under the age of 16 years and those with learning or severe physical disabilities (which might make it difficult for them to undertake a 24-hour urine collection) were excluded from the taking part in the study. Those who were pregnant *or* trying to become pregnant were also excluded as were those for whom PABA was contra-indicated because of possible allergy to hair dye, sunscreen or vitamins.

Physical examinations

Details on the physical examination, including the methods used for the 24-hour urine collection are provided in the Standard Operating Procedure Manual for the study which is available on request. Participants underwent a short physical examination by a registered nurse or a trained researcher who had undergone training in the study's standard procedures. Each health check lasted between 30 and 40 minutes. Weight, height, waist circumference, blood pressure and pulse rate were measured. A list of medications that respondents were taking was documented. Information on the use of anti-hypertensives and diuretics therapy was obtained. Weight was measured with an electronic platform scale and height with a Leicester rod. High BMI was used as an indicator of general obesity.

BMI was calculated as: $\frac{\text{weight (kgs)}}{(\text{height (m)})2}$

BMI categorisation was as per current WHO guidelines:

Normal:	18.5-24.9
Overweight:	25.0-29.9
Obese:	>30

Waist circumference was used as a measure of abdominal obesity. It was calculated as the average of a first and a second measurement value. Values of 88 cm or more for women and 102 cm or more for men were used to indicate abdominal obesity [44-45]] Blood pressure was measured using a validated digital automatic blood pressure monitor (*Omron*, M7 model). Systolic and diastolic blood pressure was calculated as the average of the second and the third of three measurements.

24-hour urine collection

We collected and assayed 24-hour urinary samples from the 599 participants in the Phase II study. Para-aminobenzoic acid (PABA), a biologically inert substance which is rapidly excreted in urine, was administered to all participants on the day of urine collection to validate the completeness of the 24-hour collection sample [46-47].

- Participants were given a standard verbal and written explanation of the process and procedures. Field workers followed a checklist to ensure that the discussion of the 24-hour collection with participants was standardised.
- Participants were asked to collect every drop of urine passed after the first voiding on day one and to finish collecting after the first voiding on day two.
- Although the participants were aware that the urine was being analysed for dietary constituents, the study was never referred to as a 'salt study'.
- Participants were asked not to change their normal diet in any way.

Equipment

Each participant was given a three litre urine storage container from the Sarstedt company (Product ref: 77.575) in a strong opaque carrier bag.

Each storage container was preloaded with a preservative – four grams of powdered boric acid (H^3BO^3) from the Fisher Scientific company (Product ref: B/3800/53). The boric acid was weighed using a Sartorius laboratory scale which was calibrated using weights from the Salter Weight Company. Owing to the presence of the acid in the storage container respondents were asked to void into a clean 500ml beaker (Sarstedt Product ref: 75.9992.812) and then to pour the contents of the beaker into the storage container. This was in order to prevent acidic splash back during micturition. Some respondents who indicated that they tended to pass a lot of urine were given two containers.

Para-aminobenzoic acid (PABA)

In accordance with the method of Bingham and Cummings (1983) [46] improved by Johansson et al (1999) [47] respondents were advised to take three 80mg doses (240mgs/day) of PABA in tablet form on the day they were collecting their urine: the first tablet with breakfast on the collection day, the second tablet with lunch and the last tablet with dinner or supper.

PABA preparations were obtained from the Labs for Applied Biology UK (Pabacheck, batch no. 50875) and from Lonsdale Health, UK (batch no. 18196). As the Irish Medicines Board does not recognise PABA as a medical preparation, it did not need to be medically prescribed to participants. As a further compliance indicator participants were asked to indicate (by ticking a box on a form) whether or not they had accidentally missed a collection of urine.

Urinary analyses

Phase II study 24-hour urine samples were returned or collected within two days of respondents finishing their collections. Once returned urines were taken to a central facility where they were weighed to the nearest gram (1 gram = 1 millilitre of urine) on a Tanita digital scale which was calibrated regularly with calibration weights from the Salter Weight Company. Volumetric analysis was performed as a quality control measure. Some samples were diluted for reasons indicated in the standard operating procedure. After aliquoting all urine samples were stored at -20°C and transported in batches to their respective laboratories. Urinary electrolyte/protein levels were measured by Claymon Biomnis Laboratories – a commercial laboratory in Dublin, Ireland.

Urine samples were assayed for:

- Sodium
- Potassium
- Chloride
- Urea
- Creatinine
- Microalbumin
- PABA

PABA analysis was done at the Medical Research Council Human Nutrition Research Laboratory in Cambridge, United Kingdom. Samples were transported to this laboratory frozen using dry ice. PABA was assayed by a colourimetric microplate method. Interference was suspected where PABA excretion was recorded as >110 per cent of the daily dose. Where this was the case, the sample was re-assayed by High Performance Liquid Chromatography. Results were reported as a percentage of the PABA dose excreted.

PABA analyses

Because PABA is excreted via the kidneys and detectable in urinary analysis, it is a useful marker for the completeness of 24-hour urine collections. When more than 85 per cent of the ingested dose appears in the urine it can be assumed that the participant supplied a complete urine sample. In cases where greater than 70 per cent and less than 85 per cent of the ingested dose, was recovered in the urine, we adjusted the measured urinary sodium levels to what they would have been had the respondent supplied a full 24-hour urine sample[2]. The equation used for adjustment is as follows [34]:

Corrected sodium level = Measured level * (93 / Percentage PABA recovery).

To avoid potential overcorrection bias no correction was performed on subjects who had >85 per cent of PABA excreted. The PABA validated estimates of salt intake are based on 488 subjects who had taken PABA and had a measured percentage dose excretion of >70 per cent.

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2 Professor Sheila Bingham also derived an equation which was less conservative and incorporated an estimated 24-hour sodium based on PABA excretion of 50 per cent -84.9 per cent. The use of this equation would result in potentially using more 24-hour urine collections. However, the regression equation used in this paper is based on regression of mean estimates and is on a different population to ours, we therefore chose to use the most conservative estimate that incorporated the simple adjustment equation above. We analysed the results of both equations, but the conservative equation is presented as it is likely to have less error.

In the original research design it was proposed that those unwilling or unable to take PABA would not be included in the study. However, given the difficulties associated with sample recruitment, we decided to include all participants willing to complete a 24-hour urine collection, including those unwilling to take the PABA tablets and those for whom PABA was contra-indicated because of possible allergy to hair dye, sunscreen or vitamins. Inclusion of these participants in the study permitted comparison of estimates of sodium excretion based on 24-hour collections with and without PABA administration.

Food Frequency Questionnaire

The main macronutrient and micronutrient intakes were estimated using data from the Food Frequency Questionnaire (FFQ). The FFQ used in the study was an adapted version of the EPIC study, and the same as that used in the SLÁN-07 study detailed above. In Phase II of the study all respondents took the questionnaire home after their physical examination and returned it with their completed 24-hour urine collection. Most completed the questionnaire at home but some participants needed assistance to complete the questionnaire. The FFQ dietary data were converted to nutrient values as described above for the SLÁN-07 study [8].

Sample size

The target sample size for the Phase II study (700 participants) was determined by pragmatic considerations, in particular by the need to ensure an appropriate age and sex distribution in the sample, and the time and resources available to the research team, given the anticipated challenge of recruiting participants for a study involving 24-hour urine collection. The most recent comparable data from the UK are based on a national sample of 692 adults [34].

Data analysis

Data were analysed by members of the research team with specialist input from Dr Tony Fitzgerald, Senior Lecturer in Statistics (Department of Epidemiology & Public Health, UCC). The data were analysed using the statistical package Stata (Version 11 StataCorp 4905 Lakeway Drive, College Station, Texas 77845 USA). Standard statistical methods for the analyses of continuous and categorical data, including analyses of variance, linear regression and chi-square tests were used. The findings on estimates of salt and potassium intake are expressed as grams per day (salt) and mg/day (potassium). Unweighted mean (sd) and median values are reported. Although the data on salt intakes included some outliers with extremely high intakes, we used analysis of variance (ANOVA) and linear regression to compare mean nutrient intakes in different subgroups. In the international literature salt intakes are summarised as mean (sd) rather than median (inter quartile range). However, all sub-group analyses were run with non parametric methods to confirm statistical significance.

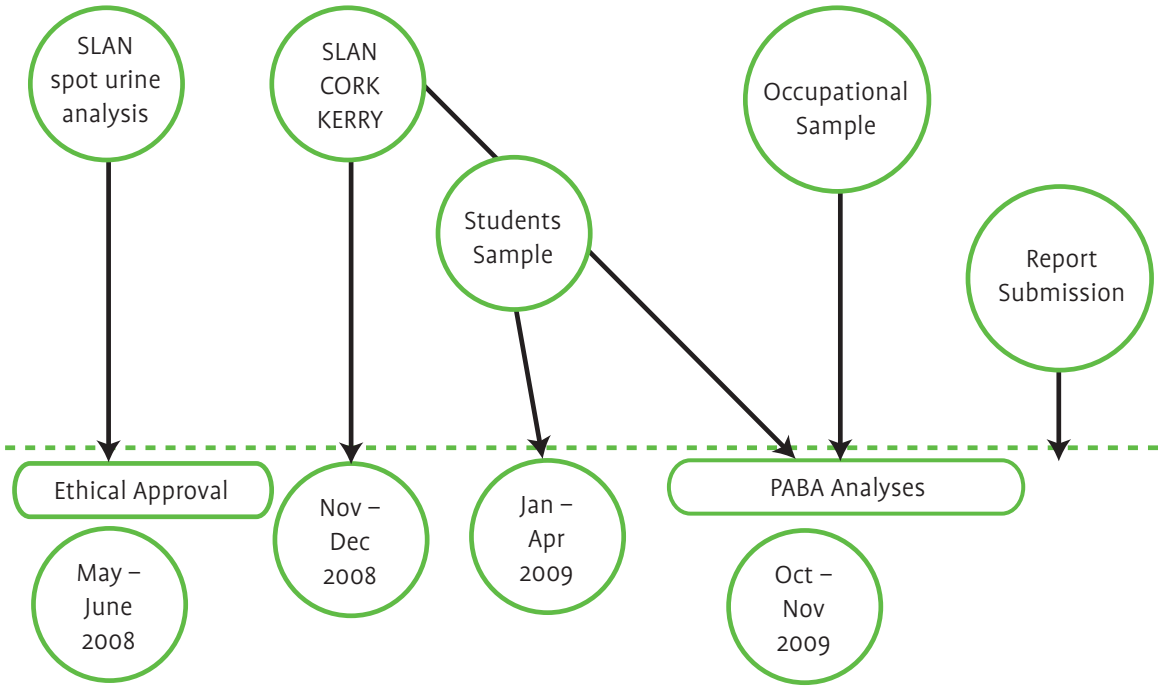
SLÁN-07 and Phase II study: Ethical considerations

The Research Ethics Committee of the Royal College of Surgeons in Ireland granted ethical approval (Ref: REC 276) for the SLÁN-07 study and for the inclusion of SLÁN-07 participants in the Phase II study. For the Phase II study ethical approval was obtained from the Clinical Research Ethics Committee at UCC. Detailed participant information leaflets were given to all respondents. They were asked to give written informed consent for the physical examination, 24-hour urine sampling, PABA intake and questionnaire completion. The consent form also incorporated a facility whereby respondents could stipulate that their GP be sent the results of their urinary analysis. Where respondents were found to have potentially abnormal findings on their physical examination (such as high blood pressure readings) they were advised to follow up with their primary care physician.

Research time line

The work was carried out over a two year period as summarised below in **Figure 1**.

Figure 1 Research Timeline



3

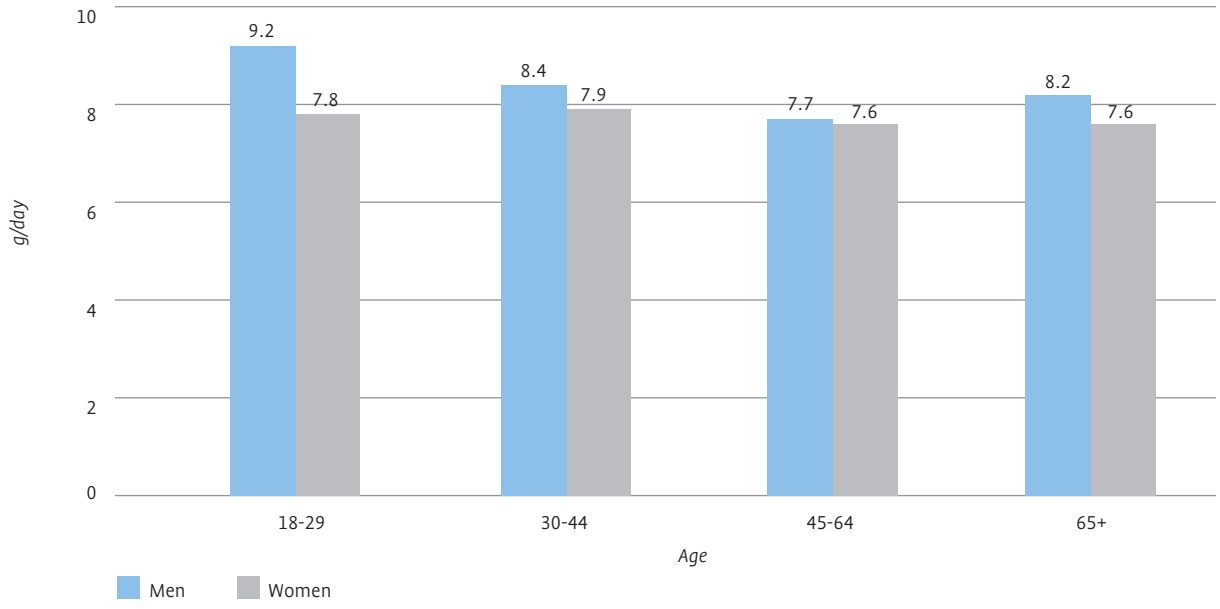
Results

Sub-Section 1

Daily salt intake estimates from SLÁN-07

Based on the SLÁN-07 FFQ data, daily salt intake (mean, sd, median) exceeded the current population level target in men (8.1 grams (3.9), 7.4 grams per day) and women (7.6 grams (3.5), 7.0 grams per day), **Figure 2**. Estimated salt intakes were higher in men than in women across all age groups. A significant age gradient was also evident ($p<0.001$), with younger men aged 18-29 years reporting higher intakes than older men or women, **Figure 2**. A significant class gradient was evident with lower intakes reported in the higher social classes (SC 1-2: 7.5 g/day; SC3-4: 8.1 g/day; SC5-6: 8.6 g/day) ($p<0.001$). The estimated daily salt intake in 68 per cent of respondents (men: 70 per cent; women: 66 per cent) exceeded the current population target of six grams per day.

Figure 2 SLÁN-07 study: Reported mean daily salt intake based on FFQ by age and gender (n= 9223)



Discretionary salt usage SLÁN-07

Approximately one third of SLÁN 2007 respondents reported always/usually adding salt to their food while cooking (30 per cent) or at the table (32 per cent). While one fifth of respondents reported that they always/usually do both (add salt to their food while cooking and also at the table), one third (35 per cent) reported that they rarely/never do either (neither add salt to their food while cooking nor at the table). Respondents who regularly added salt whilst cooking and/or at the table, had marginally higher intakes estimated from FFQ than those who rarely added salt, (p<0.001) **Table 2**.

Table 2 SLÁN-07: Mean salt intake g/day* and reported salt usage while cooking and at the table

	Salt added whilst cooking	**Salt added whilst at the table**	**Salt added whilst cooking and added to food at the table**
	Mean salt intake g/d	**Mean salt intake g/d**	**Mean salt intake g/d**
Always/usually	8.4	8.5	8.6
Sometimes	8.4	8.4	8.6
Rarely/never	8.1	8.0	8.0

**Estimated from FFQ and excludes discretionary salt*

Estimated salt intake from FFQ versus validated 24-hour urine collection

In subsequent analyses using the Phase II study data (see below, **Results: Section 5**) we have compared FFQ derived estimates of mean daily salt intake to those derived from validated 24-hour urine collections. Based on Phase II study data we estimate that FFQ underestimates salt intake in men by approximately 15 per cent whereas estimates for women are accurate with an error of less than one per cent.

Sub Section 2

Dietary sources of Salt based on Food Frequency Questionnaire from SLÁN-07 and Phase II study

Food groups contributing to salt intake

Table 3 shows the mean daily salt intake of SLÁN-2007 respondents, broken down into food groups. The data confirm the extent to which most salt consumed on a daily basis is 'hidden' salt, i.e. added to processed foods. The highest percentage of salt in the Irish diet (34 per cent) was from foods from the bottom shelf of the Food Pyramid (cereals, breads and potatoes). Meat, fish and poultry products contributed 22 per cent of salt, while soups, sauces and spreads were third highest, contributing 14 per cent. Sweets and savoury snacks, which are of little to no nutritional value, accounted for 8 per cent of salt intake.

Table 3 SLÁN-07: Contribution of food groups to overall salt intake (N=9223)

	Salt (g)	Contribution to overall salt intake (%)
Cereals, breads, and potatoes*	2.7	34
Meat, fish and poultry	1.8	22
Soups, sauces, spreads	1.1	14
Vegetables	0.9	11
Dairy products and fats	0.8	10
Sweets, savoury snacks	0.6	8
Drinks	0.1	1
Fruits	0.0	0
Milk	0.0	0

**Cereals and breads are the primary contributors to salt intake. However, potatoes were also included in this category since the FFQ analysis software did not permit the separation of these food items.*

***Some figures may not add up to 100 per cent due to rounding errors.*

FFQ data on salt intakes from the Phase II study

Figure 3 shows the distribution of reported mean daily salt intake, by gender and age based on the Food Frequency Questionnaire in the Phase II study. The findings are broadly consistent with those from the SLÁN-07 FFQ data. Mean (sd) daily salt intake was higher than population level targets in the sample as a whole, 8.2 g/day (3.6) and in both men (8.7 g/day) and women (7.3 g/day). 71 per cent of respondents (76 per cent men and 63 per cent women) had an estimated salt intake that exceeded population guidelines of 6 g/d. While there was no significant association with age in this smaller dataset there was evidence of high salt intakes in young men. Salt intake was also broadly similar across the three sampling groups in the Phase II study (General population: 7.9 g/d; Student: 8.6 g/d; Occupational:8.0 g/day), **Table 4**. **Table 4** also shows the contribution of food groups to overall salt intake in Phase II study groups compared with SLÁN-07.

Figure 3 Phase II study: Distribution of reported mean daily salt intake (g/day), by age and gender based on the Food Frequency Questionnaire (N=585)

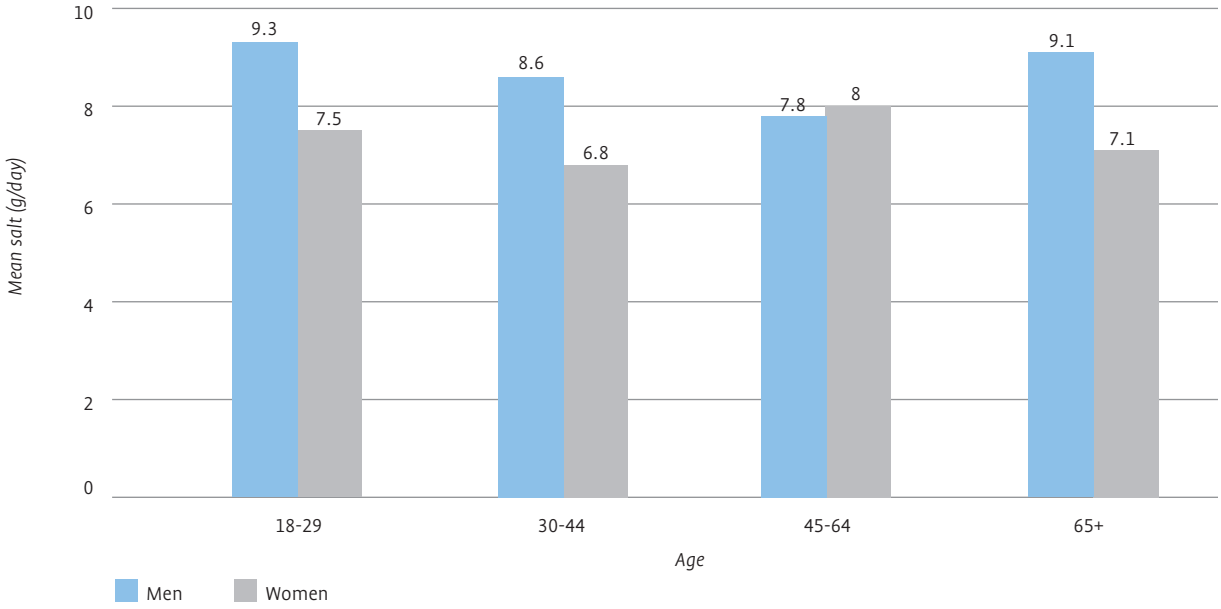


Table 4 Estimated salt intake and contribution of food groups to overall salt intake in Phase II study sample groups compared to SLÁN-07

		Contribution to overall salt intake (%)		
Sampling Group	**Gen pop**	**Student**	**Occupation**	**National SLAN-07**
Total Salt intake (g/day)	7.9	8.6	8.0	8.0
Cereals, breads, and potatoes* (%)	39	30	31	34
Meat, fish and poultry (%)	18	19	23	22
Soups, sauces and spreads (%)	14	17	15	14
Vegetables (%)	10	10	11	11
Dairy products and fats (%)	11	10	11	10
Sweets and savoury snacks (%)	6	9	9	8

**Cereals and breads are the primary contributors to salt intake. However, potatoes were also included in this category since the FFQ analysis software did not permit the separation of these food items.*

***Some figures may not add up to 100 per cent due to rounding errors.*

Discretionary salt usage Phase II study

Information on additional salt usage was available for the 'Occupational' and 'Student' groups. Approximately one-third of occupational participants reported 'always' or 'usually' adding salt to their food while cooking (27 per cent) while almost one-fifth of respondents (19 per cent) 'always or usually' add salt while at the table. Among the students 31 per cent 'always or usually' add salt to food while cooking and 18 per cent 'always or usually' add salt while at the table. 14 per cent of the occupational group and ten per cent of the student group reported that they 'always' or 'usually' do both, i.e. add salt to their food while cooking and at the table. Comparing salt intake estimated from the FFQ with reported salt usage, there were no significant differences in daily salt intake between those who regularly add salt to food while cooking and/or to food at the table and those who rarely add salt.

Sub Section 3

Salt Density estimated from the SLÁN-07 and the Phase II study Food Frequency Questionnaires

In the recent (2010) US Institute of Medicine report on *"Strategies to Reduce Dietary Sodium Intake in the United States"* dietary sodium intake density (mg of sodium per 1000 calories consumed) is used to analyse secular trends in salt intake based on dietary recall [9-10]. In this report we present estimates of dietary sodium intake density for Ireland using the SLÁN-07 FFQ data and Phase II FFQ data and we compare the findings with recent US data.

Salt Density estimates the relative quantities of salt per energy intake from food. This permits assessment of the extent to which gender and obesity related differences in salt intake can be attributed to increased calorie intake. Salt intake was estimated as follows:

Salt Density = salt in mg (FFQ)/1000 Kilocalories from food* (FFQ)

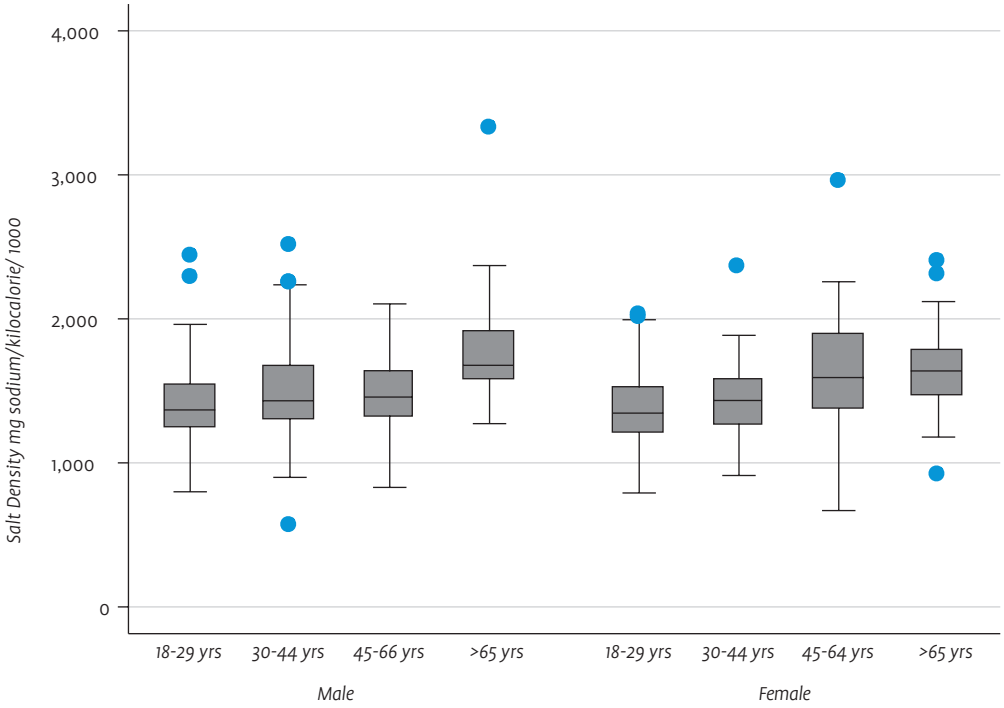
**Kilocalories from alcohol are not included in this estimate.*

Based on SLÁN 07, salt density was similar in men and women, Table 5, however it increased significantly with age (p=0.0001). The findings on salt density in the Phase II FFQ dataset (N=585) were similar, Table 5. Salt density also increased with general obesity (p=0.0003) and central obesity (p=0.02) in univariate analyses. However, in multivariate analyses, including age, sex, BMI or waist circumference, only age was associated with salt density in the Phase II FFQ dataset, Figure 4. Similarly, in the SLÁN-07 FFQ data, age was the only significant predictor of salt density in multivariate analyses.

Table 5 Salt Density (mg of sodium per 1000 kilocalories) by gender in SLÁN-07 and Phase II study

SLÁN 07 (FFQ)	N	Mean(sd)	Median
Men	4511	1501 (392)	1456
Women	4661	1501 (376)	1462
Phase II study	**N**	**Mean (sd)**	**Median**
Men	357	1480 (327)	1440
Women	228	1460 (312)	1440

Figure 4 Phase II study: Salt Density (mg per 1000 kilocalories) by age and gender



Sub section 4

SLÁN-07: Estimation of 24-hour urinary salt excretion based on spot urine samples, using gender specific validated urine volume estimates

In the sample of 1,098 men and women aged over 45 years who provided spot urine samples, mean (sd), median sodium excretion in men was 89.5 (43.3) mmol/L, 82.5 mmol/L and in women, 76.5 (43.3) mmol/L, 66.0 mmol/L. Expressing sodium in spot urine samples as a sodium to creatinine ratio provides an estimate of sodium excretion adjusted for urinary volumes. Although it provides an unreliable measure of salt intake at the individual level it is useful for group level comparisons. The findings on the sodium creatinine ratio in these samples are presented in the **Appendix**.

The sodium to potassium ratio provides a further useful index of the intake of salt and potassium rich foods that can be estimated without data on overall energy intake. The SLÁN-07 data on the sodium potassium ratio are also presented in the Appendix.

As detailed below, **(Results: Section 5)** PABA validation was used to estimate the mean volume of complete 24-hour urine collections based on data from the Phase II study. PABA validation identified complete collections when PABA dose was >85 per cent excreted. Based on validated complete collections (N=291), the mean (sd) urine volume in men was 1.97 (0.75) litres 1.90 and in women 1.67 (0.74) 1.57 litres. The sodium concentration in the spot urine samples (mmol/Litre) was converted to estimated grams per 24 hours using these gender specific validated urine volume estimations derived from the Phase II study, **Table 6**.

Table 6 SLÁN-07: Estimated daily salt intake in adults aged 45 years and older by gender, based on spot urine samples corrected for 24-hour urine volume. *Significance in estimates in men compared to women

Mean calculated Salt in grams over 24 hours	n Men = 485	n Women = 613	*p value
Mean (sd)	10.3 (5.0)	7.5 (4.2)	P<0.0001
Median IQR	9.5 (6.2,14.2)	6.5 (4.1, 9.9)	P<0.0001

Estimated salt intake and blood pressure in SLÁN-07

We examined the association between estimated salt intake in the 1,098 subjects who completed the SLÁN-07 physical examination and provided a urine specimen. Following exclusion of those on anti-hypertensive treatment including diuretics (in this sample four per cent of men and three per cent of women), positive associations with both systolic and diastolic BP were observed, **Table 7**. It should be noted that these analyses are significantly underpowered due to variation in day- to- day salt intake.

Table 7 SLÁN 07: Systolic and diastolic blood pressure (mean (sd) median) (mmHg) excluding those on anti-hypertensive medication and on diuretics

Estimated 24-hour Salt in grams	<4g	4-6 grams	>6 grams
Number of Subjects	155	149	506
Systolic Blood Pressure*	134 (19) 132	136 (21) 136	140 (20) 137
Diastolic Blood Pressure**	80 (10) 79	80 (11) 78	82 (11) 81

**Adjusted for age and sex, p=0.06*

***Adjusted for age and sex, p=0.023*

Sub Section 5

Phase II study: Salt intake estimated from 24-hour urine collection

A total of 599 subjects agreed to take part in the Phase II study. The distribution of participants by sex, age and sample group with column percentage is shown in **Table 8**.

Table 8 Phase II study: Number and proportion of participants by gender, age and sample group

	General Population	Students	Occupation	Total
Men	59 (16%)	81 (22%)	226 (62%)	366 (61%)
Women	60 (26%)	88 (38%)	85 (36%)	233 (39%)
	General Population	**Students**	**Occupation**	**Total**
18-29 yrs	2 (1.7%)	152 (89.9%)	36 (11.6%)	190 (31.7 %)
30-44 yrs	19 (15.9%)	14 (8.2%)	235 (75.5%)	268 (44.7 %)
45-64 yrs	39 (32.8 %)	2 (1.2%)	40 (12.9%)	81 (13.5%)
Over 65 yrs	59 (49.6%)	1 (0.6%)	0 (0%)	60 (10 %)
Total	119 (100%)	169 (100%)	311 (100%)	599 (100%)

PABA validation results

The PABA validated values were based on 488 subjects who had taken PABA and had a measured percentage dose excretion of >70 per cent, **Table 9**. A total of 38 participants (6 per cent) who declined or were precluded from taking PABA were not included in the PABA validated 24-hour sodium excretion. Twenty four hour urine collections with measured PABA of 85 per cent or more are assumed complete. Urinary analytes were adjusted when measured PABA excretion was 70-84.9 per cent. All other 24-hour collections were not validated and are included in the crude 24-hour salt intake but not the PABA validated 24-hour urine data. A total of 97 subjects (52 men, 45 women) from the general population provided validated 24-hour collection and so did 138 students (66 men, 72 women). From the occupational group 253 subjects (188 men, 65 women) provided a 24-hour urine collection, representing both the largest and most homogenous group in the study.

Table 9 Phase II study: Number of 24-hour urine collections performed and percentage PABA excretion Missed urine specimens

24 hour collections (N)	599 (100%)
Did not wish to take PABA N (%)	38 (6%)
PABA Ingested	561 (94%)
Proportion of PABA ingested subjects used in final adjusted sodium	
>70% PABA excretion and detectable sodium in sample[3]	488 (81%)

Missed urine specimens

11 per cent (65 subjects) reported that they omitted at least one urine specimen from the 24-hour urine collection. PABA excretion differed significantly in those who admitted to missing a urine specimen. The 19 participants (three per cent) who did not answer the question on missed specimens have similar measured PABA excretion to those who admitted to missing some samples.

Salt intake by age and gender estimated from PABA validated 24-hour urine collections

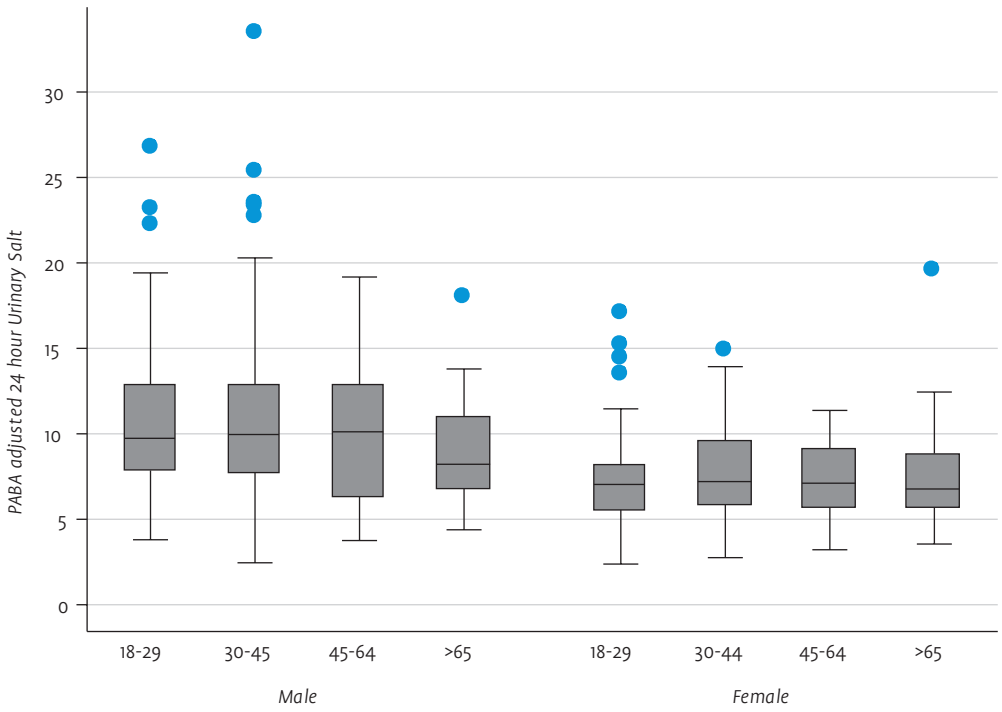
Estimated dietary salt intake (mean (sd), median) based on PABA validated 24-hour urine collections was 9.3 g/day (4.1), 8.5 g/day with higher intakes in men 10.4 g/day (4.3), 9.7 g/day than in women, 7.4 g/day (2.7), 7.1 g/day. Variation by age and gender is summarised in **Table 10 and Figure 5**.

3 Sodium was undetectable (<20mmol/L) in samples from five participants who met the PABA criteria for inclusion in the analyses. The data from these participants has been excluded. In analyses which included these participants and assigning a value of 10mmol/L, estimates of mean salt intakes were reduced by less than 0.1 grams per day.

Table 10 Phase II study: Salt intake (g/day) estimated from PABA validated 24-hour urine collections by age and gender

Men	**17-29 yrs**	**30-44 yrs**	**45-64 yrs**	**Over 65 yrs**	**Total**
Mean Salt (sd)	10.6 (4.3)	10.7 (4.3)	9.9 (4.0)	8.9 (3.1)	10.4 (10.4)
Median [IQR]	9.7 [7.9, 12.8]	10.0 [7.6, 12.9]	10.1 [6.2,12.8]	8.2 [6.7, 10.9]	9.7 [7.4,12.7]
Women	**17-29 yrs**	**30-44 yrs**	**45-64 yrs**	**Over 65 yrs**	**Total**
Mean Salt (sd)	7.3 (2.8)	7.5 (2.9)	7.2 (2.1)	7.6 (3.7)	7.4 (2.9)
Median [IQR]	7.0 [5.5, 8.1]	7.2 [5.9 9.5]	7.1 [5.6, 9.0]	6.8 [5.6, 8.8]	7.1 [5.6, 9.0]

Figure 5 Phase II study: Distribution of salt intake (g/day) based on validated 24-hour urine collections by age and gender (N=488)



When stratified by the sampling group within the Phase II study, salt intake was higher in men than in women in the general population group (p=0.0008), in the occupational group (p<0.0001), and in students (p<0.0001). Mean salt intake did not vary with age in men (p=0.13) or in women (p=0.92). In multivariate analyses adjusted for age, sex and sampling group, salt intake continued to be strongly associated with gender (p<0.001) but not with age.

Percentage of subjects with intakes higher than recommended

The proportion of participants with estimated salt intake of 6 g/day or more by age and sex is shown in **Table 11.** Overall 86 per cent (95% CI 82 – 90 percent) of men and 67 per cent (95% CI 60 – 74 per cent) of women were in this high salt intake category, (p<0.001). There was evidence that a higher proportion of younger men had salt intakes of 6 g/day or more per day (p= 0.06). A similar age trend was not observed in women. This estimate for the proportion of women consuming 6 g/day or more from the PABA validated urine samples (67 per cent) is similar to that derived from the SLÁN-07 FFQ data (66 per cent), whereas the validated estimate for men (86 per cent) is higher than in the SLÁN FFQ data (70 per cent). In only five per cent of participants, four men (1.3 per cent), 95 per cent C.I. 0.03 per cent to 2.6 per cent and 21 women (11.5 per cent), 95 per cent C. I.6.9 to 16 per cent was the estimated salt intake less than 4 grams of salt per day, the adequate intake level for salt.

Table 11 Phase II study: Proportion of participants with estimated salt intake of six g/day or more by age and sex

SALT >6 grams	17-29 yrs	30-44 yrs	45-64 yrs	Over 65 yrs	Total
Men					
Yes (%)	67 (91.8*%)	144 (87.8%)	30 (76.9%)	23 (76.7%)	264 (86.3%)
No (%)	6 (8.2%)	20 (12.2%)	9 (23.1%)	7 (23.3%)	42 (13.7%)
Total	73	164	39	30	306
Women					
Yes	50 (64.1%)	43 (70.5 %)	15(62.5 %)	14 (73.7%)	122
No	28 (35.9%)	18 (29.5 %)	9 (37.5%)	5 (26.3%)	60 (67%)
Total	78	61	24	19	182

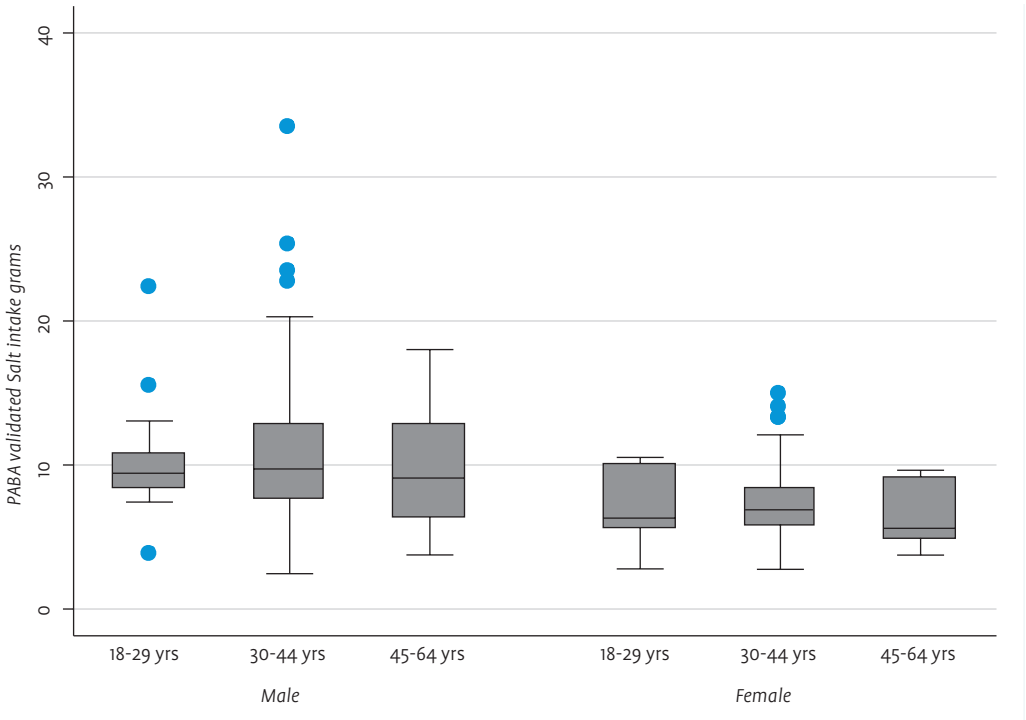
Salt intake in subjects on anti-hypertensive or diuretic medication

A total of 39 subjects in the study were on anti-hypertensive medication and 16 were on diuretic medication. In the group of 41 of these participants with PABA validated 24-hour urine collections, estimated mean salt intake was similar to that found in participants not taking these medications.

Salt intake in Phase II study sub-samples

Figure 6 shows the distribution of salt intake by age and gender in the occupational group. The distribution of PABA validated salt intake in the Phase II study general population and student sub-samples are available on request.

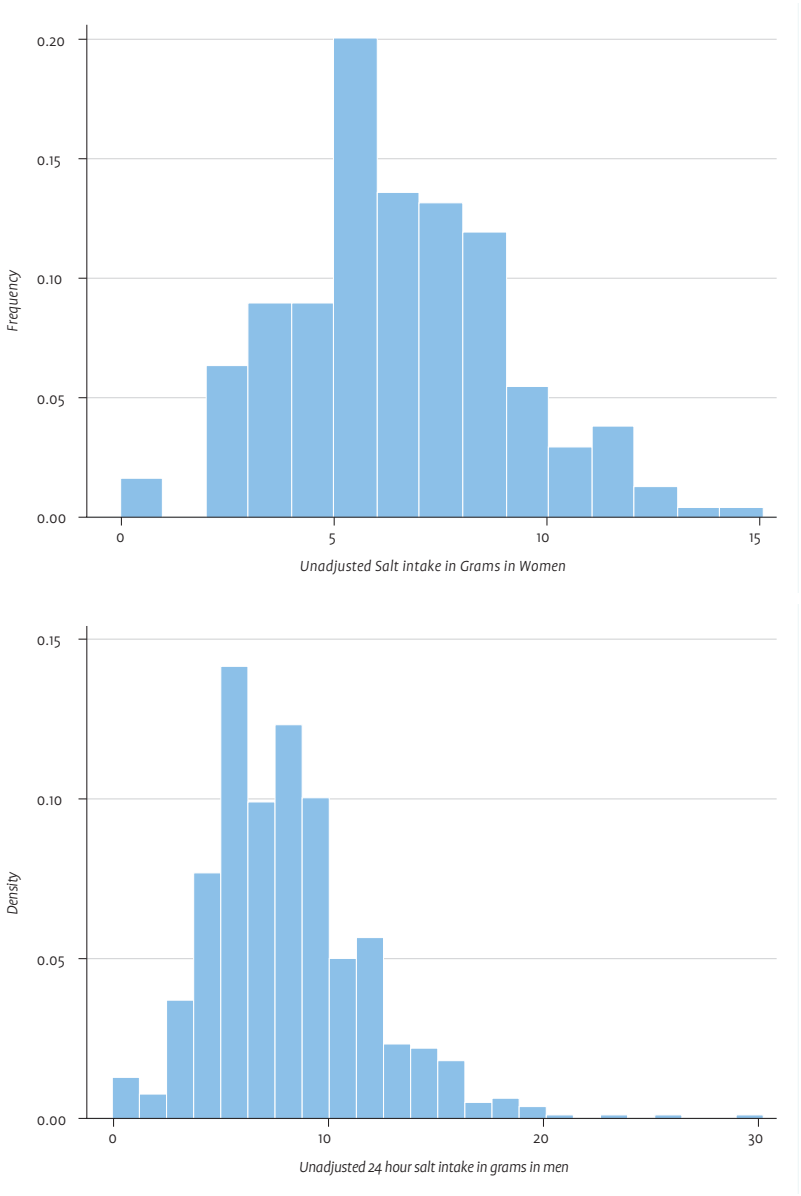
Figure 6 Phase II study: Distribution of salt intake by age and gender in the occupational sample (N=253)



Effect of PABA validation on study results

Figure 7 shows the distribution of estimated salt intake by gender in all 589 participants with detectable sodium who provided 24-hour urine collections, without correction for completeness of collection using PABA. In the absence of PABA validation, crude 24-hour urine collections underestimated mean daily salt intake by 9.6 per cent in men and 11 per cent in women. In these uncorrected analyses, salt intake (mean, sd, median) was 8.3 (3.61) 7.8 grams of salt per day. In men the uncorrected salt intake was 9.4 (3.8) 8.9 g/day and in women, 6.6 (2.44) 6.2 g/day.

Figure 7 Phase II study: Distribution of estimated salt intake by gender in all 589 participants with detectable sodium who provided 24-hour urine collections, without correction for completeness of collection using PABA. (Note: Scales are different for men and women.)



Salt intake estimated from 24-hour urine collection compared with FFQ derived estimates

Table 12 shows salt intakes by age and sex based on validated 24-hour urine collections and FFQ data in a sample of 488 participants with data from both sources.

Table 12 Phase II study: Mean (sd) median validated 24-hour salt intake (g/day) compared to salt intake estimates by the Food Frequency Questionnaire, by gender (N=488)

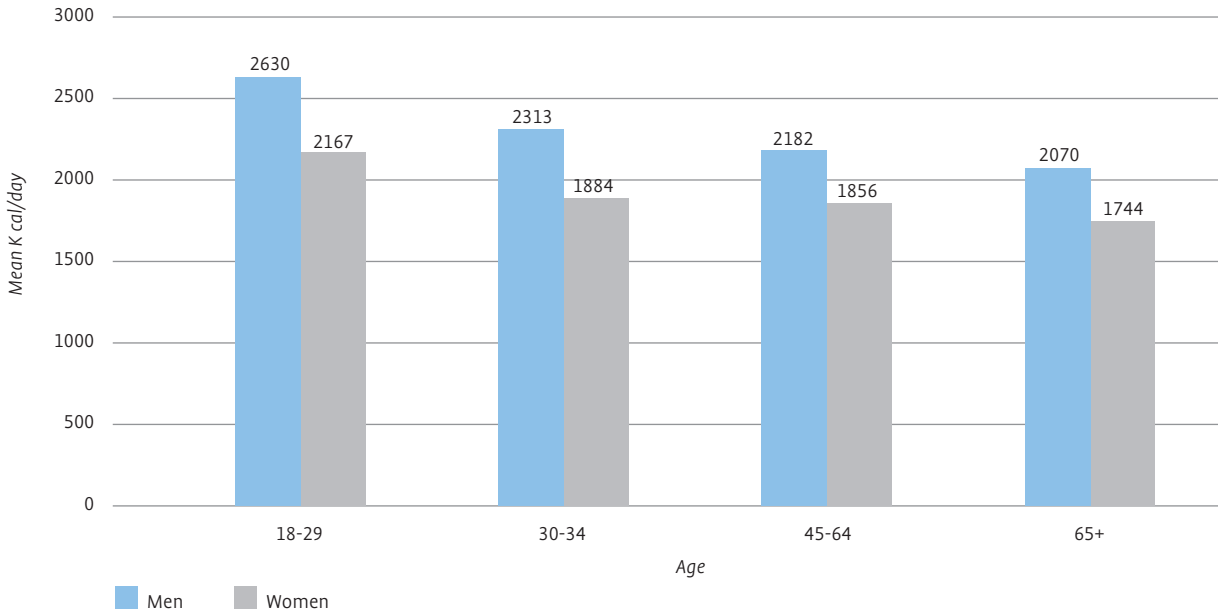
Men	**17-29 yrs**	**30-44 yrs**	**45-64 yrs**	**Over 65 yrs**	**Total**
FFQ Salt g/day	9.6 (4.4) 8.6	8.4 (3.3) 8.0	8.6 (2.9) 8.0	9.2 (4.2) 8.1	8.8(3.7) 8.1
24 Hour Salt excretion g/day	10.6 (4.3) 9.7	10.7 (4.3) 10.0	9.9 (4.0) 10.1	8.9 (3.1) 8.2	10.4 (4.1) 9.7
Women	**17-29 yrs**	**30-44 yrs**	**45-64 yrs**	**Over 65 yrs**	**Total**
FFQ Salt g/day	7.6 (3.3) 6.8	6.9 (2.6) 7.2	8.3 (6.42) 7.4	7.4 (2.6) 6.8	7.4 (3.6) 6.9
24 Hour Salt excretion g/day	7.3 (2.8) 7.04	7.5 (2.9) 7.2	7.2 (2.1) 7.1	7.6 (3.7) 6.8	7.4 (2.9) 6.8

There is remarkable concordance between estimates of daily salt intake from FFQ and validated 24-hour urine collections in women with similar overall means from both dietary assessment methods. By contrast, FFQ underestimates mean salt intake in men by an average of 15 per cent.

Phase II study: Validated salt intake: associations with general and central obesity and with calorie intake

In the Phase II study approximately 19 per cent of men and 17 per cent of women were obese (BMI >30kg/m2) and 48 per cent of men and 26 per cent of women were overweight (BMI of 24.9-30 kg/m2). The overall mean daily food energy intake amongst respondents was 2,216.kcal/day. As expected, energy intake from food was significantly higher (p<0.001) in men (2,358kcal/day) than women (1993kcal/day), and in those in the younger age groups. **Figure 8** shows the distribution of food energy intake of men and women by age.

Figure 8 Phase II study: Estimated mean Kilocalorie intake in food (FFQ) by age group and gender



Overall mean food energy intake values were lower in the Phase II study than in the national population sample (SLÁN-07). However intakes in students in the 18-29 year age group were similar to the national sample for the same age group.

PABA validated salt intake was significantly associated with both general and central obesity, defined on the basis of standard criteria, **Figure 9** and **Figure 10**.

Figure 9 Phase II study: PABA validated salt intake (g/day) by gender and general obesity

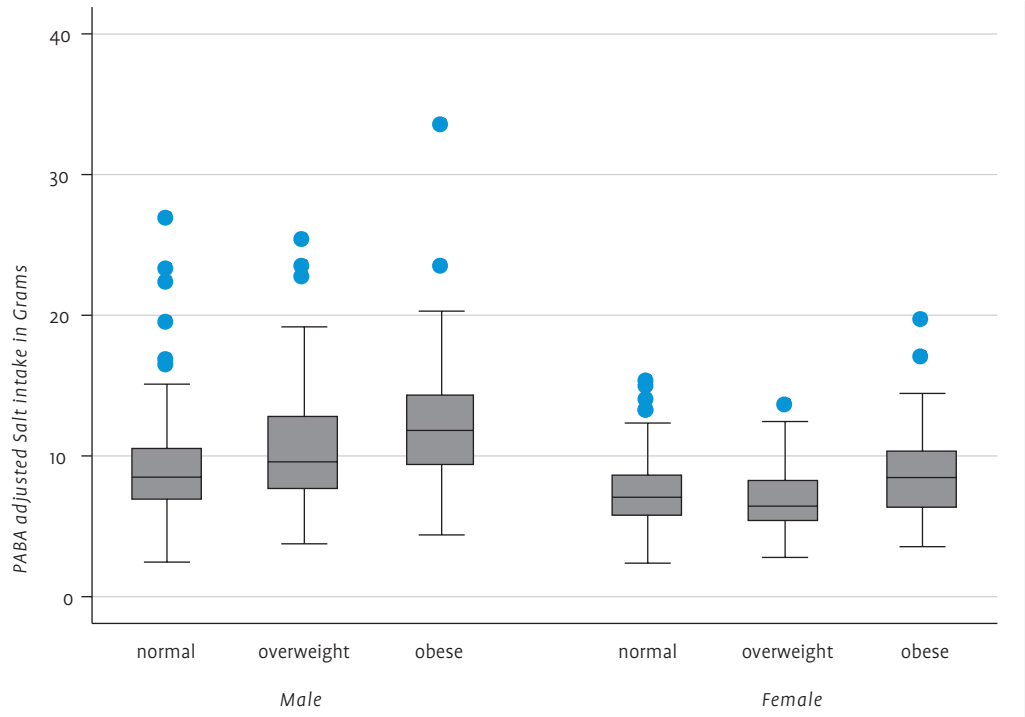
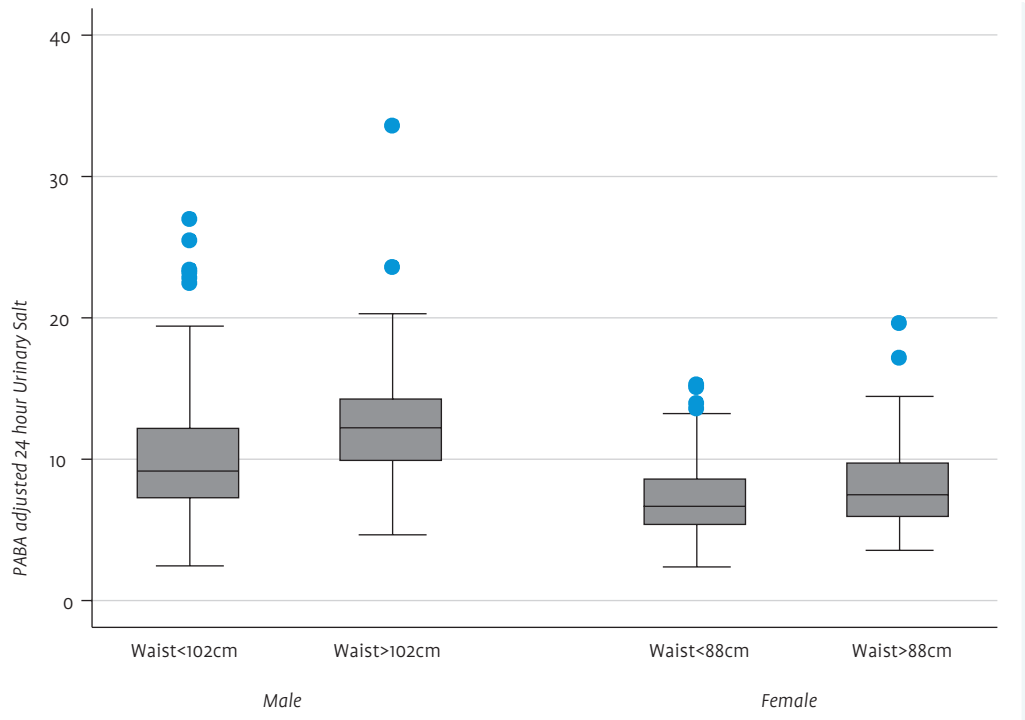


Figure 10 Phase II study: PABA validated salt intake (g/day) by sex and central obesity



In univariate and multivariate analyses we explored inter-relations between age, sex, obesity, potassium intake and food energy intake as predictors of salt intake in the occupational group subsample, (N=253:188 men, 65 women). In the univariate analyses we observed significant independent associations with sex ($p<0.001$), age ($p<0.002$), BMI ($P<0.001$), waist circumference (<0.001), potassium intake ($p<0.001$) and food energy intake ($p<0.001$), but not with age. In multivariate analyses the two measures of obesity ($p<0.001$), potassium intake ($p<0.001$) and gender ($p=0.001$) continue to be predictors of salt intake. However, estimated kilocalories from food ($p=0.31$) and age ($p=0.1$) are no longer predictors in a fully adjusted model. If calories from protein (not from carbohydrates or fat) are incorporated into the model, instead of total kilocalories from food, calories derived from protein become significant ($p=0.007$).

Phase II study: Salt intake and hypertension

We examined the association between blood pressure and salt intake in the occupational group, the largest and most homogenous sub-sample in this study. There was a statistically significant association between validated salt intake and systolic ($p=0.007$) and diastolic blood pressure ($p=0.004$), if those with a known history of hypertension are excluded. In this small sample, the association of salt intake with blood pressure remains significant when adjusted for age ($p=0.005$) but not when adjusted for age and gender.

Sub Section 6

Phase II study: Estimated potassium intake from 24-hour urine samples

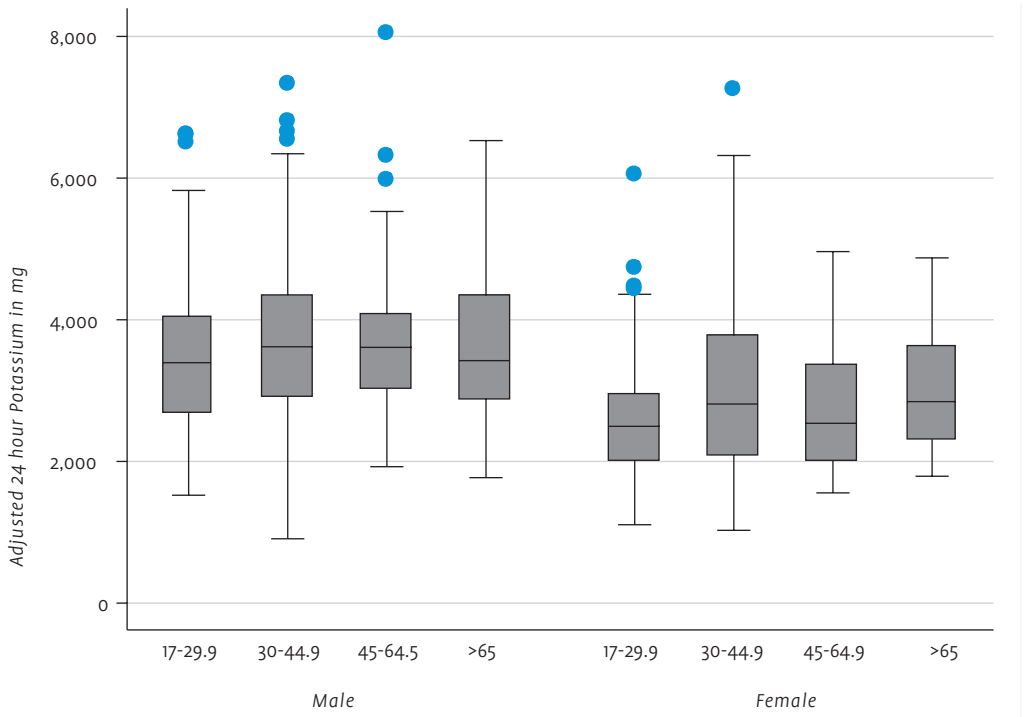
The Recommended Daily Allowance (RDA) for potassium is 3,100 mg/day. We estimated potassium intakes in the Phase II study based on measures of 24-hour urinary potassium excretion with completeness of collection validated with PABA assay as for sodium excretion. This enables precise quantification of the potassium intake in each subject for the preceding 24 hours, as virtually all ingested potassium is excreted. Daily potassium intake was validated in 488 participants. Potassium was converted into mg per day from mmol per 24 hours and presented as the nearest 10 mg. Potassium intake was significantly higher in men compared to women ($p<0.0001$), **Table 13,** but did not vary with age in men ($p=0.34$) or women ($p=0.1$). Potassium intake was greater in men but not in women with general obesity ($p<0.0001$) and central obesity ($p<0.0005$), **Figure 11**.

The association of salt intake with blood pressure remains significant when adjusted for age.

Table 13 Phase II study: Potassium intake (mgld) by age based on 24-hour validated urinary excretion, (N=488)

Men	N	Mean	Median	IQR
	306	3626 (1178)	3556	2860, 4183
Women	**N**	**Mean (sd)**	**Median**	**IQR**
	182	2786 (1042)	2614	2027, 3406

Figure 11 Phase II study: Potassium intake (mg/day) estimated from 24-hour urinary excretion by gender and BMI



Potassium intake estimated from 24 hour urine collection compared with FFQ derived estimates

Table 14 shows potassium intakes by age and sex based on validated 24-hour urine collections and FFQ data in a sample of 488 participants with data from both sources.

Table 14 Phase II study: Mean (sd) median validated 24-hour potassium intake (mg/day) compared to potassium intake estimates by Food Frequency Questionnaire, by gender (N=488)

MEN	17-29 yrs	30-44 yrs	45-64 yrs	Over 65 yrs	Total
FFQ Potassium (mg)/day	4295 (1185) 3851	3843 (1390) 3538	3959 (1154) 3969	3592 (1229) 3561	3940 (1461) 3662
24 Hour Potassium excretion (mg)/day	3436 (1159) 3393	3687 (1179) 3619	3788 (1182) 3610	3578 (1223) 3423	3626 (1178) 3556
WOMEN	**17-29 yrs**	**30-44 yrs**	**45-64 yrs**	**Over 65 yrs**	**Total**
FFQ Potassium (mg)/day	3471 (1190) 3308	3555 (1199) 3390	3871 (2335) 3366	3132 (938) 3016	3516 (1379) 3309
24 Hour Potassium excretion (mg)/day	2594 (941) 2495	3034 (1213) 2833	2622 (859) 2472	2988 (907) 2845	2786 (1042) 2845

The Food Frequency Questionnaire overestimates mean potassium intake by a significant amount in both men (15 per cent) and women (21 per cent).

Phase II study: Sodium to Potassium Ratio

We estimated sodium to potassium ratio in the 488 subjects with urine collections which were validated by PABA, Table 15. Sodium potassium ratio again was slightly but non-significantly higher in men (2.0 mmol/mmol (sd 0.81)) than women (1.9 mmol/mmol (sd 0.88)), (p=0.24). Sodium potassium ratio was associated with age in men but not in women. In multivariate analyses, sodium to potassium ratio was positively associated with age (p=0.01) but not with BMI (p=0.9), waist circumference (p=0.7) or estimated food energy in kilocalories based on the FFQ (p=0.3).

Table 15 Phase II study: Sodium to potassium ratio by age and gender

Men	N	Mean (Sd)	Median	IQR
18-29 yrs	73	2.2 (0.94)	2.0	1.5, 2.6
30-44 yrs	164	2.0 (0.76)	1.9	1.5, 2.5
45-64 yrs	39	1.8 (0.76)	1.7	1.1, 2.4
65 yrs	30	1.8 (0.62)	1.9	1.3, 2.0
Total	306	2.0 (0.81)	1.9	1.4, 2.5
Men	**N**	**Mean (Sd)**	**Median**	**IQR**
18-29 yrs	78	2.1 (0.94)	1.9	1.3,2.6
30-44 yrs	61	1.8 (0.89)	1.5	1.3, 2.2
45-64 yrs	24	2.0 (0.77)	1.8	1.3, 2.4
65 yrs	19	1.8 (0.74)	1.5	1.3, 2.1
Total	182	1.9 (0.88)	1.7	1.3, 2.4

4

Discussion and Recommendation

The findings from this study provide evidence for the effective planning and evaluation of public health initiatives focused on reducing dietary salt intake in the population. Dietary salt intakes in the Irish population remain high with the overwhelming majority of the population, 79 per cent (86 per cent of men and 67 per cent of women) consuming salt at levels well in excess of the current tolerable upper limit of six grams per day with only with only 5.1 per cent (1.3 per cent of men and 11.5 per cent of women) with intakes within the adequate intake range. These estimates of mean salt intake based on 24-hour urine collections, 9.3 for the sample as a whole (men: 10.4 g/day and women: 7.4 g/day) are remarkably similar to those from the UK Diet and Health Study conducted in 2005-06 where mean salt intake in the sample was 8.7 g/day (men: 9.7 g/day and women 7.7 g/day) [34]. The findings are also similar to those of Shortt and colleagues from a study conducted in Cork in the late 1980s which was also based on 24 hour urine collection, with overall mean 8.8 g/day (men: 9.7 g/day and women: 7.8 g/day) [38].

Given the rising prevalence of obesity in Ireland in recent years [7-8] one might have expected to see evidence of increasing salt intake over the period with increases in calorie intake and greater reliance on processed food. It is arguable therefore that recent modest changes in the salt content of processed food have mitigated these adverse trends in obesity. However, a number of caveats must be considered in relation to the interpretation of these findings. There are potentially significant volunteer biases in both the SLÁN-07 and the Phase II study, due to declining response rates for health and nutritional surveys and the particular difficulty of recruitment for studies involving 24-hour urine collections. The elderly and individuals from socially and economically disadvantaged backgrounds (where salt intakes are probably higher) were under- represented in the sample. Thus it is likely that we are underestimating average salt intakes in the population. In mitigation it can be argued that similar methodological issues arise in relation to the earlier Cork study [38] and the recent UK study [34].

The majority of the population consume salt at levels well in excess of the current tolerable upper limit.

Significant variation in salt intake with age was not detected in the Phase II study. However, there were relatively few participants in the older age categories. We observed the expected gender differences in estimated salt intake. While it may be assumed that the higher intakes in men simply reflect higher food energy intakes, the gender differences are not significantly attenuated on adjustment for estimated energy intake based on FFQ data. It should be noted however that the latter (energy intake) is estimated with relatively low precision and one cannot therefore assume that energy intake is not a significant factor in gender differences in salt intake. There is no evidence from the SLÁN-07 FFQ data that women choose foods with lower salt content or are less inclined to add salt while cooking or at the table. However, the quantity of discretionary salt may be somewhat lower in women.

Similar issues arise in relation to the increase in salt intake with obesity, which is also not explained by reported energy consumption on FFQ. This is almost certainly confounded by under reporting of calorie intakes in the overweight and obese. In analyses of the SLÁN-07 data, dietary sodium intake density (mg of sodium per 1000 kilocalories consumed) was not higher in the overweight and obese. This suggests that increasing salt intakes with overweight and obesity may be explained by food energy intakes, as opposed to a preference for high salt foods. While this is an interesting observation, the validity of sodium intake density as an indicator of salt intake needs further study.

Ireland was recently (2010) bracketed with a small number of countries, including the United Kingdom and Finland, which have implemented aggressive public health programmes to reduce salt intake [48]. While this undoubtedly overstates the position, it is clear that significant efforts have been made to work with the food sector and raise public awareness on this issue over the past five years. The findings from this work suggest that these efforts may have had some impact but they need to be intensified. It is widely accepted that health promotion initiatives targeting individual consumers are ineffective [49], given that 75 to 80 per cent of salt comes from processed food. Thus the focus of activity in this area must remain on working with the food industry. The recent history of public health initiatives in relation to tobacco and alcohol would suggest that voluntary agreements with the food sector will not be sufficient. In this context it is noteworthy that in the recent (2010) US Institute of Medicine report on *"Strategies to Reduce Dietary Sodium Intake in the United States"* it is recommended that the *"Food and Drug Administration (FDA) should expeditiously initiate a process to set mandatory national standards for the sodium content of foods."* Specifically, it is recommended that FDA should *"modify the generally recognised as safe (GRAS) status of salt added to processed foods in order to reduce the salt content of the food supply in a stepwise manner"* and the FDA should *"likewise extend its stepwise application of the GRAS modification, adjusted as necessary, to encompass salt added to menu items offered by restaurant/foodservice operations that are sufficiently standardised so as to allow practical implementation."*[9]

The poor response rate for the studies involving 24-hour urine collections highlights the challenges we face in monitoring salt intake in the population. It is noteworthy that estimates of salt intake based on random ("spot") urine samples from the SLÁN-07 study, adjusted appropriately for 24-hour urine volume, provide group level estimates of intakes that are similar for both men and women to those derived from PABA validated 24-hour urine collections. This observation, if replicated, has important practical implications for population level nutritional surveillance in this area. By contrast, salt intake estimates derived from the FFQ were remarkably accurate for women but not for men where FFQ data underestimated 24-hour urinary excretion estimates by an average of 15 per cent. As it is widely held that food frequency questionnaires underestimate salt intake, these findings will need to be replicated. Also it is interesting to note that in the Phase II study, the FFQ overestimated mean potassium intake by a significant amount in both men (15 per cent) and women (21 per cent). This observation may well reflect over-reporting of fruit and vegetable intakes.

Key recommendations from this study include the following

As most salt is added to food during processing, there is a need for more intensive engagement with the food sector by the relevant statutory agencies to ensure that significant reductions in the salt content of processed food are achieved within a reasonable timescale.

The issue of clear and accurate labelling of the salt content of processed food, using simple formats such as the traffic lights system, should be reviewed as a high priority. In particular the practice within the food industry of referring to a salt intake of six grams per day as a "guideline daily amount" is misleading and should be discontinued.

The issue of clear and accurate labelling of the salt content of processed food should be reviewed as a high priority.

Given the accumulating evidence on the health and economic costs of high salt intake, the issue of statutory regulation of the salt content of processed food should be considered by government working in collaboration with EU partners. Mandatory changes in permissible salt concentrations in processed food could be phased in over a reasonable timescale to allow consumers and the food industry to adapt.

There is a need for ongoing population monitoring for salt intake as part of the national nutrition surveillance systems. In particular, we need reliable data on salt intake in children and adolescents.

Given the difficulties associated with obtaining 24-hour urine collections from representative samples of adults and children, the group level reliability of alternative methods of surveillance of dietary salt intake, such as random ("spot") samples corrected for urinary volume and dietary sodium intake density, should be further assessed.

The annual health and economic costs of excessive salt intake should be modelled for the Republic of Ireland using these data and relevant additional data on morbidity, mortality and costs.

5

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Appendix

Sodium: creatinine and sodium: potassium ratio data from SLÁN-07

Mean sodium to creatinine ratio is a useful indicator of population dietary salt intake. Sodium to potassium ratio provides a useful index of intakes of both salt and potassium rich foods. It can be estimated without data on overall energy intake. In SLÁN-07, 1207 subjects, aged 45 and over had a physical examination, of whom 1098 provided urine samples which permitted an estimation of urinary sodium and urinary potassium and 1074 (men 476, women 598) provided data for an estimation of urinary creatinine excretion. The ratio of sodium to creatinine and sodium to potassium were calculated in mmol per mmol.

SLÁN-07: Sodium to Creatinine Ratio

The sodium creatinine (mean sd median) was 12.2 (8.7) 10.3 mmol/mmol. Sodium to creatinine levels were lower in men (10.6 (6.9) 9.2 mmol/mmol) than women (13.6 (9.8) 11.5 mmol/mmol) but did not vary significantly with age, **Table A.** The gender difference reflects greater creatinine load relating to size and muscle mass in men. Mean sodium to creatinine levels were somewhat lower in Ireland relative to mean levels found in the EPIC-Norfolk study in the UK [men: 12.7 (sd 7.1); women: 14.7(sd 8.9)] [41]

Table A SLÁN-07 study: Sodium to Creatinine Ratio by age and gender

MEN	N	Mean (sd)	Median	IQR
45-64 yrs	298	10.1 (6.1)	8.8	6.0, 12.8
≥65 yrs	178	11.3 (7.9)	9.9	6.2, 14.2
Total	476	10.6 (6.9)	9.2	6.0, 13.3
WOMEN	**N**	**Mean (sd)**	**Median**	**IQR**
45-64 yrs	434	13.9 (10.4)	11.7	7.6, 17.3
≥65 yrs	164	12.6 (7.7)	10.9	6.5, 16.6
Total	598	13.2 (8.1)	11.5	7.4, 16.8

**When calculating sodium creatinine levels some spot urines had very high creatinine which were treated as outliers*

In further analyses, sodium to creatinine levels were categorised into quintiles. On a population level, these quintiles represent increasing urinary sodium excretion due to dietary salt intake, assuming less variation in urinary creatinine levels. A higher sodium to creatinine ratio was associated with a higher potassium to creatinine ratio (data not shown) and thus may reflect a greater overall nutrient intake. **Tables B** shows mean age, BMI, systolic BP, diastolic BP, sodium creatinine ratio and sodium to potassium ratio by quintiles of sodium creatinine ratio in men and women respectively.

There was a statistically significant association between the sodium creatinine ratio and systolic and diastolic blood pressure in analyses excluding participants on diuretics and anti-hypertensive drugs and adjusted for age and gender (systolic blood pressure (p<0.001) and diastolic (p=0.002)).

Table B SLÁN-07 study: Mean (sd) median age, BMI, systolic BP, diastolic BP, sodium to creatinine ratio and sodium to potassium ratio by quintiles of sodium to creatinine ratio in men and women

	Urinary sodium: creatinine (mmol:mmol) quantities					
	<5.9	5.9–8.7	8.8–11.9	12.0–16.9	>16.9	p-value
N	119	110	103	76	68	
Men	Mean (SD)					
Age (years)	61.7 (10.9) 60	60.4 (9.5) 61	60.4 (9.4) 59	60.7 (9.4) 60	61.3 (10.3) 63	0.82
BMI (kg/m2)	28.3 (4.6) 28	28.3 (3.8) 27.8	28.7 (4.3) 28.7	29.1 (4.1) 29	28.8 (11.1) 27.2	0.61
Systolic blood pressure (mm Hg)	142 (18) 141	146 (17) 144	146 (21) 145	150 (20.6) 149	149 (20) 150	0.03
Diastolic blood pressure (mm Hg)	82 (11) 81	85 (10.4) 86	85 (12) 83	86.3 (11) 85	84 (9.1) 82	0.03
Urinary sodium: creatinine ratio*	4.0 (1.4) 4.2	7.5 (0.8) 7.4	10.4 (.9) 10.4	14.2 (1.5) 14	23.4 (7.2) 21.1	--

Urinary sodium: potassium ratio	0.9 (0.4) 0.8	1.3 (0.6) 1.18	1.7 (0.7) 1.5	2.4 (3.0) 1.8	3.3 (3.1) 2.8	--
Women						
N	99	114	99	139	147	
Age (years)	60.5(9.8) 60	58.9 (10.6) 58	58.7 (9.4) 57	59.4 (9.6) 63	58.1 (9.1) 55	0.41
BMI (kg/m2)	27 (4.7) 25.7	28.1 (5.4) 26.9	27.6 (4.8) 27.6	28.3 (4.1) 28.1	28.8 (11.1) 27.2	0.35
Systolic blood pressure (mm Hg)	131 (19.1) 127	134 (3.9) 132	136 (19.8) 133	149 (20.8) 138	141 (20.8) 138	<0.0023
Diastolic blood pressure (mm Hg)	78.5 (10.1) 77.5	78.6(10.0) 78	80.1(10.4) 79	82 (10.7) 81	82 (10.7 81)	<0.028
Urinary sodium:creatinine*	4.3 (1.2) 4.5	7.5 (0.8) 7.6	10.4 (0.9) 10.3	14.4 (1.4) 14.3	25.9 (11.9) 22.6	--
Urinary sodium: potassium	0.7 (0.40) 0.7	1.5 (3.3) 1.1	1.4 (0.7) 1.3	2.7 (2.9) 2.2	2.5 (1.8)	

**When calculating sodium creatinine levels some spot urines had very high creatinine which were treated as outliers*

SLÁN-07: Sodium to Potassium Ratio

The mean sodium to potassium ratio was marginally but not significantly higher in men (1.9 mmol/l (sd 2.9) compared to women (1.8 mmol/l (sd 2.5), (p=0.78). There were no significant differences with age in this sample, **Table C.**

Table c SLÁN-07 study: sodium to potassium ratio from spot urine samples by age and gender

Men	N	Mean (Sd)	Median	IQR
45-64 yrs	304	2.0 (3.3)	1.4	0.9, 2.0
65 yrs	181	1.8 (2.2)	1.4	1.0, 2.2
Total	485	1.9 (2.9)	1.4	1.0, 2.1
Women	**N**	**Mean (Sd)**	**Median**	**IQR**
45-64 yrs	440	1.7 (2.5)	1.3	0.9, 2.0
65 yrs	173	1.8 (2.5)	1.4	0.9, 2.0
Total	613	1.8 (2.5)	1.4	0.9, 2.0

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