

NatCen

Social Research that works for society

Diet and Health

Study 2014

(Sodium study)

Nurse Project Instructions

Contents.

1	Background & Aims	3
2	The Research Team	4
3	Summary of Survey Design	5
4	The Sample	6
4.1	Sample Design	6
4.2	Eligibility Criteria	6
5	Overview of Nurse Visits	7
5.1	Participant Recruitment	7
5.2	Nurse Appointments	7
5.3	First nurse visit.....	8
5.4	Second nurse visit.....	8
5.5	Typical Scenario	9
6	Participant & Nurse Documents	10
7	Serial Numbers.....	12
8	Introducing the Diet and Health Study	14
9	The First Nurse Visit.....	15
9.1	CAPI Prompt	15
9.2	Informed Consent	15
9.3	Checklist of participant documents & equipment	16
9.4	24-hour urine collection sheet.....	17
9.5	24-hour urine collection.....	18
9.6	PABA (Para-aminobenzoic acid).....	19
10	Labelling	20
11	The Second Nurse Visit	21
11.1	Checking the urine collection sheet	22
11.1.1	24-hour urine collections out of range.....	22
11.2	Weighing the urine sample	23
11.3	24-hour urine Sub-sampling Procedure	24
11.4	Labelling the 24-hour urine monovettes.....	25
12	Packaging and Despatch	26

13 Household questionnaire	27
14 Participant Incentive	30
14.1 Participant Feedback.....	30
Appendix A. Sub-sampling 24-hour urine.....	31
Appendix B. Completed consent form	32
Appendix C. Completed 24-hour urine collection sheet	33
Appendix D. Completed 24-hour urine despatch note.....	35

1 Background & Aims

Consumption of dietary sodium (or salt) is related to high blood pressure and cardiovascular disease. Salt consumption can be assessed by measuring sodium levels in urine, ideally in a sample collected over a 24-hour period.

Public Health England (an executive agency of the Department of Health) and the Food Standards Agency Scotland have commissioned this study to monitor progress towards the dietary target to reduce salt intake to approximately 6g per day. The study is being carried out in England and Scotland and involves adults aged 19-64. The aim is to collect usable 24-hour urine samples from a minimum of 600 adults in each country..

***Avoid mentioning** the term **'salt'** to the participant*

We do not want people to adjust their diet for the purpose of this study

If asked about nutrients or dietary markers simply mention nutrients

'such as sodium or potassium'

Individuals will initially be recruited by NatCen's Telephone Unit (TU) via Random Digit Dialling across 90 (45 in each country) postcode sectors. Details of those agreeing to take part will then be passed to the nurse fieldwork stage. At this stage participants will be asked to collect all urine passed during a 24-hour period. You will need to conduct two short visits to each household. During the first nurse visit, you will need to explain the procedures and leave the collection equipment. You will then collect the 24-hour urine collection on the second visit, complete the collection sheet and despatch note and send them to the laboratory for analysis.

Fieldwork is being carried out in five waves: TU are carrying out recruitment in mid-March – mid-August, and nurse appointments will be carried out during May – September, with the majority being covered in the first three waves.

NatCen is conducting the fieldwork and MRC Human Nutrition Research (HNR) will be responsible for the analysis of the urine samples.

The study has received ethical approval.

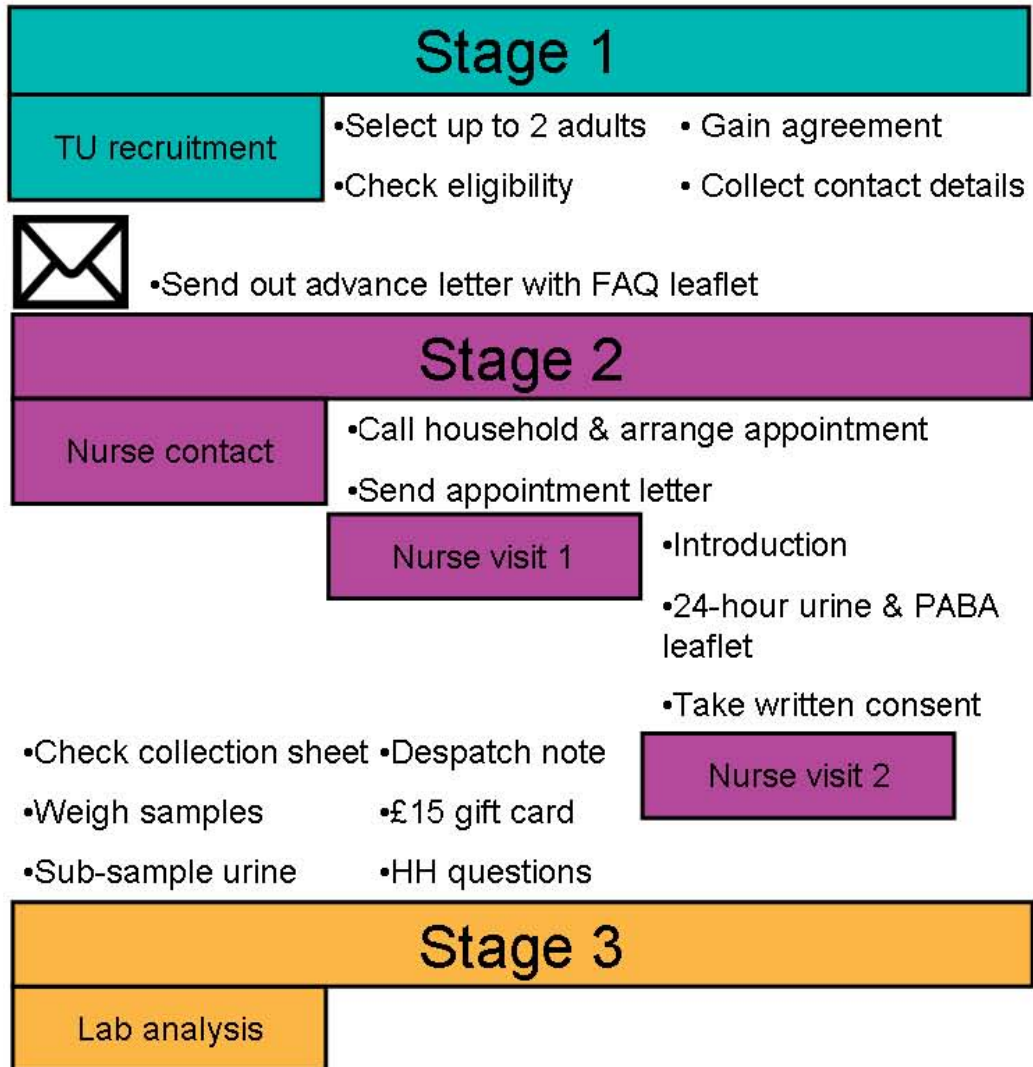
2 The Research Team

The study is being co-ordinated by NatCen:

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3 Summary of Survey Design

The fieldwork structure is as follows:



4 The Sample

4.1 Sample Design

A requirement of the study is that a representative sample of the population in England and Scotland, aged 19 - 64 years is achieved.

The initial sample will be recruited through Random Digit Dialing (RDD). RDD is a method where a representative sample of telephone numbers is generated at random from a frame of all possible telephone numbers in a postcode sector. For this study we have selected 45 different postcode sectors (points) for both England and Scotland.

Each nurse assignment will vary in size depending on the number of expected agreements the TU are able to achieve in a particular postcode sector, although on average we expect to issue between 14 and 21 cases in each.

The required study outcome is to have collected a minimum of 600 **usable** (i.e. not just collected) urine samples per country that consists of a balanced sample of men and women. Fieldwork will be monitored closely to ensure that we achieve this.

4.2 Eligibility Criteria

When making an appointment, the Telephone Unit will check that participants are of the eligible age range (19 - 64 years), although ultimately eligibility to take part in the study will be decided by the nurse.

EXCLUSION CRITERIA

Urine samples will **not** be taken from **pregnant** or **breastfeeding** women.

Participants on medication are eligible, but will be asked to make a note of certain prescribed medications taken during the 24-hour collection on the urine collection sheet. Some medication will exclude participants from taking PABA.

Participants unable to take PABA can still take part in the study. For more information about PABA see section 9.6.

Women who are menstruating will be asked to collect urine on **non-period days**.

5 Overview of Nurse Visits

5.1 Participant Recruitment

Participants will initially have been contacted by the Telephone Unit (TU) with the aim of introducing the study and gaining agreement for you to contact them. After this short telephone interview the advance letter detailing the purpose and background of the study with the FAQ leaflet will be sent out from Brentwood, stating that you will be in touch in the next few weeks.

At the start of your assignment, you will be sent Nurse Record Forms (NRF) with the participant's contact details, address and any information that the TU has recorded for you, in your work packs. The pack will contain the pre-printed appointment letters with pre-paid envelopes for you to use once you have made the appointment as well as personalized labels with the participant's ID, sex and date of birth (DOB).

5.2 Nurse Appointments

For this study you will be making your own appointments with participants via telephone. As for all other nurse surveys you should make contact with the participants, as soon as you receive the NRF. You must make contact with them within the first three weeks following the issue of work to you. Once you have done this you need to send them confirmation of the appointment using the appointment letters in your work pack.

At the same time, please double check sex and DOB of the participants on the labels to ensure these match the NRF. If any of the details are incorrect, please contact the Nurse Unit in the first instance so that the labels can be reprinted with the correct information and sent out to you prior to the first nurse visit.

Remember: There can be up to 2 participants per household and where possible you should aim to visit the household at a time that is convenient for both participants.

5.3 First nurse visit

The purpose of the first nurse visit is to follow the procedure below with each participant:

- Encourage the participant to take part
- Answer any questions they may have
- Check eligibility
- Provide the participant with detailed leaflets about the 24-hour urine collection instructions and PABA
- Obtain written consent
- Hand the equipment over to the participant
- Allocate a date for the participant to carry out the 24-hour collection
- Label consent form and urine collection sheet
- Arrange a date for the second visit (either the day the collection ends or the day after 24-hour collection)
- Leave the participant with a completed appointment card, to remind them when you will be returning to pick up their 24-hour urine collection.

We estimate this first visit will take 20-30 minutes (whether you have one or two participants). Please note it is ok to discuss the information about the visits with both participants at the same time, although you will need to make sure that informed consent is taken individually and both interviews are completed appropriately.

5.4 Second nurse visit

This should take place on the day the 24-hour collection finishes or the day after.

During the second nurse visit you will:

- Check the urine collection sheet with the participant
- Weigh the 24-hour urine collection according to protocol
- Complete the 24-hour urine despatch note
- Collect a sub-sample of 2 aliquots of the 24-hour urine collection
- Dispose of the remaining urine and equipment
- Label the 24-hour urine despatch note and urine monovettes
- Complete CAPI household questionnaire
- Prepare the aliquots for despatch.

Once the urine samples have been prepared for despatch, you will ask one participant in the household to complete a short socio-demographic CAPI questionnaire on behalf of the household.

Participants will not receive results of their urine analysis. Each participant who provides a complete 24-hour urine collection will receive a **£15 gift card** for their participation in this study.

5.5 Typical Scenario

A typical scenario might be as follows:

First Nurse Visit: e.g. Monday

- Allocate (randomly assigned by CAPI) and agree a day and time for the participant to carry out the 24-hour urine collection.

Day 1 collection: e.g. Wednesday

- The 24-hour urine collection should start with the morning's second urine pass and continue through the day and night.

Day 2 collection: e.g. Thursday

- The 24-hour urine collection will end with the morning's first urine pass (i.e. it should include the first morning urine pass).

Second Nurse Visit: e.g. Thursday or Friday

- You will need to **weigh** the sample, **check** the collection sheet, **complete** the despatch note, **attach** the PABA blister pack, **enclose** labels AL1 (7) and AL2 (8) and prepare the samples for **despatch**.

6 Participant & Nurse Documents

The following documents will be provided for the study:

Advance letter

An advance letter and FAQ (see below) will be sent to all participants who have agreed to take part in the study at the Telephone Unit stage. It details the purpose and background to the study, what it involves, and also tells the participant the nurse will be contacting them to make an appointment. These letters will be sent out from Brentwood; however you will have a copy to show participants (*An example of the advance letter is in your briefing pack*).

FAQ leaflet

A leaflet answering some frequently asked questions will be enclosed with the advance letter. This will cover common questions participants might have before of the nurse visit. You will have a copy of this leaflet in your work pack to prepare you for some common questions (*An example of the FAQ leaflet is in your briefing pack*).

Nurse appointment letter

You will be provided with pre-addressed appointment letters. You need to date (top) and sign (bottom) the letter and write in the appointment details (i.e. the date and time of visit 1 and the participant's name) before sending to the participant in a pre-paid envelopes (provided in your pack) (*An example of an appointment letter is in your briefing pack*).

24-hour urine leaflet

The 24-hour urine leaflet provides detailed information for the participant about how to collect the 24-hour urine collection. The instructions cover the protocol that you will also explain at your first visit. Please read the leaflet so you know exactly what the participant needs to do for the study. You will leave a copy of the leaflet with the participant. Make sure participants have read and understood the leaflet in order to obtain informed consent. (*An example of the 24-hour urine leaflet is in your briefing pack*).

PABA information leaflet

The PABA information leaflet gives details about the PABA tablets. Each participant should be given a copy and allowed time to read through it. Participants will be asked to take three tablets during the 24-hour collection period. PABA levels will be measured to assess how complete the 24-hour collection is (*See section 9.6 for further information about PABA*).

However, if the participant is allergic or thinks they may be allergic to PABA **they can still take part** in the study without taking PABA (*An example of the PABA leaflet is in your briefing pack*).

Nurse Record Form (NRF)

The NRF will contain the address details of the household, including serial number and telephone number(s). You will also be given the names of up to two people in the household selected to take part and whether any person refused to take part. There may also be some useful information about the location of the household recorded by the TU (*An example of the NRF is in your briefing pack*).

Consent form

Participants should be given the instructions for making a 24-hour urine collection and the PABA information leaflet to allow them to make an informed decision about taking part (bearing in mind that people can participate without taking PABA, but their participation is more valuable if they do take it). Each participant wishing to take part in the study **must** sign the consent form. The consent form is carbonized; the participant should retain one copy and the second copy will be returned to the office. As with any other survey with consents for biological samples, completion of consent forms are checked in the office after they are returned, to ensure that the written consents match the samples gained and received in the lab.

Note: samples that cannot be matched with valid consent forms need to be destroyed. Nurses will be informed of any errors picked up through the checking process (*See Appendix B for an example of a completed consent form*).

24h-urine collection sheet

The 24-hour urine collection sheet needs to be completed by participants during (not after) their collection. At the return visit, you need to go through the collection sheet with the participant to spot and fill in any missing information. You also need to check for 'out-of-range' samples i.e. collected for less than 20 or more than 28 hours (See section 11.1.1 for details about handling unusable samples in the household).

As with the despatch note, the collection sheet **must be sent** with the samples. See section 9.4 for details about completing this form (See Appendix C for an example of the urine collection sheet).

Despatch note

A completed despatch note **must be sent with each sample set**. Details needed are the full serial number (in the form of a label), nurse name and number. Also needed is the weight of the collection. The 24-hour urine collection must be weighed and recorded twice in CAPI. The weights, as recorded in CAPI, are then transferred onto the despatch note.

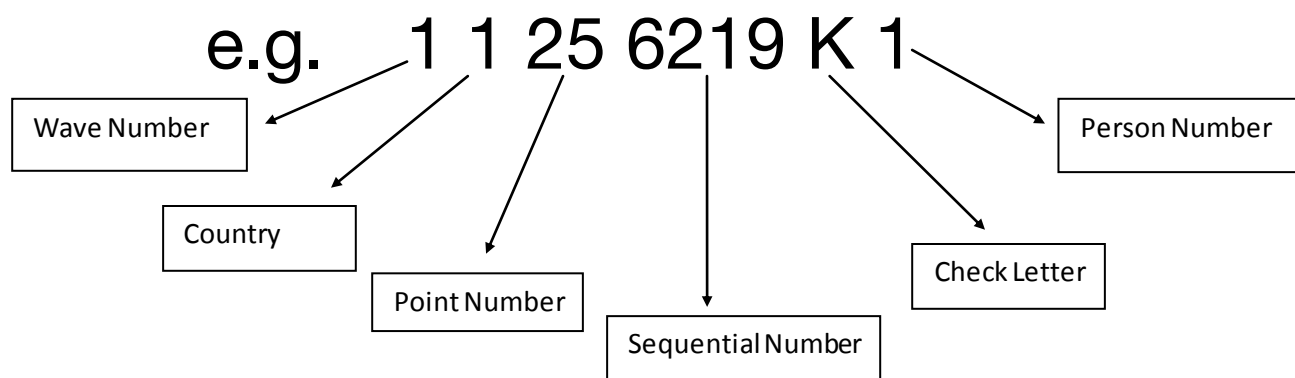
If a participant has used both collection containers then record the weight of urine in each container, again first in CAPI and then on the despatch note.

Please complete the despatch note very carefully – any errors that cannot be rectified are likely to result in the sample being destroyed. The lab will notify

Brentwood of any such errors and these will be passed onto nurses (See Appendix D for an example of a completed despatch note).

7 Serial Numbers

Each household in the survey has been assigned a unique identity number. This number is called the serial number. It allows us to distinguish which documents relate to which person. It is made up of different components:



Wave Number	The first digit indicates the wave (waves 1 through 5)
Country	The second digit indicates the country (1=England, 2=Scotland)
Point Number	A two digit number for the point
Sequential Number	A four digit number for the HH.
Check Letter (CKL)	A letter of the alphabet to uniquely identify the household.
Person Number	The last digit will be a number assigned to each person in the household in the CAPI programme. This can only be 1 or 2.

The serial number, including check letter can be found on the address box at the top of the Nurse Record Form (NRF). The Person Number is found next to the individual participants of the NRF.

<p>SERIAL NO: 11256219 K</p> <p>ADDRESS : 98 KIRKLEY ROAD</p> <p>ENFIELD</p> <p>LONDON</p> <p>POSTCODE: N8 7EB</p> <p>TEL 1: 0207 694 4598</p> <p>TEL 2: 07982 674865</p> <p>Location details: Take second left at Green Man pub. No 98 is opposite Seven Seas fish and chip shop.</p>	<p>RESPONDENT DETAILS:</p> <p>Resp 1</p> <p>Name Dr Alice D’Arcy</p> <p>DoB 12/11/1976</p> <p>Sex F</p> <p>TU status Agreed</p> <p>Resp 2</p> <p>Name Mr Donald McTay</p> <p>DoB 04/05/1976</p> <p>Sex M</p> <p>TU status Refused</p> <p>Date of CATI interview 03/04/14</p>
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So in the example above, the person number for Alice D’Arcy would be 1 and the person number for Donald McTay would be 2.

Therefore,

Alice’s full serial number: 11256219 K 1

Donald’s full serial number: 11256219 K 2

NB: See section 10 for detail about labelling.

Please complete outcomes for each participant on the second page of the NRF. Even if the participant does not wish to take part at the nurse visit stage you will still need to record the final outcome code for each participant. CAPI will record the outcome as well, but make any notes on the NRF; particularly details of any refusals and reasons for unproductives so you can enter these details in the CAPI admin block. As for other Nurse fieldwork you will not be required to return the NRF’s and should shred them once you have transmitted your work for the complete household.

8 Introducing the Diet and Health Study

What to say when introducing the study and booking appointments / on the telephone:

- ***Thank you for agreeing to take part in this study.***

What is the purpose of this study?

“This study has been commissioned by Public Health England/Food Standard Agency Scotland. Its aim is to monitor nutrient levels in people’s diets measured in 24-hour urine samples.”

What do I have to do?

- I’d like to visit you in person to go through exactly what’s involved in more detail.
- You will be asked to collect all the urine you produce over a full 24-hour period to participate in the study.

How long will the study take?

- We will ask you to collect urine for a full day i.e. 24 hours. You will collect urine at home and outside the home.
- The 24-hour urine collection needs to be collected over a continuous 24-hour period and it is essential that you collect all the urine you produce over this time. I will visit again to pick up the full collection shortly after completion.

What do I get from the study?

- You will receive a £15 gift card upon completion of the study as a token of our appreciation.

Why can’t I have my results?

- Your nutrient levels will vary depending on what you have eaten recently. For example, if you have had a take-away, your nutrient levels may be quite different to what they would be otherwise.
- Although results are not reliable at an individual level, they provide a good measurement of nutrient levels for groups of people.

What will happen with the results of the study?

- The information will be used to assess nutrient levels in the population and will provide vital information about diet in England/Scotland at this time.

9 The First Nurse Visit

9.1 CAPI Prompt

If participants are eligible, a prompt will appear in the CAPI asking you to explain the purpose of the 24-hour urine collection and the use of PABA, explain the instructions for collection in detail, obtain consent and provide participants with the information leaflets for 24-hour urine and PABA together with the equipment needed for the study.

Participants who are lactose intolerant or allergic to the following cannot take PABA but are still eligible to take part if they are willing to carry out the 24-hour urine collection:

- vitamin preparations
- hair dyes
- sunscreen lotions

Participants who take sulphonamide based antibiotics are also excluded from taking PABA. See 9.6 for list of sulphonamide based medication.

Participants on other (non-sulphonamide) medication are eligible, but you will need to ensure that the participant has made a note of prescribed medicines and dietary supplements taken during their collection period on the 24-hour urine collection sheet, as prompted.

Participants are still eligible if they refuse to take PABA but are willing to carry out the 24-hour urine collection (although their participation is more valuable to us if they do take it).

9.2 Informed Consent

You will be required to answer any questions the participant may have. If the participant is willing to take part, they must **initial and sign** the consent form to indicate that they have read the 24-hour urine leaflet and PABA leaflet and would like to take part in the study. It is equally important that you counter sign the consent form in the presence of the participant.

See Appendix B for an example of a completed consent form.

9.3 Checklist of participant documents & equipment

Participant documents	Purpose
<i>FAQ leaflet</i>	<i>Enclosed with the advance letter</i>
24-hour urine leaflet	Use to explain 24-hour urine collection when obtaining consent. Leave with participant.
PABA information leaflet	Give to inform about the purpose of PABA, when introducing the 24-hour urine collection.
24-hour urine consent form	Complete with participant after 24-hour urine has been explained and questions are answered. Ensure consents are initialed.
24-hour urine collection sheet	Give to participant to complete during collection as instructed. Check when collecting their 24-hour urine collection. Enclose with aliquots of 24-hour urine collection sent to lab.
24-hour urine despatch note	Complete on visit 2 once urine has been weighed twice and entered into CAPI. Enclose with aliquots of 24-hour urine collection sent to lab.
Equipment used by participants	Purpose
3 PABA tablets	To verify completeness of the 24-hour collection
5L screw cap container	Collection container for urine.
<i>(upon request)</i> 2L screw cap container	For collections made away from the home. Can also be used as an overflow container should the participant fill the 5L container.
1L plastic jug	For the participant to pass urine into and decant into the 5L container
Funnel	To aid decanting urine from the plastic jug into the 5L container.
Plastic carrier bag	For transporting the equipment when away from home.
Safety pin reminder	For the participant to pin the under- and outer- garments together during the period of the collection to remind that the urine about to be passed needs to be collected.
Coloured stickers	To distinguish equipment between 2 participants in the same household

9.4 24-hour urine collection sheet

It is important that urine samples are collected on all days of the week as our diet differs between weekdays and weekends. Therefore, CAPI will randomly allocate a day to the participant on which they should start the urine collection. In some cases the allocated day may not be suitable for the participant; you will then randomly allocate an alternative start day with the participant using CAPI. However, we encourage you to discuss the allocation of the collection day with the participant and emphasise the importance of the representativeness of the study across the whole week.

If there are 2 participants in the household, CAPI will assign the same day to both participants. If the date is unsuitable for one of the participants try to agree a date that is suitable for both participants.

You will fill in Section A, the participant details and the agreed start date for 24-hour collection. Remind the participant about when to take the PABA tablets (as indicated on the 24-hour urine collection sheet). The participant needs to complete Section B on the collection sheet during the collection period. Details needed are:

- Start date and time of 24-hour urine collection
- Date and time PABA tablets taken
- End date and time of 24-hour urine collection
- Date and time of any missed collections
- Names of medication and supplements taken during this period

We are particularly interested in participants recording the names of diuretics (water tablets) they are taking during the 24-hour urine collection period. Most common conditions associated with taking diuretics are ankle swelling, blood pressure and heart failure.

Whilst it is important for the analysis to know about participants taking diuretics this will not influence their eligibility for taking PABA.

Common diuretics	
Frusemide/Furosemide	Metolazone
Bendroflumethiazide	Chlortalidone
Indapamide	Cyclopenthiiazide
Amiloride Hydrochloride	Eplerenone
Spironolactone	Triamterene
Osmotic diuretics	Xipamide
Potassium-sparing Diuretics	Bumetanide
Diuretics with potassium	Torasemide

9.5 24-hour urine collection

The 24-hour urine collection period should **start with the second void** of the morning. The 24 hour period will last throughout the night and will include the first morning void on the following day. For example, if the participant starts the 24-hour collection with the second morning void on a Tuesday then they stop collecting after their first morning void on Wednesday.

During the period of collection, ask participants to pass all urine in to the plastic jug and then pour it in the 5L container using the funnel provided. **It is extremely important that all urine produced over the 24-hour period is included in the collection.** During this period, ask participants to pass stools after passing urine, so that urine is not lost. If some urine is lost, please advise the participant to note the missed collection on the urine collection sheet. If a participant expects to be away from home during the collection period, they can request a smaller 2L collection container and take this with the jug and funnel with them instead of the larger 5L container. However, on return anything collected into the 2L container should be transferred to the main 5L collection container.



Advise women not to collect urine on period days.



9.6 PABA (Para-aminobenzoic acid)

Each participant will have three PABA tablets which are to be taken, as indicated on the urine collection sheet, during their 24-hour collection. The first PABA tablet should be taken at the start of the collection i.e. **after** the participant has flushed away the first urine of the day and recorded the time as the start time. The second PABA tablet should be taken 4-6 hours after the first tablet and the third PABA tablet should be taken 4-6 hours after the second tablet.

PABA is an intermediate in the synthesis of folic acid in bacteria. PABA is consumed in small amounts as part of our usual diet and is found in small quantities, for example, in liver, kidney, brewer's yeast, molasses, whole grains, mushrooms and spinach, and can be made by intestinal (gut) bacteria. Larger amounts of PABA are found in some vitamin preparations. Following ingestion, PABA is passively absorbed mainly from the small intestine. From there, it enters the portal circulation. Some metabolism of PABA occurs in the liver and PABA and its metabolites are mainly excreted in the urine. PABA may interfere with sulphonamide based antibiotics. Although not directly harmful to the participant PABA may stop the antibiotic from working. Please note we will not ask participants to stop any of their sulphonamide medication but simply ask them not to take PABA.

In the CAPI schedule (and below) you will have a short list of sulphonamide medication that excludes participants from taking PABA.

The PABA tablet is very small and best swallowed whole. It will not dissolve in water or any other drink. If crushed between teeth PABA tastes a bit acidic and is unpleasant but there is no long lasting after taste. If the participant chooses to crush the PABA tablet, please advise them to ensure the **entire** tablet is consumed.

Analysis of the PABA will allow us to check whether the urine collection is complete, however, it is important that participants also record any missing samples on the urine collection sheet.



<i>Sulphonamides</i>	
Co-Trimoxazole	Sulfamethoxazole
Septrin	Monotrim
Sulfadiazine	Sultrin
Trimethoprim	

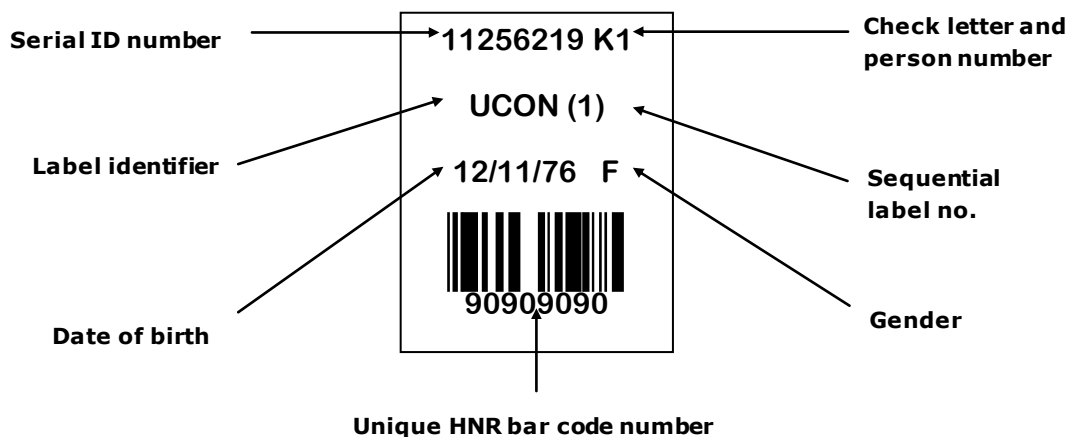
10 Labelling

You will be provided with pre-printed serial ID labels in your work pack for all serial IDs in your point. Each set of labels will be personalized with the sex and DOB of the participant. Please ensure you are using the correct set of labels by checking that the **sex** and **DOB** printed on the label with the participant.

For each participant a set of the following 8 labels will be provided rolled up as a continuous strip.

<i>Label</i>	<i>Function</i>
UCON (1)	Consent form (office copy)
UCON (2)	Consent form (participant copy)
UCOL (3)	Urine collection sheet
UDESC (4)	Urine despatch note
U1 (5)	Urine monovette 1
U2 (6)	Urine monovette 2
AL1 (7)	For use at HNR – enclose in postal pack
AL2 (8)	For use at HNR – enclose in postal pack

Example label:



Label strips for participants that do not consent to urine should be returned to the Nurse Unit as soon as their non-participation has been confirmed. This minimizes the risk of mixing up labels for new participants.

It is very important that the correct label set is used for each participant. If incorrect labels are used there is a risk of matching the 24-hour urine samples/analysis and/or documents to the wrong participant which is likely to result in the sample being destroyed.

11 The Second Nurse Visit

During the second visit you will need to weigh the 24-hour urine collection according to protocol (*see section 11.2 and Appendix A*) and obtain **two** aliquots of well mixed urine. This second visit should take place on the day or the day after the 24-hour collection is completed so that samples reach HNR for further processing without further delay.

For example, if the participant collects the 24-hour urine collection between Monday morning and Tuesday morning the second nurse visit should take place on Tuesday or Wednesday.

If the sample despatch is delayed, due to unforeseen problems, nurses should still send the samples as soon as possible but clearly indicate the delay in returning the samples on the despatch note.

24-hour urine collection equipment

Equipment and documents	Purpose
Salter Electron Scales	For weighing the urine collection container, always set on KG
2 x 10ml Sarstedt urine monovettes and 2 x extension tubes for urine monovettes	For aliquoting urine from the 24-hour urine collection
Labels	To label Sarstedt urine monovettes and participant documents (labels 1-6) Two labels for use at HNR, AL1 (7) and AL2 (8), to be sent to the lab with the monovettes in the postal pack
Disposable gloves Apron Work mat	Needed for handling and aliquoting the 24-hour urine collection in the household
Pre-labelled and pre-paid jiffy bag and packing material (postal pack)	For despatch of aliquoted samples
24-hour urine collection sheet	Check collection sheet completed by participant and enclose with samples
24-hour urine despatch note	Complete and enclose with samples
Coloured stickers	To distinguish equipment between 2 participants in the same household

11.1 Checking the urine collection sheet

The completeness of the 24-hour collection will be verified in two ways: through participants self-report and the use of PABA as an objective measure. During the 24-hour collection, participants are asked to record any missed collections on the urine collection sheet. Therefore, it is important that at the second visit, you check this sheet and ask participants whether the 24-hour urine collection is complete, and if not, note on how many occasions urine was not included in the collection.

If the participant has collected their urine for less than 20 hours or more than 28 hours the lab will definitely not be able to include the collection in their analysis.

Participants will **still receive the £15 gift card**, but further weighing and sub-sampling of the collection will not be necessary. You may discretely dispose of the participant's urine collection in the household's toilet and proceed with the household questionnaire in CAPI.

11.1.1 24-hour urine collections out of range

Where participants have collected all their urine and completed the study over a 24 hour period, but their urine collection exceeded the duration of 28 hours or ended after less than 20 hours their collection will not be analysed.

Participants might not be fully aware of their error and will not provide you with the information straight away, which is why you need to check their collection sheet thoroughly, prompting for missing information.

As mentioned above, participants who provide a sample out of range will still receive their **£15 gift card**;

However:

- **Never** mention to participants that 'it doesn't matter for how long you collect, you will still get the £15 gift card'!
- **If in doubt** whether a sample falls within range, do despatch the samples as you would normally
- If a participant has **obviously/admittedly stopped** their collection prematurely, i.e. they have acknowledged that they have not completed the protocol; no gift card will be handed out to the participant as their participation is not productive.

11.2 Weighing the urine sample

It is important that the urine is weighed strictly according to the weighing protocol to ensure valid measurements of the collection and to allow us to do the necessary calculations. If the weight recorded is incorrect the study will not produce valid results.

Nurses who worked on previous studies have reported discrepancies between obtained weights extending beyond expected fluctuation. Therefore, we have developed a protocol that will ensure valid and accurate measurement across samples by making sure all nurses follow the same procedures.

Nurses working on the Diet and Health study will be accredited for following the weighing protocol using the **Salter Electro Sampson scales**. Only nurses passing the accreditation will be eligible to work on this study in order that we retain the integrity and quality of the urine analysis results.

Protocol for weighing urine

The following steps should be followed when weighing urine using the Salter Electro Sampson scales. These same steps must be followed by all nurses to ensure that every nurse is weighing urine in exactly the same way every time.

1. Ensure that the lid of the 5L container is securely fastened.
2. Before you start, check that the scales are tared to zero.
3. Place the 5L container on the middle of the hook of the scale.
4. Stand and hold the scale handles in both hands with your palms facing down. Extend your arms slightly, making sure the handles of the scale are at the level of your chest.
Bend your elbows and hold the scale and urine approximately 18 inches (1.5 feet) from your chest, making sure you are able to hold the container still. It is critical that the container remain completely still.
5. Hold the scale and container still in position for a minimum of five seconds.
7. Record the weight and repeat the process.

The same steps should be followed if there is urine in the 2L container which cannot be transferred into the 5L container.

11.3 24-hour urine Sub-sampling Procedure

- Lay out the disposable work mat to prepare the sub-sampling
- Start by checking if there is any urine in the 2L container
- Transfer the urine in the 2L container into the 5L container if possible. If you think that only SOME of the urine will fit inside the 5L container then DO NOT TRANSFER
- Weigh the container(s) with the 24-hour collection at least twice.
- Record weight in CAPI
- Transfer onto the despatch note
- Gently invert and rotate the 5L collection container at least 20 times so that the 24-hour urine collection is mixed thoroughly, but without becoming frothy.
- Transfer some urine from the well-mixed 24-hour collection to the jug
- Collect 2 sub-samples from the 24-hour urine collection. To do so, place an extension tube onto the Sarstedt urine monovette and then draw up the sample of urine from the jug.
- Once filled removed the extension tube from the urine monovette, replace the cap and snap off the urine monovette plunger.
- Label each urine monovette using the labels U1 (5) and U2 (6) provided.



See Appendix A for an illustration of the protocol for urine monovette use.

After collecting the samples, carefully dispose of the remainder of the 24-hour urine collection in the participant's toilet (not from a height). Participants should be advised that the containers, jug and funnel can be rinsed and disposed of with the household waste or recycled.

11.4 Labelling the 24-hour urine monovettes

You will need to label and package the urine monovettes before leaving the household.

Holding the urine monovette horizontally, the correct label for each urine monovette should be peeled off the label strip. The top of the label should be positioned onto the urine monovette and then wrapped round, ensuring the label does not crease. See section 10 about what labels you should use.

12 Packaging and Despatch

Packaging will take place during the second nurse visit and despatch as soon as possible after the visit.

The packaging consists of the following:

- Two Noax tubes with absorbent liners (rigid tube with green lid)
- Rigid outer packaging e.g. a plastic or cardboard box
- A pre-labelled and pre-paid padded envelope

Please ensure that all samples are properly sealed. Place each urine monovette into a Noax tube. To prevent the urine monovette from getting stuck in the Noax tube, place it upright i.e. the urine monovette lid and the Noax tube lid should be together in the same orientation. Place the Noax tubes into the rigid outer packaging provided and then place in the pre-labelled and pre-paid padded envelope. Remaining labels AL1 (7) and AL2 (8) can be enclosed in the rigid outer packaging.

The despatch note should be completed; the correct label UDESP (4) stuck on (see Appendix D for an example of a completed despatch note) and placed inside the padded envelope. Check the details on the despatch note and ensure that they are correct. Please note there is one despatch note per participant.

Samples should be despatched either the day the 24-hour collection ends or the day after.

NB please check the post box has a collection on the same / next day (if Monday to Friday) before you post the sample to avoid any delay in samples getting to the lab.

Urine should only be sub-sampled and despatched if the participant has provided a complete 24-hour urine collection or a collection between **20-28hours**. If the participant has not completed the study (see 11.1.1 for definition), you should not sub-sample or despatch the samples.

The despatch note, participant urine collection sheet, labels AL1 (7) and AL2 (8) and the PABA tablet blister pack need to be sent with the samples to HNR using the packaging provided.



13 Household questionnaire

After the urine collection has been sub-sampled and prepared for despatch you need to ask one of the participants a short household questionnaire that will cover economic activity. Though we aim for this to be completed in all households, this module appears at the end of the CAPI schedule and can be skipped, if participants refuse to answer the questions.

If the first participant refuses to answer this questionnaire, CAPI will bring up the prompt again at the end of the schedule for the second participant.

The household questionnaire covers questions on economic activity of the household.

It is unique for the sodium study that these questions are asked by nurses, as other studies have preceding interviewer visits where this questionnaire is covered. Therefore, we have provided some guidance on how to complete this questionnaire.

HHldr

At the start of the economic activity block you will need to establish in whose name the accommodation is owned or rented. This may not necessarily be the person who you are speaking to.

If the accommodation is owned or rented by someone else in the household then this person is the **household reference person (HRP)**. If more than two people own/rent the accommodation then you need to establish who the highest income earner is (income – earnings, benefits, pensions). If both people have the same income then the person who is oldest is the HRP.

If the HRP is not present, but the participant is able to provide information on their behalf, then the questionnaire can be completed by proxy interview.

SrcInc

Code the sources of income for the HOUSEHOLD REFERENCE PERSON AND SPOUSE/PARTNER **only**. Don't include income for other adults in the household.

HRPActiv

This set of questions deals with what the HRP was doing in the seven days ending on the Sunday preceding the interview. If the HRP's occupational status has changed since that date, we are interested in **the reference week only**, even though the temptation is to talk about what the participant is doing currently.

Paid work:

It should be left to the participant to decide whether or not (s)he is in 'paid work', but it must be paid work to count. 'Paid work' at this question means any work for pay or profit done in the reference week. It is to be included, however little time is spent on it, so long as it is paid.

Temporarily sick or on leave:

Someone who was temporarily sick or on leave from a job in the reference week should still be coded as in paid work. Longer-term absences are a little more complicated. If the total absence from work (from the last day of work to the reference week) has exceeded six months, then a person is classed as in paid work only if full or partial pay has been received by the worker during the absence, and they expect to return to work for the same employer (i.e. a job is available for them).

Maternity/Paternity leave:

If the participant is on maternity or paternity leave, with a job to go back to, this should be coded as in paid work (but temporarily away).

Career breaks:

In some organisations, employees are able to take a career break for a specified period and are guaranteed employment at the end of that period. If a participant is currently on a career break, (s)he should be coded as being in paid work only if there is an arrangement between the employer and employee that there will be employment for the employee at the end of the break. This is not dependent on his/her receiving payment from the employer during the break. Leave it up to the participant to define whether or not (s)he has a job to go back to.

Seasonal employment:

In some industries/geographical areas (e.g. agriculture, seaside resorts), there is a substantial difference in the level of employment from one season to the next. Between 'seasons', participants in such industries should not be coded as being in paid work. (However, note that the odd week of sick leave during the working season would be treated like any other worker's occasional absence, and coded as being in paid work.)

Casual work:

If a participant works casually for an employer, but has not worked for them during the reference week, (s)he should be coded as not being in paid work, even if (s)he expects to do further work for the employer in the future.

Unpaid work:

Participants should be coded as 'doing unpaid work for a business that you/a relative owns' if their work contributes directly to a business, firm or professional practice owned by themselves and/or relatives, but who receive no pay or profits. Unpaid voluntary work done for charity etc, should not be included here.

Training schemes:

People on Government Training Schemes may count themselves as being in paid work, but they should be coded as 'on a Government scheme for employment training'. The main schemes which are running at the moment are Youth Training and Training for Work (used to be called Employment Training or Employment Action).

Looking for paid work or a Government training scheme

'Looking for paid work or a Government training scheme' may cover a wide range of activities, and you should not try to interpret the phrase for the participant. Those looking for a place on a government scheme should only be coded as such if the search is active rather than passive. In other words, a participant who has not approached an agency but who would consider a place if an agency approached her/him, should not be coded as looking for a scheme.

Intending to look for work but prevented by temporary sickness or injury:

'Intending to look for work but prevented by temporary sickness or injury' should only be used if the sickness/injury has lasted for less than 28 days. If it has lasted longer than this, code as 'doing something else'.

Permanently unable to work because of long-term sickness or disability:

'Permanently unable to work because of long-term sickness or disability' should only be used for men under 65 and women under 60. Those older than this should be coded as 'retired', 'looking after the home or family' or 'doing something else', as appropriate.

Retired:

'Retired' should only be used for people who retired from employment at around retirement age, or who were permanently sick prior to reaching retirement age.

14 Participant Incentive

All participants who provide a 24-hour urine collection will receive a **£15 gift card** as a 'thank-you'. Remember this should **not** be presented as 'payment' but as a token of appreciation. You will need to activate the gift card in the household and leave it with the participant.

You will receive a float of gift cards. They are not of any monetary value until activated by Love2shop upon receipt of your transmission. If you anticipate needing more gift cards, contact Logistics in Brentwood who will arrange for you to be sent some more. Do this as soon as you have done your selections so that the cards will reach you before your final visit to the address.

The CAPI program will automatically prompt you to enter the last **8 digits of the gift card** (shown in bold on the front of the card) for each participant.

When prompted by CAPI you should write the relevant amount in the area on the top right hand side of the card, give to your participant and inform them that the card will be activated and ready to use after approximately 48 hours. Please note that this is dependent on you transmitting the case promptly and may take up to 72 hours if the case is transmitted on a Friday.

There is no need to get the participant to sign a receipt.

Most participants who start the study will complete it and provide complete collections. Occasionally, participants may decide not to continue. In order to receive the gift card participants must **fully complete** the study (i.e. provide a **complete 24-hour urine collection**). Where participants attempted a 24-hour urine collection that is out of range (i.e. provided less than 20 hours or more than 28 hours) without 'giving up' they should still receive a £15 gift card for their effort (*See section 11.1.1*).

If the participant 'gave up' during the collection period, they are not eligible for the gift card. **This should be made clear to participants during the first nurse visit.**

14.1 Participant Feedback

We will not be sending the results of individual urine tests to participants or their GPs. If asked, use the information below to explain to participants why this is the case.

The level of nutrients in an individual's urine is heavily influenced by their dietary intake during that day.

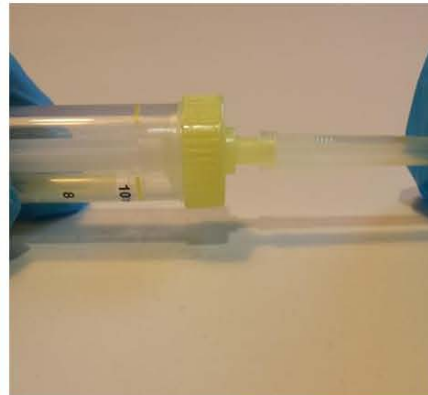
If we were able to measure an individual's nutrient levels over a three or four day period and take an average from all the measurements, we would obtain an accurate estimate of their nutrient levels.

However, if for example an individual has had a greasy take away on the day we take our sample, their nutrient levels will be different to usual on that occasion and the individual measurement will not be an accurate reflection of the individual's regular nutrient levels.

Appendix A. Sub-sampling 24-hour urine



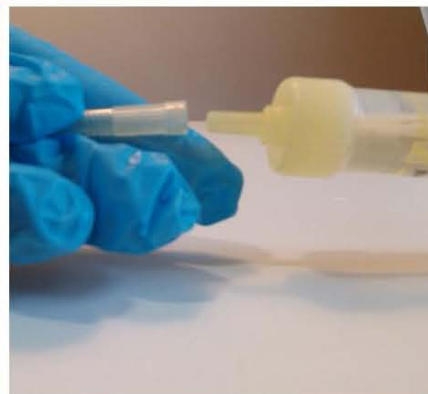
1. Remove the small push cap.



2. Push the extension tube on the urine monovette nozzle.



3. To fill the urine monovette, pull back the plunger until you hear the click .



4. Remove the extension tube.



5. Replace the cap.




6. Break off the stalk of the plunger

Appendix B. Completed consent form



Diet and Health Study 2014 - CONSENT FORM -

11256219 K1
UCON (1)
12/11/76 F

90909090

MREC Reference Number: 13/EE/0417

Please use capital letters and write in ink

Please initial boxes

1. I confirm that I have read and understand the 24-hour urine leaflet dated 04.11.2013 (version 1) and PABA leaflet dated 04.11.2013 (version 1) for the above study. I have been given the opportunity to ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw from the study, at any time, without giving a reason and without my medical care or legal rights being affected.
3. I agree to take PABA tablets to support the 24-hour urine collection.
4. I consent to provide a 24-hour urine sample for laboratory analysis.
5. I give permission for any remaining urine to be stored and, with ethical approval as appropriate, used in future research studies.

AD

AD

AD

AD

AD

Alice D'Arcy

01/05/2014

Alice D'Arcy

Name of Participant (Please print)

Date

Signature

Jenny Bloggs

01/05/2014

Jenny Bloggs

Name of Nurse (Please print)

Date

Signature

When completed: please retain top copy for NatCen and give bottom copy to participant


You can cancel this permission at any time in the future by writing to us at the following address:
NatCen Social Research, 35 Northampton Square, London EC1V 0AX.
Telephone: 0800 526 397 and ask for Pauline Burge

Annex 9_24-hour urine consent_v1_041113_DH02014. For use from 01.05.2014

Appendix C. Completed 24-hour urine collection sheet

Diet and Health Study 2014 24-hour urine collection sheet

SECTION A: NURSE TO COMPLETE

11256219 K1 UCOL (3) 12/11/76 F  90909090	Nurse Name	Jenny Bloggs
	Nurse Number	N 0 1 0 1
Participant Sex	<input type="checkbox"/> M	<input checked="" type="checkbox"/> F
Participant DOB	<input type="text" value="1"/> <input type="text" value="2"/> / <input type="text" value="1"/> <input type="text" value="1"/> / <input type="text" value="7"/> <input type="text" value="6"/>	
Start date of 24-hour collection	<input type="text" value="0"/> <input type="text" value="5"/> / <input type="text" value="0"/> <input type="text" value="5"/> / <input type="text" value="1"/> <input type="text" value="4"/>	
Participant consented to take PABA tablets?	Yes	<input checked="" type="checkbox"/> No <input type="checkbox"/>

SECTION B: PARTICIPANT TO COMPLETE

1. DATE / TIME OF 24-HOUR COLLECTION PERIOD

Order of events	PABA tablet taken?	Date	Time	Please tick	
				AM	PM
START: Flush this urine away and record start time		05 /05/ 14	07 : 35	<input checked="" type="checkbox"/>	
1 st PABA tablet Take at start time	Y	05 /05/ 14	07 : 35	<input checked="" type="checkbox"/>	
2 nd PABA tablet Take 4-6hrs after 1 st tablet	Y	05 /05/ 14	12 : 15		<input checked="" type="checkbox"/>
3 rd PABA tablet Take 4-6hrs after 2 nd tablet	Y	05 /05/ 14	17 : 00		<input checked="" type="checkbox"/>
END: Collect this urine and record end time		06 /05/ 14	07 : 45	<input checked="" type="checkbox"/>	

Note: For collections at 12 o'clock mid-day, tick PM; at 12 o'clock mid-night, tick AM.

2. MISSED URINE

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

However, if you have MISSED any urine collections, even just through spillage or overflowing, please make a note in the table below:

	Date	Time	Please tick		Comments (e.g. spillage, overflow, full sample)
			AM	PM	
1	05 /05/ 14	08 : 40	✓		Small spillage
2	05 /05/ 14	23 : 35		✓	Full sample
3	/ /	:			
4	/ /	:			

3. MEDICINES AND DIETARY SUPPLEMENTS

We also need to know about certain medicines and dietary supplements/vitamins you have taken over the 24-hour urine collection.

Did you take any sulphonamide based antibiotics? Yes No

Did you take any diuretics (also known as water tablets)? Yes No

Did you take any dietary supplements/vitamins? Yes No

If you answered YES to any of these questions, please enter the names of these in the table below:

1	Bendroflumethiazide 2.5mg
2	Seven Seas pure cod liver oil capsule
3	
4	

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

Many thanks for taking part in this study!

As a token of our appreciation the nurse will give you a £15 gift card for completing this study.

Appendix D. Completed 24-hour urine despatch note

Diet and Health Study 2014 24-hour urine despatch note

To be completed by the nurse

P 11256219 K1 UDES (4) 12/11/76 F 90909090 90909090 F bel	Nurse Name	Jenny Bloggs
	Nurse Number	N 0 1 0 1

- Q1 Did the participant consent to taking PABA tablets?
Yes
No
- Q2 Did the participant keep the PABA tablet blister pack?
Yes Attach the blister pack to this form, including any remaining tablets
No
- Q3 Did the participant consent to the storage of any remaining urine?
Yes
No
- Q4 Is there any urine inside the 2L container?
Yes Go to Q5
No Go to Q6
- Q5 Can all the urine in the 2L container be transferred into the 5L container?
Yes Transfer all the urine into the 5L container
No Leave the urine in the 2L container, do not transfer
- Q6 Are the digital scales provided set to kilograms?
Yes
No Set the scales to kilograms

24-hour urine despatch note_v1_230114_DHS2014. For use from 01.05.2014.

Q7 5L container: Tick this box if there is urine in the 5L container

- Weigh the urine a **first time** following the protocol (remaining still for at least 5 seconds) and record the weight in **kilograms**:

| | kg

- Weigh the urine a **second time** following the protocol (remaining still for at least 5 seconds) and record the weight in **kilograms**:

| | kg

- If the first and second weights differ by more than 0.02kg, weigh the urine a **third time** following the protocol (remaining still for at least 5 seconds) and record the weight in **kilograms**:

| | kg

If NO urine in 2L container: go to Q9

Q8 2L container: Tick this box if there is urine in the 2L container

- Weigh the urine a **first time** following the protocol (remaining still for at least 5 seconds) and record the weight in **kilograms**:

| | kg

- Weigh the urine a **second time** following protocol (remaining still for at least 5 seconds) and record the weight in **kilograms**:

| | kg

- If the first and second weights differ by more than 0.02kg, weigh the urine a **third time** following the protocol (remaining still for at least 5 seconds) and record the weight in **kilograms**:

| | kg

Q9 **Using the 5L container only**, mix the urine thoroughly by inverting / rotating 20 times before sub-sampling. Fill 2 urine monovettes using the extension tubes and discard the remaining urine and equipment as per instructions provided.

Please use the packaging provided and post the following items to HNR:

- ✓ Completed 24-hour urine collection sheet
- ✓ Completed 24-hour urine despatch note
- ✓ Filled urine monovettes
- ✓ Labels AL1 (7) and AL2 (8)
- ✓ PABA tablet blister pack, incl. any remaining tablets

24-hour urine despatch note_v1_230114_DHS02014. For use from 01.05.2014.