PROTOCOL FOR POPULATION LEVEL SODIUM DETERMINATION IN 24-HOUR URINE SAMPLES

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Section 1: Introduction

Overview of the WHO/PAHO Protocol for Population Level Sodium Determination in 24-hour Urine Samples

The PAHO/WHO Protocol for Population Level Sodium Determination in 24-hour Urine Samples is a resource to countries that want to start, contribute to and share information on dietary salt reduction initiatives. It will assist with:

- **Planning and preparing the scope and environment for a survey study to estimate dietary salt intake**
- **Recruiting and training field staff for data collection**
- **Reporting and disseminating the results**

While the substance of concern to health is sodium, strategies to reduce its intake are aimed at its main source in the diet – salt (sodium chloride) – used in the household at the table or in cooking and as an additive in industrially-manufactured foods.

Primary aims	• Estimate the average intake of dietary salt in men and women in the Americas in the age stratum 25 to 64 through measurement of 24 hour urinary sodium excretion. • Provide information for designing and implementing interventions aimed at reducing population level dietary salt. • Determine subsequent estimates of salt intake in the same population in aid of monitoring intake over time. • Provide trends in salt intake against which to monitor and evaluate the effectiveness of interventions aimed at population level dietary salt reduction.
Additional aims	• Estimate the average intake of dietary potassium through joint measurement of 24-hour urinary potassium excretion. • Estimate the average intake of iodine through joint measurement of 24-hour urinary iodine excretion. • Determine creatinine excretion.
Other possible aims	• Estimate intake of sodium, potassium and iodine in populations otherwise differentiated e.g. by ethnicity, socio economic status, geographic location, other target age groups, etc. • Support health economic analysis by estimating salt intake for specific age strata • Estimate fluoride excretion as well.

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Intended audience	The protocol is primarily intended for principle investigator(s) of studies of sodium, potassium and iodine intake. Parts of the manual are also intended for field staff who are to interact with survey participants.
Structure	The protocol has seven Sections following a sequence that helps to implement population level sodium, potassium and iodine determination in 24-hour urine samples. Section 8 shows the full dataset required for health economic analysis of sodium reduction strategies. There is both general information and specific instructional material that can be extracted and used for: • Training • Data collection
Important conversions	5g salt (NaCl) = 2,000 mg sodium = 87 mmol sodium = 87 mEq sodium 23 mg sodium = 1 mmol sodium 39.1 mg potassium= 1 mmol potassium 126.9 mg iodine = 1 mmol iodine 113.12 g creatinine = 1 mol creatinine

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Rationale for Population Level Sodium Determination in 24-hour Urine Samples

Background

In Latin America and the Caribbean, chronic non-communicable disease (CNCD) is the main cause of disability and premature mortality.[1] Hypertension, a principal risk factor for a number of CNCD, in particular cardiovascular (CVD) and renal diseases, affects up to a third of adults in the Pan American Region.[2]

There is compelling evidence (epidemiological, clinical and animal-experimental) of the direct relationship between salt consumption and blood pressure (BP) and that current levels of salt intake are a major factor increasing BP.[3,4,5] If people reduce dietary salt, whether they are normotensive or hypertensive, raised blood pressure can be avoided, hypertension better controlled, thousands of deaths from stroke, heart and renal disease prevented [6]and healthcare systems spared substantial treatment and health-related costs. [7,8,9,10,11]

PAHO is spearheading an initiative, guided by an Experts Group, to reduce dietary salt intake at the population level across the Americas. Its first product, a Policy Statement, has the goal – reduce salt intake to the internationally recommended target of <5g per adult per day by 2020.[12]

Rationale for surveillance of salt intake

Fundamental to the PAHO initiative is for Member States to estimate a baseline of population level dietary salt intake, and from there, to monitor trends in intake and the effectiveness of any interventions within and betweeen populations.

The best estimate of the population profile distribution and average level of dietary salt intake is provided by measuring 24-hour urinary sodium excretion in a representative sample of individuals. [13]

Rationale for complementary food consumption information

To guide policy development and associated population level interventions aimed at reducing dietary salt, not only is information needed on salt intake but also on the main food sources of salt in the diet and the typical frequency of their consumption. There are several methods available to collect information on food consumption, among them 24-hour food recall. The INTERMAP Study is an international, cross-sectional, epidemiologic study where in-depth 24-hour dietary recall was used to identify foods that account for most dietary sodium intake. [14]

While the instruments that collect food consumption information are typically very detailed in terms of the food products listed in order for survey participants to be able to select the specific products they consume, it is recommended to group the products into a smaller number of broad categories. They become the basis for raising awareness among consumers as to the food categories that contribute the most salt to the diet, and are also the basis for policies and interventions with industry that include target setting per category. If a category is too wide and varied, it is difficult to set a target; if there are too many categories, target setting and monitoring can become unmanageable.

There are a number of examples of food categories to consider, among them the 12 food categories used in the Salt Campaign of the European Commission [15] and the 19 basic product groups and 8 non-basic groups in the Choices Programme [16].

Rationale for joint surveillance of potassium	Low dietary potassium is associated with hypertension [17] and stroke [18] and supplementing potassium to hypertensive individuals lowers blood pressure [19] and reduces the use of anti-hypertensive medications [20]. Increased potassium intake also reduces the hypertensive response to high dietary sodium. Some populations are deficient in dietary potassium if they rely on processed foods, however there is a deficiency in data on intake of potassium in most populations. Estimating potassium and sodium intake at the same time can inform the design of potential population interventions to improve both sodium and potassium intakes.
Rationale for joint surveillance of iodine	To address the concern regarding the possible detrimental effect of dietary salt reduction on programs to prevent Iodine Deficiency Disorder (IDD) that rely on salt as a carrier of iodine, it is recommended that iodine intake be assessed along with salt. The inclusion of this variable in studies of salt intake that use 24-hour urine samples would in fact benefit IDD-prevention programs. The method provides the most accurate and appropriate indicator of whether populations, regardless of age, gender or climatic environment, are receiving the recommended amounts of this nutrient, which, judging from current salt intake and salt iodization levels, may be insufficient, sufficient and even excessive. [21]
Use of spot- or timed urine testing	Collecting 24-hour urine samples has been considered difficult, and therefore the use of the spot-urine method has been proposed as an alternative. To estimate intake of sodium, potassium and iodine, the use of spot urine is *not* recommended unless the following conditions are met: • A baseline estimate of these analites has been conducted using the recommended methods for 24-hour urine assessment. • A calibration study for use of spot urine has been done in the specific population of interest. Once the above conditions are met, 'timed' urine collections (over three or more hours with provision of water) are preferred over non-timed ('spot') samples as they reduce the errors due to residual urine in the bladder. **Even if the above conditions are met, the results are likely to be unreliable especially for population subgroups or time trends.** See Section 7 for further information and advice on calibration.

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Section 2: Field Protocol

Overview of the Field Protocol

Components

The protocol for Sodium Determination in 24-Hour Urine Samples can stand-alone or be an additional module to an existing CNCD risk factor instrument (e.g. PanAmerican STEPS – the Pan American Version of the WHO STEPwise Approach to Risk-Factor Surveillance [22]). If stand-alone, the following are the required components of the protocol:

	Description	Purpose
1	Questionnaire on demographic and behavioral information	To obtain data on: • Socio-demographic information • Tobacco and alcohol use • Dietary habits • Physical activity • Knowledge, attitudes and behavior towards dietary salt
2	Questionnaire on personal medical history, including drug treatment	To determine the proportion of adults that: • Currently suffer from CNCD, and their complications • Are under daily long term medical treatment for any condition
3	Physical measurements with simple methods	To determine the proportion of adults who: • Are overweight and obese, and • Have high blood pressure
4	24-hour urine sample collection	To determine sodium, potassium and iodine excretion. To determine creatinine excretion.
5	A 50-100 g sample of household salt	To determine the iodine content of household salt.

If performed as part of another risk factor study that collects the data described in components 1 to 3, only components 4 and 5 of the protocol are required.

The data elements for components 1 to 3 are provided below. They were developed with reference to the framework for risk factor surveillance in PanAmerican STEPS and an instrument from the University of Warwick WHO Collaborating Centre for Nutrition. The WHO/PAHO Expert Group for Cardiovascular Disease Prevention through Population-wide Dietary Salt Reduction developed the questions on knowledge, attitudes and behavior towards dietary salt.

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Core and expanded data

Each of the first three components of the protocol has a minimum core of required data and a set of expanded desirable data for collection, shown below. Whether core or core plus expanded data are collected depends on what can realistically be accomplished in each country setting (financially, logistically and in terms of human and clinical resources).

	Core	Expanded

1	• Basic demographic information including:
	  o Country and region of origin (if relevant)
	  o Age
	  o Sex
	• Tobacco use
	• Alcohol consumption
	• Physical activity
	• Sedentary behavior
	• Fruit and vegetable consumption
	• Knowledge, attitudes and behavior towards dietary salt
		• Expanded demographic information including:
		  o Ethnicity
		  o Highest level of education
		  o Employment
		  o Household income
		• History of tobacco use
		• Patterns of alcohol drinking
		• Oil and fat consumption
		• History of raised blood pressure
		• History of diabetes

2	• Current drug treatment used • Personal medical history	• Family medical history
3	• Height (cm) and weight (kg) • Waist circumference (cm) • Systolic and diastolic blood pressures (mmHg) and heart rate (bpm)	• Hip circumference (cm)

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Planning and Conducting a 24-hour Urine Collection Study

Below are the recommended tasks to plan and conduct a 24-hour urine collection study. The timeframes will be situation specific, to be estimated to support the planning process.

Intended audience

This information is primarily intended for those fulfilling the following roles:

- Site coordinator
- Coordinating committee

Tasks and timeframes

Tasks	Timeframe
Develop implementation plan	
Identify scope of study	
Gain ethical approval	
Schedule data collection	
Adapting and translating the Field Protocol Questionnaire	
Pilot test	

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Selecting the Sample

Sample population

The sample size is determined by precision, variability within and between subjects, statistical power, play of chance, representativeness, feasibility and cost. Below is a matrix showing the relationship between sample size, precision in the difference in excreted sodium to be detected and variations in measurements.

In general, to detect approximately 1 g reduction in salt intake over time using 24-hour urinary sodium excretion, with a standard deviation of 75 mmol/day (alpha = 0.05, power = 0.80), a minimum sample of 120 individuals per age and sex stratum is recommended. To account for attrition (e.g. non participation, incomplete collection or implausible values), which may be as high as 50%, up to 240 people per age and sex stratum should be invited to participate.

Requirements for sample selection

- Random or otherwise probabilistic sample
- Sample selected using culturally appropriate methods
- Stratification by age group and sex with a minimum of four groups i.e. men and women each in two age groups 25-44 and 45-64 (or men and women each in four age groups 25-34, 35-44, 45-54, 55-64)
- If a sentinel site is selected, must be justifiable and feasible for long term monitoring
- Age and sex of respondents and non-respondents are noted
- If sodium excretion data from 24-hour urine samples are to inform health economics analysis of changes in sodium intake, see the table below for the full dataset required.

Exclusion criteria

- People unable to provide informed consent
- Those with known history of heart or kidney failure, stroke, liver disease
- Those who recently began therapy with diuretics (less than two weeks)
- Any other conditions that would make 24-hour urine collection difficult

If pregnant women are included in the sample, their results must be analyzed separately from those of other adult participants.

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Matrix to Determine Sample Size

Minimum difference in sodium excretion to be detected δ (mmol/day)	Standard deviation *s* (SD)	Sample size n (for each age stratum)
10	10	16
10	15	35
10	20	63
10	25	98
10	30	141
10	35	192
10	40	251
10	45	318
10	50	392
10	55	475
10	60	565
10	65	663
10	70	769
10	75	883
10	80	1005
20	10	4
20	15	9
20	20	16
20	25	25
20	30	35
20	35	48
20	40	63
20	45	79
20	50	98
20	55	119
20	60	141
20	65	166
20	70	192
20	75	221
20	80	251
30	10	2
30	15	4
30	20	7
30	25	11
30	30	16
30	35	21
30	40	28
30	45	35
30	50	44
30	55	53
30	60	63
30	65	74
30	70	85
30	75	98
30	80	112
40	10	1
40	15	2
40	20	4
40	25	6
40	30	9
40	35	12
40	40	16
40	45	20
40	50	25
40	55	30
40	60	35
40	65	41
40	70	48
40	75	55
40	80	63
50	10	1
50	15	1
50	20	3
50	25	4
50	30	6
50	35	8
50	40	10
50	45	13
50	50	16
50	55	19
50	60	23
50	65	27
50	70	31
50	75	35
50	80	40

$$n = 2\frac{\left[z_{\frac{(\alpha-\beta)}{2}} + z_{(1-\beta)}\right]^2}{\Delta^2}$$

where α = 0.05 and (1-β)= 0.80, 1.96 and 0.8416 respectively

$\Delta = \delta/s$

where Δ = standardized difference i.e. (μ1 - μ2) / *s*

δ = clinically important difference to be detected

s = standard deviation

Implementation Plan

A detailed implementation plan for the 24-hour Urine Sample study is needed for all stakeholders involved in the surveillance process.

Purpose

The implementation plan is to:

- Set out the scope of the surveillance and desired goals
- Identify required resources
- Lay out an action plan
- Develop a communication strategy
- Provide a budget as the basis for funding

Core parts of the implementation plan

Below are the core parts needed for the implementation plan. Some have references to Sections within this document where there is information to assist with preparation.

Core part	Detail	References
Executive summary	High level summary of main points including: • Current situation • Goals and objectives • Scope • Resources • Budget	
Current situation	Specify: • Whether the study will determine a baseline of sodium intake or assess change in intake o If to assess change in intake, reference the baseline study • If a risk factor survey has already been conducted. • If there is an existing infrastructure (human capacity, equipment, other studies) on which the 24-hour urine sample collection could be built.	Section 1

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Core part	Detail	References

Goals and objectives	• Identify planned goals and use of the information collected to:
	  o Describe the current level of dietary salt intake in populations (if available)
	  o Track the direction and magnitude of trends in salt consumption
	  o Plan and evaluate a health promotion or preventive campaign
	  o Collect data from which to predict likely future demands for health services
	• Specify objectives that support gathering 'essential' information only.
	• Describe broad timeframes.
		Section 1

Scope	• Specify the scope of surveillance to be conducted (coverage of core and expanded data) • Specify if future sodium determination surveillance can be assured	Section 2
Sampling method	• Identify the sample size and sample frame that will be used. • Identify geographical coverage • Describe sample design	Section 2
Resources	• Specify the resources in terms of all personnel and equipment required for sodium determination in 24-hour urine sampling study. • Describe resources that have been committed or expected, including support from WHO/PAHO. • Specify resources from other organizations.	
Action plan	Prepare a chart of the main tasks with estimated start date and timeframe for completion of each.	Section 2
Communication strategy	Specify the methods for informing and involving all stakeholders relevant to the sodium determination project, including community leaders, members of the public, and media.	
Budget	Provide a detailed budget that includes: • Total funds required for each year planned to implement all sodium determination activities as identified in the scope (including future surveys). • Sources of funding. • Funding gaps.	

Applying for Ethical Approval

Studies that are to use the WHO/PAHO Protocol for Sodium Determination in 24-hour Urine Samples must undergo technical and ethical review and approval. This is to ensure that the study:

- Is conducted in a technically and ethically sound manner;
- Recognizes and protects the rights of participants; and
- Ensures wide access to the information collected in the study.

Process	Usually, ethical approval should be sought by submission of a proposal and application to a national ethics review committee or other equivalent body. However, if such a body is not institutionalized, it is recommended that an application for ethical review be prepared and submitted through an ad hoc local mechanism within the Ministry of Health.
Informed consent	The informed consent must be obtained from every survey participant before conducting any interviews or collection of any samples.
Making a submission	Use the existing templates for proposals supplied by the appropriate ethics committee or equivalent body. If such a template does not exist, identify and contact the relevant bodies, seek guidance on rules, the submission process and any procedures to follow.

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Timeframes and Data Collection Considerations

Data collection should be carefully planned to take place over a defined period of time and during appropriate seasons.

General timeframes

The following table shows the recommended phases of a sodium determination study. Timeframes are situation specific:

Phase	Timeframes
Planning and scoping	
Recruiting and training	
Data collection	
Data analysis and reporting	

Data collection

Some key factors to consider when identifying an appropriate time to conduct the study:

Factors to consider	Guidelines
Seasons	• Confine the study period to one season to avoid dietary changes • Avoid festive seasons (E.g. Ramadan, Christmas, Holy Week, and other national or religious holidays) • Avoid seasons when food is in unusually short supply.
Calendar year	Confine the study to one calendar year
Major events	Avoid data collection during periods prior to local, regional, or national elections to avoid confusion with political campaigns.
Civil unrest, turmoil, famine, etc.	Avoid conducting a study at any time when pressing matters occupy the minds and lives of the population.
Collection timeframe	Keep the timeframe as close as possible (within reason) to the recommended timeframe.

Data collection locations

It is recommended that all components of the study be conducted/administered in the household setting. Ideally participants/respondents are to collect all their urine samples at home and otherwise, they are to bring home any urine passed away from home. The total urine passed in the 24-hour period is to be picked up at the household within one day of the 24-hour collection period. It is recommended that if food consumption information is collected, this is done during the second visit to the household.

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Adapting the WHO/PAHO Protocol for Sodium Determination in 24-hour Urine Samples

Using a standardized protocol for Sodium Determination in 24-hour Urine Samples enables comparisons between countries. However, some adaptations may be required to account for differences in cultures or settings.

When to adapt the protocol

Adaptations may be needed to provide valid data from the surveillance. The following are often what need adaptation: terminology, providing additional information, deleting questions on behaviors that do not apply.

Process

The process of adapting the protocol may involve the following:

- Identifying the instructions or questions that require local adaptation
- Adding or deleting questions
- Adding other forms as appropriate
- Seeking feedback and advice
- Translating and back translating the adapted instructions or questionnaires
- Pilot testing the questionnaires

Documents to translate

Below are some of the documents that may need translating, including where they can be found:

Documents	References
Component 1 questionnaire	PanAmerican STEPS
Component 2 questionnaire	PanAmerican STEPS
Guidelines for field work	Section 3
Consent forms	PanAmerican STEPS
Knowledge, attitudes and behavior questionnaire	Section 4
Instructions to participants	Section 5

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Pilot Testing

A pilot test of the entire data collection process must be conducted among a limited number of people with a broad range of backgrounds prior to implementing the actual full study. Pilots should involve all aspects of the survey including:

- Approaching potential participants
- Seeking and obtaining informed consents
- Making arrangements/appointments for second visits after the participant-led 24-hour urine sample collection
- Site preparation and set-up
- Collecting all data needed
- Identifying participants who may need a follow-up
- Basic analysis

Test group	Identify and approach willing participants to be part of the pilot test. The test group should include the following: • Both men and women • Cover the age range 25-64 • More than one ethnic group (if appropriate) • Participants with different levels of education • Participants from a range of socio-economic groups • Participants from distinctly different regions in the same country
Test environment	Where possible conduct the pilot test under the field conditions expected for the final full study i.e. the household setting.
Timeframe	When planning the pilot test, allow sufficient time for adjustments to be made prior to starting full data collection.

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Section 3: Data Collection Guide

Guidelines for data collection for components 1 through 3 of the protocol can be obtained from the Pan American STEPS Manual, Part 3, Sections 1 through 4, *except for the core questions on knowledge, attitudes and behavior towards dietary salt, which are in Section 4 of this manual.*

The information below serves the field staff/survey team involved in components 4 and 5 of the protocol for 24-hour urine sample collection.

Instructions for Field Staff, Equipment and Analytic Methods

Instructing participants

Field staff must explain the collection protocol, obtain informed consent and provide the record sheet on which participants note the start and finish times of their 24-hour urine collection, any missed urine collections, and any medication taken during the collection.

In the morning of the start of the 24-hour period, the participant must void the bladder and note the time. **This "first-pass urine" is discarded**. All urine passed thereafter is collected in the container provided, including the first urine of the following morning, with the final time recorded. Respondents are given detailed written instructions (see Section 5).

At the time of the first visit to the household, field staff must inform the participant of the second visit.

The second visit must be made within one day of the completion of the 24-hour collection period. A sample of household salt is taken during the second visit.

If food consumption information is required, it is collected during the second visit.

Equipment supplied to participants

- A 5 liter capacity screw cap container to store the collected urine
- A 1 litre container with a wide opening into which urine is voided, with or without the use of a funnel
- Optional 2 liter capacity screw cap container for temporal collections of urine made away from the home
- Funnel for women to be used during urine collection, kept inside a re-sealable plastic bag when not used
- Plastic carrier bags for transporting the equipment away from home
- An aide-memoire to help participants remember to collect their urine e.g. a safety pin to pin the under- and outer garments together during the period of the collection as a reminder that the urine about to be passed should be collected

The use of PABA to assess completeness of the urine collection is <u>not</u> recommended. It requires that each participant take a PABA pill three days prior to the start of collection thereby increasing the risks of non-compliance and attrition. In addition, laboratory facilities for the testing of PABA in the urine are limited and where they exist, will increase the costs of the study.

At the completion of the collection	• Field staff measure the total volume of urine, mix it thoroughly in its container and withdraw three 10-ml aliquots into separate labelled tubes for storage and shipping for analysis. The rest of the urine is discarded. • Sodium, potassium, iodine and creatinine content in the urine are to be measured in certified laboratories, as is the iodine content of the household salt.
Analytic methods	• Sodium and potassium content in the urine may be determined through Ion Selective Electrode (indirect) with a Beckman Coulter Synchron CX5PRO System. • Creatinine content may be determined through the Creatinine (urinary) Jaffe kinetic method, standardized, also to be measured by Beck Coulter synchron CX5PRO System. - Iodine in urine may be determined with the traditional kinetic method of Sandell-Kolthoff [23] or by Inductively Coupled Plasma (ICP) Spectrometry. - Iodine content of household salt can be determined quantitatively with the titration method. In addition to the titration method, there are possibilities of using potentiometry or spectro-photometry. [23]

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Guide to Physical Measurements

Component 3 of the WHO/PAHO protocol for Sodium Determination in 24-hour Urine Samples requires that selected physical measurements be taken to determine the proportion of participants in the study who:

- **Have raised blood pressure.**
- **Are overweight and/or obese.**

Below is a description of:

- **The physical measures and what they mean.**
- **The equipment needed.**
- **How to assemble and use the equipment.**
- **How to take the measurements and accurately record the results.**

Physical measurements

Blood pressure is measured to determine the proportion of participants with raised BP. Heart rate, measured at the same time as BP with automated devices, is a common independent cardiovascular risk factor. Height and weight measurements are taken to calculate the body mass index (BMI), needed to determine the prevalence of overweight and obesity in the population. Waist circumference measurements provide additional information on overweight and obesity. Hip circumference is an expanded data option to measure overweight and obesity.

Units of measurement

Below are the standard units for the physical measurements in component 3 of the protocol, including their upper and lower limits for data entry purposes.

Physical Measure	Unit	Minimum	Maximum
Systolic blood pressure (SBP)	mmHg	40	300
Diastolic blood pressure (DBP)	mmHg	30	200
Height	cm	100	270
Weight	kg	20	350
BMI (Body Mass Index)	kg/m^2	11	75
Waist circumference	cm	30	200
Hip circumference	cm	45	300
Heart rate	beats/minute	30	200

Sequence of questions and measurement

As is the case with many risk factor studies, physical measurements are to be taken immediately after the personal medical history. Physical measurement results are to be recorded on the same participant instruments as personal medical history.

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Participant instructions	Prior to taking physical measurements, explain to the participant that the following measurements will be taken: **For core** • Blood pressure • Heart rate • Height • Weight • Waist circumference **For expanded, additional** • Hip circumference

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Measuring Blood Pressure and Heart Rate

Equipment needed	Validated digital automatic blood pressure monitor e.g. OMRON. For the choice of validated blood pressure measuring devices see http://www.bhsoc.org/bp_monitors/automatic.stm. • Appropriate size cuffs
Preparing the participant	Prior to measuring blood pressure, ask the participant to sit in a quiet comfortable place for at least 5 minutes with back support and his/her legs uncrossed. If the questions in components 1 and 2, on behavior and personal medical history, have been asked just before the physical measurements are to be taken, the participant should rest for at least 5 minutes before blood pressure measurement is started. Do not talk to the participant whilst BP is being taken.
Three measurements	WHO recommends taking three blood pressure measurements. During the data analysis, the mean of the second and third readings is calculated. The participant must rest for one minute between each of the readings. The measurement and recording of heart rate should be done three times along with the measurement and recording of blood pressure. Heart rate and blood pressure results are displayed simultaneously with automated equipment.
Recording the blood pressure measurements	The following steps are required: • after each of the three measurements, record the result in the participant's instrument; • after all three readings are taken, double-check that all three results are correctly recorded in the instrument; • inform the participant of their blood pressure readings only after the whole process is completed.
OMRON procedure	The instructions below apply to the use of an OMRON blood pressure monitor. However, more detailed operating instructions are included with the device and should be reviewed before taking any blood pressure measurements. Note that if a different digital automatic blood pressure monitor is used, instructions should be read carefully.

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Applying the OMRON cuff

Follow the steps below to select an appropriate size of cuff and apply it:

Step	Action
1	Place the **left arm**[*] of the participant on the table with the palm facing upward.
2	Remove or roll up clothing on the arm.
3	Select the appropriate cuff size for the participant using the following table: **Mid Arm Circumference (cm)** / **Cuff Size** 17-22 / Small (S) 22-32 / Medium (M) >32 / Large (L) If the cuff is the correct size, the marker at the end of the cuff will fit between two other markers in the mid section of the cuff. The cuff is the wrong size if the end is outside the markers. It is advisable to select the larger size cuff if there is a question of which size is best. Some Omron cuffs are not marked in which case they must be labeled with markers.** Otherwise, use the mid arm circumference of each arm to select the correct cuff size.
4	Position the cuff above the elbow and aligning the mark ART on the cuff with the brachial artery.
5	Wrap the cuff snugly onto the arm and securely fasten with the Velcro. **Note:** The lower edge of the cuff should be placed 1.2 to 2.5 cm above the inside of the elbow joint.
6	Keep the level of the cuff at the same level as the heart during measurement.

[*]If the right arm is used, indicate this in the right hand side margin of the participant's Instrument.

**Even if cuffs are marked by the manufacturer to indicate the acceptable range of arm circumference for the size of cuff, the markings may not agree with the current recommended range and need to be checked and possibly remarked. [24] Marking can be performed easily using a ruler and permanent marker. The ideal arm circumference for a cuff is 2.5 times the cuff's bladder width. Cuffs can be used on arms that have a circumference ±4 cm of 'ideal'. To mark or remark the cuff, start the measurement at the end that contains the bladder. Permanently mark the cuff at the ideal arm circumference then draw a line across the cuff at 4 cm on either side of the ideal (ie draw two lines). The cuff is the right size if when wrapped around the mid arm, the end is between the two marked lines.

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Taking the BP measurement with an OMRON

Follow the instructions below to take the blood pressure measurements:

Step	Action
1	Switch the monitor on (dark purple button) and press START (light purple button).
2	The monitor will start measuring when it detects the pulse and the "heart" symbol will begin to flash. The systolic and diastolic blood pressure readings should be displayed within a few moments (systolic above and diastolic below). The heart rate will also be displayed.
3	Record the reading in the participant's instrument.
4	Switch the monitor off, but leave the cuff in place.
5	Wait one minute, then repeat steps 1-4 two more times.
6	Inform the participant of the blood pressure readings only after the whole process is completed.

When to use a sphygmomano-meter

The sphygmomanometer is generally not recommended, but may be used in the following circumstances:

- the OMRON is not functioning
- the OMRON display shows multiple errors;
- to cross check OMROM blood pressure readings in various clinical states such as irregular pulse, peripheral circulatory disturbance, extreme hypotension;
- when systolic BP is >200 mmHg (appropriate measurement of systolic BP requires inflating the cuff to a pressure of 40 mmHg above the systolic BP; OMRON maximum inflation pressure seldom exceeds 240 mmHg);
- for calibration of the OMRON Monitor.

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Procedure for sphygmomanometer

Follow the steps below and refer to the operating instructions included with the device to measure the blood pressure of a participant using the sphygmomanometer.

Step	Action
1	Apply the cuff (as detailed above).
2	Put stethoscope earpieces in ear and set to bell.
3	Palpate pulse at either brachial or radial artery. Take a pulse on count for one full minute.
4	Pump up pressure and inflate cuff until unable to feel pulse.
5	Continue to inflate cuff 40 mmHg beyond this point.
6	Apply the bell of the stethoscope to the right antecubital fossa.
7	Listen for pulse sounds while deflating the cuff slowly.
8	Record the systolic blood pressure (SBP) when a pulse is first audible.
9	Record the diastolic blood pressure (DBP) when the pulse sound disappears.
10	Deflate the cuff fully and let the arm rest for one minute (between each reading).
11	Repeat Steps 2-10 twice to obtain three readings. Record the readings to the nearest 2 mmHg.*
12	Check that all readings re correctly filled in on the instrument.
13	Inform the participant of the blood pressure readings only after the whole process is completed.

* Analyze blood pressure readings by 2 mmHg to test for terminal digit preference as a quality assurance method. (Terminal digit preference is the tendency to record to 10 mmHg rather than 2 mmHg.)

Continued on next page.

Measuring Height

Equipment needed

Portable height/length measuring board.

Assembling the measuring board

Follow the steps below to assemble the measuring board:

Step	Action
1	Separate the pieces of board (usually 3 pieces) by unscrewing the knot at the back.
2	Assemble the pieces by attaching each one on top of the other in the correct order.
3	Lock the latches in the back.
4	Position the board on a firm surface against a wall.

Measuring height

Follow the steps below to measure the height of a participant:

Step	Action
1	Ask the participant to remove their: • footwear (shoes, slippers, sandals, etc) • head gear (hat, cap, hair bows, comb, ribbons, etc.) **Note:** If it would be insensitive to seek removal of a scarf or veil, the measurement may be taken over light fabric.
2	Ask the participant to stand on the board facing you.
3	Ask the participant to stand with: • feet together • heels against the back board • knees straight
4	Ask the participant to look straight ahead and not tilt their head up.
5	Make sure eyes are the same level as the ears.
6	Move the measuring arm gently down onto the head of the participant and ask the participant to breathe in and stand tall.
7	Read the height in centimeters at the exact point.
8	Ask the participant to step away from the measuring board.
9	Record the height measurement in centimeters in the participant's Instrument.

Continued on next page.

Measuring Weight

Equipment needed

- portable electronic weighing scale;
- a stiff wooden board to place under the scales, if you are likely to have problems with uneven surfaces (such as dirt or mud floors or carpet);
- a generator, if electronic scales are being used and electricity is not guaranteed in all survey areas (check if scale can work with batteries)

Set up requirements

Make sure the scales are placed on a firm, flat surface.
Do not place the scales on:

- carpet
- a sloping surface
- a rough, uneven surface.

Electronic scales

Follow the steps below to put electronic scales into operation:

Step	Action
1	Put the scale on a firm, flat surface.
2	Connect the adaptor to the main power line or generator.
3	Turn on the scale.
4	Switch the scale on and wait until the display shows 0.0.

Measuring weight

Follow the steps below to measure the weight of a participant:

Step	Action
1	Ask the participant to remove their footwear (shoes, slippers, sandals, etc) and socks.
2	Ask the participant to step onto scale with on foot on each side of the scale.
3	Ask the participant to: • stand still • face forward • place arms on the side and • wait until asked to step off.
4	Record the weight in kilograms on the participant's instrument. If the participant wants to know his/her weight in pounds, convert by multiplying the measured weight by 2.2.

Continued on next page

Measuring Waist Circumference

Equipment needed

- constant tension tape (for example, Figure Finder Tape Measure)
- pen
- chair or coat stand on which the participant will place their clothes.

Privacy

A private area is necessary for this measurement. This could be a separate room, or an area that has been screened off from other people within the household.

Preparing the participant

This measurement should be taken without clothing, that is, directly over the skin.

If it is not possible, the measurement maybe taken over light clothing. It must not be taken over thick or bulky clothing. This type of clothing must be removed.

How to take the measurement

This measurement should be taken:

- at the end of a normal expiration;
- with the arms relaxed at the sides;
- at the midpoint between the lower margin of the last palpable rib and the top of the iliac crest (hip bone).

Measuring waist circumference

Follow the steps below to measure the waist circumference of a participant:

Step	Action
1	Standing to the side of the participant, locate the last palpable rib and the top to the hip bone. You may ask the participant to assist you in locating these points on their body.
2	Ask the participant to wrap the tension tape around themselves and then position the tape at the midpoint of the last palpable rib and the top of the hip bone, making sure to wrap the tape over the same spot on the opposite side. **Note:** Check that the tape is horizontal across the back and front of the participant and as parallel with the floor as possible.
3	Ask the participant to: • stand with their feet together with weight evenly distributed across both feet; • hold the arms in a relaxed position at the sides; • breathe normally for a few breaths, then make a normal expiration.
4	Measure waist circumference and read the measurement at the level of the tape to the nearest 0.1 cm, making sure to keep the measuring tape snug but not tight enough to cause compression of the skin.
5	Record the measurement on the participant's Instrument.

Continued on next page.

Measuring Hip Circumference

Equipment needed

- constant tension tape (for example, Figure Finder Tape Measure)
- pen
- chair or coat stand on which the participant will place their clothes.

Privacy

A private area is necessary for this measurement. This could be a separate room, or an area that has been screened off from other people within the household. Hip measurements are taken immediately after waist circumferences.

Preparing the participant

This measurement should be taken without clothing, that is, directly over the skin.

If it is not possible, the measurement maybe taken over light clothing. It must not be taken over thick or bulky clothing. This type of clothing must be removed

How to take the measurement

This measurement should be taken:

- with the arms relaxed at the sides
- at the maximum circumference over the buttocks.

Measuring hip circumference

Follow the steps below to measure the hip circumference of a participant:

Step	Action
1	Stand to the side of the participant, and ask them to help wrap the tape around themselves.
2	Position the measuring tape around the maximum circumference of the buttocks.
3	Ask the participant to: • stand with their feet together with weight evenly distributed over both feet; • hold their arms relaxed at the sides.
4	Check that the tape position is horizontal all around the body and snug without constricting.
5	Record the measurement on the participant's Instrument. **Note:** measure only once and record.

Continued on next page.

Section 4: Questionnaire on Knowledge, Attitudes, Behavior toward Dietary Salt

1. Do you add salt to food at the table?

a) never

b) rarely

c) sometimes

d) often

e) always

2. In the food you eat at home salt is added in cooking

a) never

b) rarely

c) sometimes

d) often

e) always

3. How much salt do you think you consume? (READ LIST)

a) Far too much

b) Too much

c) Just the right amount

d) Too little

e) Far too little

f) Don't Know

g) Refused

4. Do you think that a high salt diet could cause a serious health problem?

a) Yes

b) No

c) Don't know

d) Refused

5. If Yes in 4 above, what sort of problem?

a) high blood pressure

b) osteoporosis

c) stomach cancer

d) kidney stones
e) none of the above
f) all of the above
g) don't know
h) refused

6. How important to you is lowering the salt/sodium in your diet?
a) Not at all important
b) Somewhat important
c) Very important

7. Do you do anything on a regular basis to control your salt or sodium intake?
a) Yes
b) No (SKIP to QX)
c) Don't know
d) Refused

8. If answer is Yes in 7 above, what do you do?
a) Avoid/minimize consumption of processed foods
b) Look at the salt or sodium labels on food
c) Do not add salt at the table
d) Buy low salt alternatives
e) Buy low sodium alternatives
f) Do not add salt when cooking
g) Use spices other than salt when cooking
h) Avoid eating out
i) Other (specify) _____

Section 5: Detailed Instructions for Participants in 24-hour Urine Collection

We are interested in measuring the dietary intake of certain nutrients – sodium, potassium and iodine. The best way to get this information is by analyzing the urine sample you collect during a 24-hour period.

We cannot get this essential information in any other way!

We are not testing for drugs or viruses.

Your co-operation is very much appreciated.

Why 24 hours?

The content of some nutrients in urine fluctuates according to what we last ate, how much fluid we drink, how much we exercise and also on the weather. Collecting urine over 24 hours gives much more reliable information than a single sample about the typical intakes of these nutrients in a person's diet.

Equipment provided

You have the following equipment provided for making your collections. All equipment is disposable and used only for this study.

1. A sheet to record the essential information about the collection.
2. Urine-collecting equipment for the home:
    a. 5 litre screw-capped plastic collection bottle to store the collected urine during the day. This bottle contains a preservative for keeping the urine at room temperature.
    b. a 1 litre plastic jug and funnel for temporal reception of the urine samples.
    c. a funnel to help women collect urine, which may also help participants in transferring urine samples from the 1-L plastic jug to the 5-L plastic bottle.
    d. a safety pin (to attach to your underclothes or nightwear simply as a reminder for you to make your collection)

3. Urine-collecting equipment for outside the home:
    a. a 2 liter screw-capped plastic collection bottle (without preservative)
    b. two plastic bags for carrying the equipment outside the home

Don't forget to take the jug and 2 liter bottle with you if you leave your home during the day.

Before making the urine collection

The health professional will help you choose the day on which you would like to make the 24-hour urine collection. You may prefer to choose a day when you will be mostly at home or only going out for a short time.

If you are female, you should not make your collection during menstruation.

How to make your collection for the whole day (24 hours)

You have been asked to collect all the urine you pass in one day into the container you have been given. It is not difficult; here is how you do it.

- On the day that you start your collection, you will pass urine – DISCARD this urine, DO NOT put it into the container. Collect from the second time you pass urine. Record the date and time on the Collection Sheet as follows:

  Date started Day ☐☐ Month ☐☐ Year ☐☐

  Time started Hour ☐☐ Minutes ☐☐

- From then onwards until the next day, ALL urine you pass in the next 24 hours, both during the day and night, must be collected.
- The last collection is the urine you pass on the second day at approximately the same time you started the day before.
- This completes the 24-hour collection. Record the following on the Collection Sheet:

  Date finished Day ☐☐ Month ☐☐ Year ☐☐

  Time finished Hour ☐☐ Minutes ☐☐

  NOTE: DO NOT WORRY IF YOU HAVE NOT COLLECTED FOR 'EXACTLY' 24 HOURS, AS LONG AS YOU RECORD EXACT TIME OF START AND FINISH.

- You should pass all urine directly into the 1 litre plastic jug, then pour the urine into the large container, using the funnel if necessary. If you need to open your bowels, always remember to pass urine first before you pass a stool.
- Each time you add a new urine specimen to the large container, screw the lid tight and swirl the urine around a few times, to mix it with the preservative.
- Any urine collected in the small bottle must be transferred to the large bottle as soon as possible e.g. after returning home.

If you miss a sample

If during the 24-hour collection period a sample is missed for any reason, such as because of a bowel movement, record this on the Urine Collection Sheet.

Once you have completed your collection

As soon as possible after you have completed your 24-hour urine collection, the health professional will arrange a time for him/her to pick up the large container with the total volume of collected urine. In the meantime, store your complete collection in a cool, dark place.

If you have any other questions

We hope this leaflet answers the questions you may have. If you have any other questions, contact the health professional. You are free to withdraw from this study at any point.

Section 6: Household Salt Collection and Iodine Determination

This protocol requires assessments of the iodine content of table and cooking salt. It is therefore important to ask participants for large samples of both types of salt (50-100 gm) where both are used in the household. Because this amount of salt might represent the whole supply in the household, field staff should bring sufficient amounts of both types of salt to replace the samples taken.

In the laboratory, both salt samples should be thoroughly mixed using the same procedure of dry samples to ensure homogeneity. Then, the presence of iodate in the salt should be first identified using a qualitative test kit. For samples that produce a positive reaction (usually a change in color), the quantity of iodine in the samples should then be determined by titration, solubilising not less than 10 gm for refined and small crystal-size salt, and not less than 50 gm for raw or large crystal-size salt. Samples that are negative with the test kit should be analyzed for the quantitative content of iodide using an appropriate method with the same amounts of salt as specified above for the positive samples.

Section 7: Use of Spot Urine to Estimate 24-hour Excretion of Sodium, Potassium and Iodine

Some researchers have used spot-urine samples to determine the daily excreted amounts of either sodium, potassium or iodine. The sample is only one urine pass collected during the day, frequently not the first pass of the morning made just after awakening. [25] However, the content of sodium, potassium or iodine would depend on the volume of urine, which may be very variable among individuals of the same population, and highly affected by age, sex, ethnic background, weather and body mass index and physical activity. Some "correction" has been proposed by dividing the analyte concentration by the creatinine concentration, based on the fact that creatinine excretion is more constant during the day within an individual, as it mainly depends on lean body mass. However, this correction has been found even less precise than expressing the absolute content by volume, especially in populations with undernutrition. [26]

Although the use of spot-urine is discouraged as a method to determine sodium, potassium or iodine intake because of the limitations and uncertainty inherent in the method, for some populations it may be used to approximate 24-hour excretion of these analytes if a "calibration" is carried out. This "calibration" could be made based on the expected 24-h volume of urine or the 24-h total excretion of creatinine, by appling one of the two following equations:

Approximate 24-h analyte excretion = [analyte] (mg or µg/L) x 24-h urine volume (L) (A)

or

Approximate 24-h analyte excretion = [analyte/Creatinine] (mg or µg/g creatinine) x expected 24-h creatinine excretion (g) (B)

With either equation, the "correction factors" should be calculated in a subsample of individuals from the same population subjected to the same environmental conditions and studied in a 24-hour period. Although equations associated to general parameters, such as body weight and height, age and gender have been published [27,28,29,30], they are specific to certain populations and cannot be reliably extrapolated from one site/population group to another. Thus, in many instances the calculation of these "correction factors" is as difficult as determining directly the 24-hour total excretion of the analytes of interest. Finally, it has been suggested that a spot urine in the afternoon/early evening could provide advantages when compared to a morning one. [31] Here, it is important to point out that **even if the above conditions are met, the results are likely to be unreliable especially for population subgroups or time trends. Until more studies are carried out to assess simpler but reliable methods of urine collection for the purpose of estimating daily excretions of these analytes, 24 hour urine collections are recommended.**

Section 8: Dataset for Health Economic Analysis

	Chronic disease risk factor variable	***Required breakdown***
1	**Salt intake (NaCl as g per day)**	
	Mean	By sex and (adult) age group
2	**Smoking (prevalence)**	
	Mean	By sex and (adult) age group
3	**Systolic blood pressure (mmHg)**	
	Mean	By sex and (adult) age group
	Std deviation (SD)	By sex and (adult) age group
4	**BMI (kg/m^2)**	
	Mean	By sex and (adult) age group
	Std deviation (SD)	By sex and (adult) age group
5	**Total blood cholesterol (mmol/L)**	
	Mean	By sex and (adult) age group
	Std deviation (SD)	By sex and (adult) age group

	25-34	*35-44*	*45-54*	*55-64*
Male				
Female				
	25-34	*35-44*	*45-54*	*55-64*
Male				
Female				
	25-34	*35-44*	*45-54*	*55-64*
Male				
Female				
Male				
Female				
	25-34	*35-44*	*45-54*	*55-64*
Male				
Female				
Male				
Female				
	25-34	*35-44*	*45-54*	*55-64*
Male				
Female				
Male				
Female				

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