

BMJ Open Protocol for developing the evidence base for a national salt reduction programme for India

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ABSTRACT

Introduction: The scientific evidence base in support of salt reduction is strong but the data required to translate these insights into reduced population salt intake are mostly absent. The aim of this research project is to develop the evidence base required to formulate and implement a national salt reduction programme for India.

Methods and analysis: The research will comprise three components: a stakeholder analysis involving government, industry, consumers and civil society organisations; a population survey using an age-stratified and sex-stratified random samples drawn from urban (slum and non-slum) and rural areas of North and South India; and a systematic quantitative evaluation of the nutritional components of processed and restaurant foods. The stakeholder interviews will be analysed using qualitative methods to summarise the main themes and define the broad range of factors influencing the food environment in India. The population survey will estimate the mean daily salt consumption through the collection of 24 h urine samples with concurrent dietary surveys identifying the main sources of dietary sodium/salt. The survey of foods will record the nutritional composition of the chief elements of food supply. The findings from this research will be synthesised and proposals for a national salt reduction strategy for India will be developed in collaboration with key stakeholders.

Ethics and dissemination: This study has been approved by the Human Research Ethics Committees of the University of Sydney and the Centre for Chronic Disease Control in New Delhi, and also by the Indian Health Ministry's Screening Committee. The project began fieldwork in February 2014 and will report the main results in 2016. The findings will be targeted primarily at public health policymakers and advocates, but will be disseminated widely through other mechanisms including conference presentations and peer-reviewed publications, as well as to the participating communities.

INTRODUCTION

High blood pressure is responsible for about 170 000 deaths in India each year.¹ India

currently has an estimated 140 million people living with hypertension, a figure which is projected to rise to 214 million by 2030. Habitual excess salt consumption² is a main determinant of the disease burden ascribed to high blood pressure³ leading to many serious but avoidable complications, premature mortality and significant health-care costs.⁴ In addition to the adverse effects of salt on blood pressure and vascular risk, a range of other serious health problems are also implicated including gastric cancer and osteoporosis.⁵ On the basis of the evidence linking salt, blood pressure and vascular risk,^{6 7} the WHO recommends that all member states implement a salt reduction programme. A 30% lowering in the mean population salt intake by 2025 has been included as one of the targets of the '25 by 25' United Nations–WHO initiative for the control of non-communicable diseases.⁸

Underpinning these recommendations are a number of comprehensive, authoritative reviews pertaining to the adverse effects of excess salt and the likely positive impact of salt reduction.^{5 9–11} Some studies reporting on the health effects of salt and salt reduction have been inconclusive;^{12 13} however, there are various methodological problems with these studies as detailed by the Science Advisory of the American Heart Association.¹⁴ When the totality of the evidence is evaluated in an objective and systematic way, it is clear that most populations are eating salt far in excess of physiological requirements; many individuals suffer serious illnesses as a consequence, and there is a high likelihood that reduced salt intake would produce substantial health gains.^{5 15–19} A series of modelling exercises have highlighted the likely cost-effectiveness of national salt reduction strategies, with data for India



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suggesting a cost of less than Rs.4400 (about US\$70) per disability-adjusted life year (DALY) averted, and great potential to prevent very large numbers of premature cardiovascular deaths.²⁰

While the scientific evidence base providing the rationale for salt reduction is strong, the data required to translate those scientific insights into policy and reduced population salt intake are mostly absent.^{18 21} A majority of countries (India included) do not have the required data and the insights needed to develop and implement salt reduction programmes tailored to national circumstances.^{22 23} This research seeks to assemble the key baseline data needed to ensure that a coordinated salt reduction strategy can be delivered and thus achieve by 2025 the WHO target of a 30% reduction in dietary salt intake.

METHODS AND ANALYSIS

Overall goal and specific objectives

The overall goal of this 3-year project is to develop the knowledge base required to formulate a national salt reduction programme for India. This will be done by conducting an integrated, multifaceted research programme comprising stakeholder assessments, population surveys and food supply evaluations. It is hoped that this research will then provide the data required to formulate and implement a plausible national salt reduction programme for India (figure 1). The specific objectives for each research component are:

1. Stakeholder survey—to obtain a comprehensive understanding of consumer and other stakeholder opinions in relation to the most effective mechanisms for reducing salt intake.
2. Population survey—to estimate the mean daily salt consumption of the Indian population, the sources of variation about this mean, the main sources of salt in the diet and population knowledge about the adverse effects of salt on health.

3. Food survey—to estimate the mean and variation in the nutritional quality of common processed and restaurant foods.

Using the information collected in the above pieces of work, a comprehensive policy response and action plan will be developed for consideration by the Indian government. This is likely to include a range of interventions targeted at (1) stores, (2) street vendors, (3) chain restaurants, (4) food manufacturers and (5) consumers. Specific consideration will be given to the role of regulation.

The stakeholder survey

Inclusion criteria: The participants for the stakeholder survey will be recruited from the central and state governments and health departments; WHO representatives from the Indian Office and the South East Asia Regional Office; the Indian Council of Medical Research; the World Bank; the salt manufacturing industry; food manufacturers; academia; non-governmental organisations; developmental agencies and civil society. Additionally, community members from the population survey sites in urban, urban slum and rural areas will be invited to participate.

Recruitment: This will be done through existing contacts and networks using a purposive approach to sampling in an effort to secure representation from all key groups. Where the required contacts do not currently exist, they will be identified from desk research and an invitation will be made by a senior member of the research team based in India. In every case, participants will be contacted directly by telephone or email to seek their involvement. They will be provided with a participant information sheet, have any questions answered and be asked to sign a consent form before the study begins.

Data collection: This will comprise in-depth interviews and focus group discussions, done separately with each of the main participant groups, with each group

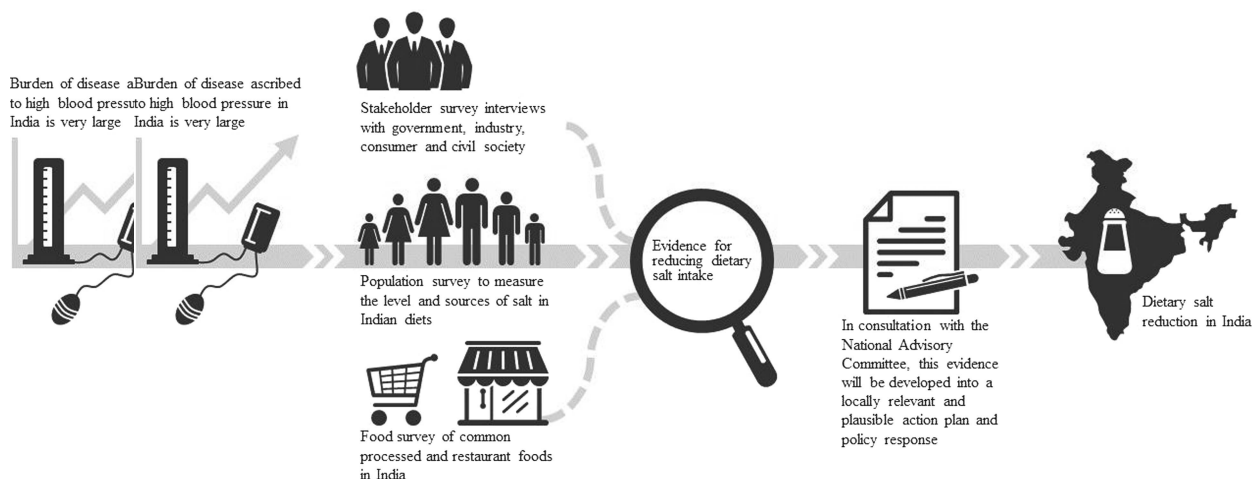


Figure 1 The research and development plan 1.

facilitated by a professional researcher and anticipated to last between 1 and 2 h. Interviews and discussions will be held at locations convenient to participants and will be audio recorded.

The primary outcome: Sought from the stakeholder survey will be a comprehensive understanding of the national landscape in regard to the potential for new food policy more broadly and for salt reduction in particular. The feasibility, barriers and opportunities will be identified such that the actions required to deliver a locally applicable and acceptable salt reduction strategy are understood.

Sample size and data analysis: About 50 in-depth interviews will be conducted and three focus groups, each involving 8–12 participants, will be held. The discussion from the focus groups and in-depth interviews will be transcribed, translated if required and analysed according to key themes using NVivo software. The findings will be provided back to the participants for review and comment prior to dissemination.

The population survey

The geographical sites: Sites have been selected to include slum and non-slum urban areas as well as rural communities. In North India, the urban part of the survey will be conducted in Delhi and the rural part in Faridabad, Haryana. In South India, the sites will be in Andhra Pradesh, with Hyderabad selected for the urban component and the West Godavari district for the rural component. In both cases, the areas for study have been selected on the basis of existing collaborations with the respective communities.

Recruitment of participants: This will be done using a stratified random sampling method to recruit individuals from urban, urban slum and rural areas into six age and sex groups. Before data collection begins, the Panchayat (local administrative body) will be engaged and permission to conduct the study in each area will be sought. In North India, census enumeration blocks (CEBs) and villages are sampled at random from within the study area. Households are then selected at random and an individual from within each household is selected at random until recruitment numbers in each stratum are fulfilled. In South India, the CEBs and villages are selected to be broadly representative of those in the State using a purposive process. A census list including information about the age and sex of all inhabitants is then compiled for each CEB and village, and a random sample of the population is invited to participate until recruitment numbers in each stratum are fulfilled. While the sampling processes are slightly different, the intent for North and South India is to recruit about equal numbers into each of the six strata defined by age and sex for each of the urban, urban slum and rural populations.

Data collection: This will occur during a pair of visits made within a week by a trained field researcher. The first action will be to provide the potential participant

with the Participant Information Sheet and obtain consent. This will be done in the local language through a face-to-face invitation made at home. Consenting individuals will then be asked a series of questions about demographics; lifestyle behaviors; disease history; medication use; and knowledge, attitudes and practices related to salt. A 24 h dietary recall survey will be completed and measurements of height, weight, waist circumference and blood pressure will be made using established methods.²⁴ Participants will be provided with the materials required to complete a 24 h and spot urine collection including a detailed instruction sheet. A day will be agreed on for the urine collection, and a second visit will be scheduled to collect the urine sample and complete a second 24 h dietary recall survey. Efforts will be made to collect diet recall data and urine samples on weekdays and weekends. Urine samples will be collected, the volume measured and an aliquot transferred to a central laboratory for analysis.

Outcomes: The primary outcome will be 24 h urinary sodium. Secondary outcomes will be 24 h urinary potassium, the ratio of sodium to potassium, knowledge levels, current practices relating to sodium and the main sources of sodium/salt in the diet.

Sample size and data analysis: A minimum of 1200 adults (600 from North India and 600 from South India) will be recruited in approximately equal numbers from urban, urban slum and rural areas (about 400 in each area). Recruitment will be further stratified to ensure that across the study there are about 200 individuals in each of six age (20–39, 40–59, 60+) and sex strata. Assuming an SD of salt consumption of 4.5 g/day²⁵ and a mean intake of between 8 and 16 g/day, the study will estimate the mean level of salt consumption to within ± 0.3 g/day with 95% CI. For subgroups of men versus women, urban versus rural and older versus younger individuals, it will be possible to estimate mean levels of salt consumption to within ± 0.7 g/day and to detect differences in consumption between subgroups of 1.2 g/day or greater. If the survey were to be repeated in a few years, there would be 90% power ($\alpha=0.05$) to detect 0.5 g/day or greater differences in average salt consumption levels between the surveys.

Urinary sodium, potassium and creatinine will be determined using the ion selective electrode method for sodium and potassium analysis and the buffered kinetic Jaffe reaction without deproteinisation for the urine creatinine assay. Overall population estimates will be made by weighting the age-specific and sex-specific estimates obtained from the survey using population weights calculated from census data. The results will also be reported for major participant subgroups defined by sex, age and area of residence with evidence for differences between subgroups tested. Estimates of sodium consumption will also be made directly from the dietary survey data and compared with those obtained from the 24 h urine samples.

Surveys of packaged and restaurant foods

The dietary intake data collected during the population survey will provide direct quantitative insight into the foods consumed by the population. To determine the contribution of salt from each food source requires additional information about the composition of the foods eaten. For fresh products, this can be obtained from food composition tables,²⁶ and there are also some existing data about the composition of recipes for foods eaten at home or at traditional street hawker-type food service outlets.²⁷ However, for packaged foods and chain restaurant products, there are no databases that systematically record the composition of the many different items now available.

Retail outlets to be surveyed: Using information gleaned from the stakeholder analysis and the dietary survey, supplemented by desk research, the range of sales outlets from which the population obtains packaged foods and chain restaurant foods will be identified. These outlets are anticipated to include large supermarkets, smaller shops and corner stores as well as a range of local and international chain restaurants.

Food products to be included: For each outlet identified, systematic surveys will be conducted to document the range of products sold and the salt content of each item (table 1). This will be done using Internet searches (mainly to seek data about chain restaurants) and by undertaking in-store surveys of food packaging (mainly to seek data about packaged foods). Where data are not available for larger corporations, we will make written requests in an attempt to access the data. The survey processes will be based on those previously detailed.^{28 29}

Process for in-store data collection: Permission to collect data from larger stores will be sought by letter, email or telephone to head offices while smaller stores will be visited in person. Once permission is obtained, data collection comprises the systematic recording of every packaged food item in the store using a smartphone application to record the barcode and take photographs of the front of the pack, the nutrition information panel and the ingredients list. The photos are uploaded to a central database and the data (table 2) are entered and the products categorised into about 600 different sub-groups. For fast-food chains, in-store nutrition data will be sought from pamphlets, tray liners, food packaging or other sources, as might be available.

Outcomes: This will be the proportion of products with nutritional information about sodium provided in line with established government and international recommendations, and the levels of sodium in products. The levels of other nutrients will also be recorded and reported where they are available. The collated information will be compiled with that from existing food composition databases to enable a robust evaluation of the dietary survey data.

Data analysis: The analysis will focus on the separate levels of sodium in packaged and chain restaurant foods, both overall and according to major food categories,

and for leading manufacturers and retailers. The sample size cannot be fixed in advance because there are few data available to describe the number of processed or restaurant foods for sale or the availability of nutritional information.

Formulation of a national salt reduction strategy

The information collected during the stakeholder consultations, population surveys and evaluations of the food supply will be used to develop a comprehensive understanding of potential mechanisms for reducing dietary sodium/salt in India. These insights will be developed into an action plan and policy response. This will be done in consultation with a National Advisory Committee which includes a diverse range of members from national government organisations, multilateral health agencies, the civil society and research organisations. Consideration will be given to stakeholder and consumer opinions and key social and cultural factors, including geographical diversity, as well as evidence of effectiveness of different approaches to salt reduction around the world. The goal is to develop a locally

Table 1 Main data items collected for the population survey

Data field	Variable
Demographics	Age, years
	Sex
	Religion
	Education
	Number of people in household
	Employment status
Self-assessed health	Household income
	0–100 (0=worst, 100=best)
Tobacco use	Current/ever
Drinking	1 week or less, >1 week
	<12 months, >12 months, never
Physical activity	Vigorous, moderate or walking in a usual 7 days
Disease history	High blood pressure
	Low blood pressure
	High cholesterol
	Heart attack
	Stroke
	Angina
	Diabetes
	Chronic kidney disease
Prescription medication	Antihypertensive
	Lipid lowering
	Aspirin
	Glucose lowering
Physical measurements	Height
	Weight
	Waist circumference
	Blood pressure
Knowledge, attitudes and behaviours	Dietary habits, use of salt in cooking, control of salt intake, etc
	24 h dietary recall
	Multiple pass method

Table 2 Main data items collected for the food composition survey

Variable	Format
Product name	As per product label
Brand name	As per product label
Serves per pack	As per product label
Serving size	g or mL
Energy	kJ or kcal/100 g or 100 mL
Protein	g/100 g or 100 mL
Fat, total	g/100 g or 100 mL
Saturated fat	g/100 g or 100 mL
Trans fat	g/100 g or 100 mL
Polyunsaturated fat	g/100 g or 100 mL
Monounsaturated fat	g/100 g or 100 mL
Carbohydrate	g/100 g or 100 mL
Sugars	g/100 g or 100 mL
Fibre	g/100 g or 100 mL
Sodium	mg/100 g or 100 mL
Calcium	g/100 g or 100 mL
Gluten	g/100 g or 100 mL
Contains/may contain	As per the product label
Symbols and health claims	Health or nutrient claims or symbols*

*Includes vegetarian or non-vegetarian status.

Data can also be entered as salt in g/100 g or 100 mL.

relevant national salt reduction programme using existing frameworks for the development of salt reduction strategies.^{30 31} It is anticipated that the strategy will have three main elements: working with the food industry to reformulate processed foods as well as meals provided at chain restaurants and smaller hawker-type outlets; sustained, locally relevant public education campaigns to change consumer behaviour; and efforts to change the food environment through the establishment of standards and educational programmes and by working in settings such as schools, hospitals and workplaces. As far as possible, the different elements of the strategy will be integrated into existing government and stakeholder programmes and activities.

Ethics and dissemination

The project began fieldwork in February 2014 and will report the main results in 2016. The findings will be targeted primarily at public health policymakers and advocates, but will be disseminated widely through other mechanisms including conference presentations and peer-reviewed publications, as well as to the participating communities.

CURRENT STATUS

Key stakeholders have been identified and initial email contact has been made with 61 potential participants. Follow-up is ongoing with the goal of completing the interviews and focus groups in 2014. The population survey has started in North and South India and is also anticipated to be completed in all sites by the end of

2014. Photographs have been collected for about 7500 products from 10 retail outlets in Hyderabad and Delhi.

DISCUSSION

India has relatively well organised strategies for prevention of non-communicable disease and has already highlighted salt reduction as a priority.³² As such, the time is ripe for a programme of work that can define the path towards policy actions targeting salt reduction. An effective Indian salt reduction programme would be anticipated to avert very large numbers of heart attack, stroke and other blood pressure-related diseases.³³ With cardiovascular diseases already the leading cause of death in most parts of India,¹ and cardiovascular disease events occurring on average a decade earlier than in the West,³⁴ the potential significance of salt reduction for the health of the population is enormous.^{22 23}

Several successful interventions to reduce dietary salt intake have demonstrated effectiveness in high-income countries. A salt reduction programme led by the Food Standards Agency and CASH (Consensus Action on Salt and Health) was launched in the UK in 2003, and it has since reduced dietary salt intake to 8.1 from 9.5 g/day as measured by 24 h urinary sodium excretion in a random sample of the population.^{35 36} This reduction in salt intake was accompanied by a significant fall in the population's blood pressure and mortality from stroke and ischaemic heart disease.³⁶ The success of the UK programme is largely due to establishing progressively lower targets for salt levels in foods. Japan and Finland also implemented successful salt reduction strategies in the 1970s and have reported reductions in daily salt intake of 2.3 and 4.7 g/day, respectively, driven by public education programmes (Japan), food reformulation targets and mandatory warning labels for foods high in salt (Finland).^{33 37} An important new approach is now being taken by South Africa, which has recently passed legislation making salt reduction in processed food mandatory, with initial reductions to be achieved by 2016, and further reductions enforced by 2018.³⁸ These and other completed and ongoing programmes, in conjunction with the collection of the new data described above, will support the development of the programme for India.

The key strengths of the current project are the new scientific data that will emanate from the large population surveys and the evaluations of the food supply. These will be important new data for India and will underpin the case for action. By conducting this survey work in conjunction with a stakeholder evaluation, there will be comprehensive information available for the development of practical strategies which should greatly increase the likelihood that the study outcome will translate into action. The study also benefits from the use of the best current method of quantification of dietary sodium intake based on 24 h urine collection.

The study also has some limitations. The population survey has been restricted to two states in India and has

a relatively small sample size because of logistical and budgetary constraints. It will not provide definitive data about salt consumption patterns across the entirety of India but is not dissimilar in design to the annual National Nutrition Monitoring Bureau survey conducted by the National Institute of Nutrition³⁹—that survey is a very well-respected source of data on the nutritional status of the Indian population. The purposive nature of aspects of the sampling strategy have been used to ensure that, despite the relatively small sample size, broadly representative data are obtained from urban areas of different levels of affluence as well as rural areas. This is an approach that has been used in national surveys conducted in other countries⁴⁰ to make inferences about national levels of risks, and is a reasonable pragmatic compromise. The food composition surveys will likewise initially be focused on a relatively small sample of packaged and restaurant foods in the study areas in North and South India. Further expansion of that aspect of data collection may be required before the scale-up and roll-out of a national salt reduction strategy can be done.

In conclusion, this study will generate substantive new data and should clearly define the potential for salt reduction in India. The findings will be targeted primarily at policymakers and activists, but will be disseminated widely through other mechanisms including conference presentations and peer-reviewed publications, as well as to the participating communities.

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