







# BMJ Open Protocol for a systematic review assessing the measurement of dietary sodium intake among adults with elevated blood pressure

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## ABSTRACT

**Introduction** Accurate sodium intake estimates in adults with elevated blood pressure are essential for monitoring salt reduction progress and preventing cardiovascular diseases. However, sodium assessments are challenging in this high-risk population because many commonly used antihypertensive drugs alter urinary sodium excretion. Despite the high cost and substantial participant burden of gold-standard 24-hour urine collection, the relative performance of existing spot-urine based equations and dietary self-report instruments have not been well studied in this population, who will benefit from salt restriction. This systematic review aims to describe the current methods of assessing dietary sodium intake in adults with elevated blood pressure and determine what method can provide a valid and accurate estimate of sodium intake compared with the gold standard 24-hour urine collection.

**Methods and analysis** Studies assessing sodium intake in adults aged 18 years and above with reported elevated blood pressure will be included. Five electronic databases (MEDLINE, Embase, Global Health, WoS and Cochrane CENTRAL) will be systematically searched from inception to March 2021. Also, a manual search of bibliographies and grey literature will be conducted. Two reviewers will screen the records independently for eligibility. One reviewer will extract all data, and two others will review the extracted data for accuracy. The methodological quality of included studies will be evaluated based on three scoring systems: (1) National Heart, Lung and Blood Institute for interventional studies; (2) Biomarker-based Cross-sectional Studies for biomarker-based observational studies and (3) European Micronutrient Recommendation Aligned Network of Excellence for validation studies of dietary self-report instruments.

**Ethics and dissemination** As the proposed systematic review will collect and analyse secondary data associated with individuals, there will be no ethical approval requirement. Findings will be disseminated in a peer-reviewed journal or presented at a conference.

**PROSPERO registration number** CRD42020176137.

## INTRODUCTION

High dietary sodium (salt) intake is associated with increased blood pressure (BP) and risk of cardiovascular diseases (CVDs), stroke

## Strengths and limitations of this study

- First systematic review to examine the methods used in estimating dietary sodium intake in adults with elevated blood pressure.
- Comprehensive appraisal of observational, interventional and validation studies described the design, evaluation, and use of methods for estimating dietary sodium consumption in adults with prehypertension and/or hypertension as defined by the seventh report of Joint National Committee.
- Findings will encourage salt restriction in the clinical treatment of hypertension, improve public health in terms of salt restriction overall and ensure that salt policies are based on the best data available.
- Due to the expected heterogeneity of research questions, study designs, participant characteristics, exposure or interventions, statistical analyses and outcome measures, only a narrative synthesis will be conducted for all the included studies.

and kidney disease in adults. The WHO recommends a daily sodium intake of less than 2 grams per day (g/day) (less than 5 g/day for salt).<sup>1</sup> Most countries have daily mean population salt consumption far exceeds this recommendation.<sup>2</sup> High sodium intake was reported as the leading dietary risk factor of mortality that accounted for approximate 3 million deaths globally in 2017.<sup>3</sup> Substantial reductions in salt intake are therefore urgently needed.

Sodium restriction is recommended as an important lifestyle modification both in prehypertension and hypertension.<sup>4</sup> Estimating dietary sodium intake may be beneficial in patients with uncontrolled BP despite appropriate pharmacotherapy, as it might provide an insight into patient's compliance regarding dietary sodium restriction. A recent systematic review and meta-analysis of 133 randomised trials with 12 197 participants suggested that the magnitude of BP



lowering achieved with sodium reduction follows a dose-response relationship. The authors concluded that for every 50 mmol reduction in 24-hour sodium excretion, there is about a 1 mm Hg reduction in systolic BP (SBP) and a 0.3 mm Hg reduction in diastolic BP (DBP).<sup>5</sup> A 10 mm Hg reduction in SBP reduced the risk of major CVD events by 20% and all-cause mortality by 13%.<sup>6</sup>

Accurate estimation of mean sodium intake at population or individual level is essential to study the adherence to a low salt diet, the association between sodium intake and chronic disease outcome, and to establish targeted salt reduction interventions. Dietary self-report instruments and urine biomarker methods are commonly used for estimating sodium intake. The most accurate measure is mean sodium excretion from 24-hour urine collections and is regarded as the gold standard method for measuring the individual or population level of salt intake. A 24-hour urine collection is recommended to evaluate average sodium intake since over 90% of sodium consumed by healthy individuals is excreted through kidneys, and it estimates total sodium consumption from all sources.<sup>7</sup> However, such an approach is resource-intensive and has a high participant burden. Moreover, 24-hour urine collection is limited by undercollection and lack of suitable methods to identify incomplete samples accurately.<sup>8</sup>

Spot urine samples have recently been identified as a convenient and affordable alternative for monitoring dietary sodium intake, especially in low-income countries where 24-hour urine sampling may be logistically challenging. Nonetheless, spot urine estimates may have limited usefulness in comparing sodium intake in different ethnic groups due to the varied validity reported.<sup>9</sup> At the individual level, dietary self-report instruments such as a food record, 24-hour dietary recall or Food Frequency Questionnaires are time-consuming. They often underestimate salt intake due to under-reporting and difficulties in quantifying sodium concentration in recipes. Also, the discretionary salt use in home cooking or at the table is challenging to assess and often not included in standard dietary self-report instruments.<sup>9</sup> Furthermore, sodium in medicines and health supplements may also be an essential sodium intake source, which may be missed in dietary self-report instruments.<sup>10</sup>

Several systematic reviews or meta-analyses have attempted to describe the association between sodium intake and specific chronic disease outcomes include BP, CVDs and obesity, by appraising the evidence from prospective cross-sectional, observational and community-based intervention trials.<sup>4 5 11 12</sup> In the context of measurement methods of dietary sodium intake, reviews were conducted on the methodological issues in cohort studies that relate sodium intake to CVDs outcomes,<sup>13 14</sup> differences of population's and individual's salt intake estimates when using dietary assessment methods or spot urine collection concerning reference method, that is, 24-hour urine collection in healthy adults,<sup>15-17</sup> general methodological flaws in assessing population salt intake,<sup>9 14 18 19</sup>

and methods for evaluating the completeness of 24-hour urine collections.<sup>20</sup> Nonetheless, questions remain about the validity and accuracy of alternative approaches for estimating population and individual sodium intake among adults with prehypertension and hypertension against the gold-standard method in research or clinical settings.

## Objectives

Our primary objective is to systematically synthesise the existing evidence on the utility and validity of various methods to assess dietary sodium intake in adults with raised BP. The secondary objective is to summarise the performance of existing spot urine-based predictive equations and dietary self-report instruments to estimate sodium consumption compared with the 24-hour urine collection in the population under study.

## METHODS AND ANALYSIS

The protocol adheres to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses-Protocol (PRISMA) 2015 statement.<sup>21</sup>

## Eligibility criteria

Studies that meet the following inclusion criteria will be included in the review:

1. Studies on adults aged 18 years and above with elevated BP. Elevated BP will be indicated for a participant with either: a self-reported physician diagnosis of prehypertension or hypertension; use of hypertension medication; or a SBP  $\geq 120$  mm Hg and/or DBP  $\geq 80$  mm Hg defined according to the seventh report of Joint National Committee criteria.
2. Use and/or evaluation of urinary sodium excretion (biomarker) or dietary self-report instrument for measuring population or individual sodium (salt) intake in mg/mEq/mmol/g over a day or 24-hour period.
3. Observational (cross-sectional survey, case-control and cohort studies), interventional (randomised, non-randomised controlled and non-controlled trials, quasi-experimental studies) and validation studies.
4. English-language articles.

Studies will be excluded from the review if they are animal studies, studies conducted in pregnant/lactating women or individuals with reported comorbidities that may interfere with normal sodium metabolism, renal function, urinary excretion, and therefore the sodium measurement (cardiac, pulmonary, hepatic, gastrointestinal, renal including transplant and dialysis, metabolic syndrome, overweight/obesity, endocrine and neurological), case report, case series, reviews, meta-analyses, conference proceedings, posters, news, commentary, editorials, practice guidelines and clinical updates. As the review intends to describe the sodium assessment studies were undertaken in adult humans with elevated BP in free-living or natural settings, controlled-feeding studies or studies of sodium supplementation where the amount

of sodium in the diet was controlled by investigators will be excluded.

### Search methods for identification of studies

In order to identify relevant studies that described the design, evaluation and/or use of a method for estimating dietary sodium consumption in adults with elevated BP, a comprehensive search procedure was developed. Five electronic databases will be searched systematically from inception to March 2021 without the restriction of language:

1. Medical Literature Analysis and Retrieval System Online (MEDLINE) via Ovid (1946 to present).
2. Excerpta Medica Database (Embase) via Ovid (1947 to present).
3. Global Health via Ovid (1910 to present).
4. Web of Science Core Collection (1900 to present).
5. Cochrane Central Register of Controlled Trials (CENTRAL; 2021, Issue 03) in the Cochrane Library (1974 to present).

To formulate a systematic search strategy, three key concepts were defined for determining the key terms of the search, their synonyms and related terms: (1) adult with elevated BP; (2) dietary sodium intake and (3) method of dietary sodium assessment. Subsequently, the existence of controlled vocabulary terms such as Medical Subject Headings (MeSH) was verified in each database. The search terms, which consist of free-text terms and controlled vocabulary terms, were combined using the Boolean operators 'OR' (for the same concept) and 'AND' (for different concepts). Truncations and wildcards were also used to capture the variations of search terms. The search strategy for Ovid MEDLINE was developed first (see [table 1](#)) and then will be adapted for other electronic databases when MeSH terms are unavailable (online supplemental tables S1-S4). The search strategy will be peer-reviewed by two members of the research team.

The reference lists of retrieved articles will be hand-searched, and any missing articles will be added by snowballing. Other nutritional data sources, including governmental and non-governmental websites, will also be searched for relevant grey literature using key terms (online supplemental table S5). The retrieved records will be sent to the bibliographic software EndNote V.X9 (Clarivate Analytics, 2019), where they will be stored, organised and duplicates will be removed.

### Screening and data extraction

The study selection process will follow the PRISMA guidelines.<sup>22</sup> One reviewer (YCS) will screen the titles and abstracts of the references obtained from the searches against predetermined eligibility criteria. Studies that are not relevant will be excluded. Those identified as meeting the inclusion criteria will be assessed independently in full by two reviewers (YCS and KHY), and final decisions will be made regarding inclusion or exclusion. Any discrepancies in terms of article selection will be resolved

**Table 1** Search strategy for Ovid Medline from 1946 to March 2021

No	Search terms
1	exp prehypertension/and exp adult/
2	exp hypertension/and exp adult/
3	(blood pressure adj2 (elevated or high or raised or uncontrolled or controlled or increase or low* or reduc*)).tw.
4	1 or 2 or 3
5	exp sodium, dietary/
6	sodium chloride, dietary/
7	diet, sodium-restricted/
8	((sodium or salt) adj3 (intake or consum* or reduc* or low*)).tw.
9	5 or 6 or 7 or 8
10	((diet* or nutrition* or food) adj2 (survey or questionnaire or record or recall or diary or habit* or assess* or evaluat* or estimat*)).tw.
11	((urin* or biomarker or 24-hour or spot) adj3 (excret* or valid* or calibrat* or accur* or predict* or equation or precis* or measure)).tw.
12	10 or 11
13	4 and 9 and 12
14	limit 13 to humans

by discussion between the two reviewers or the third reviewer (DM) if the discrepancy cannot be resolved.

One reviewer (YCS) will extract data from the included studies using pre-defined and piloted forms in a Microsoft Excel spreadsheet. Two other reviewers (KHY and DM) will review the extracted data for accuracy and discrepancies between reviewers will be discussed to reach a consensus. The data to be extracted will include (where applicable) ([box 1](#)).

For studies that only reported results of the population of interest as a subgroup, data will be extracted for subgroup defined by age (18 years and above) and presence of elevated BP (SBP  $\geq 120$  mm Hg or DBP  $\geq 80$  mm Hg, or with a self-reported history of prehypertension, hypertension or diagnosed hypertension).

### Quality assessment of included studies

A study quality assessment of the included articles will be undertaken by one reviewer (YCS) double-checked by a second reviewer (KHY), according to three quality rating tools: (1) United States National Institute of Health National Heart, Lung and Blood Institute (NHLBI) scoring system for interventional studies<sup>23</sup>; (2) Biomarker-based Cross-Sectional Studies (BIOCROSS) critical appraisal tool for observational studies reporting biomarker data<sup>24</sup> and (3) European Micronutrient Recommendation Aligned Network of Excellence (EURRECA) scoring system for validation studies of dietary self-report instruments.<sup>25</sup> Disagreements will be resolved by consensus or by consulting a third reviewer

**Box 1 Data to be extracted from the included studies**

- ▶ Study characteristics (author, year of publication, study design, setting, sample size and study objective).
- ▶ Characteristics of study population (sex, age, ethnicity, hypertension status, use of antihypertensive or sodium-altering drugs).
- ▶ Descriptions of assessment method used or evaluated:
  - Sodium or salt measurement method (biomarker, dietary self-report instruments).
  - Level of sodium estimates (population or individual).
  - Duration of assessment.
  - Sample collection and handling.
  - Quality assurance measure (eg, completeness of 24-hour urine collection).
  - Predictive equations used or developed for using spot urine to estimate 24-hour urinary sodium excretion.
  - Reference method used (only for validation studies).
  - Administration mode (self-administered or interviewer administered).
  - Discretionary salt use.
  - Statistical methods used (mean difference and SD, correlation coefficient, percentage agreement and Bland-Altman lower and upper limits of agreement).
  - Confounder adjustment.
- ▶ Main findings

(DM). Three quality rating tools will be used considering the included studies' intervention study designs, the assessment of biomarker outcomes and dietary exposures in observational epidemiological studies.

**NHLBI scoring system for interventional studies**

This tool will measure a list of different criteria which will be then used to give each included study an overall quality rating of good (low risk of bias), fair (intermediate risk of bias) or poor (high risk of bias).

**BIOCROSS for biomarker-based observational studies**

BIOCROSS tool combines the evaluation of cross-sectional study (and other observational studies) design with specific characteristics of biomarker-based studies. The tool has five domains to assess the different quality features of biomarker-based cross-sectional studies: (1) study rationale; (2) design/methods; (3) data analysis; (4) data interpretation and (5) biomarker measurement. The 'biomarker measurement' domain consists of three items that evaluate the method of measurement, handling and modelling for a biomarker.

The score considers ten dimensions. For every positively evaluated dimension, 1 point will be assigned (maximum total score=10 points). The included studies will be rated based on the awarded points with overall study quality of high (>7 points), fair (4–6 points) or poor (≤3 points).

**EURRECA scoring system for validation studies of dietary self-report instrument**

This system examines five variables: (1) type of sample and sample size of the study; (2) statistics to assess validity, agreement or misclassification; (3) data collection; (4)

consideration of seasonality in the design of validation study and (5) supplements included and validated. The scores could range from 0 (poorest quality) to a maximum of 7 (highest quality).<sup>25</sup> Based on the score allocated, the studies will be then ranked according to their methodological quality as very good/excellent (≥5 points), good (3.5 points≤score <5 points), acceptable/reasonable (2.5 points≤score <3.5 points) or poor (<2.5 points).

**Data synthesis**

The PRISMA flow chart<sup>21</sup> will be used to document the number of studies identified during the search process and those excluded and included according to the outlined eligibility criteria. Given the anticipated heterogeneity of research question, study design, assessment of dietary sodium intake and statistical analyses, it would not be appropriate to pool results in a meta-analysis. Therefore, data will be aggregated, and qualitative synthesis directed by review objectives is planned. The individual studies will be grouped by dietary sodium assessment method (eg, biomarker or self-report dietary instruments) to ease identifying patterns within and across studies. A summary for each review objective will be reported through tabulation and textual descriptions.

**Limitations**

This review was designed to synthesise the current evidence on the dietary sodium assessment methods among adults with elevated BP in natural setting. Therefore, the limitations of review results when applied to populations with different patterns of comorbidities or settings should be recognised and efforts to broaden the generalisability of the body of evidence are warranted.

**Patient and public involvement**

Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**ETHICS AND DISSEMINATION**

Ethical approval will not be required because the data used in this systematic review will not be individual patient data, and there will be no concerns about confidentiality. The results will be disseminated by the publication of a manuscript in a peer-reviewed journal or presented at a relevant conference.

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**Contributors** YCS and DM conceived and designed the protocol. YCS defined the concept and search strategy, screening and data extraction process, risk of bias assessment and data synthesis from the included studies. YCS wrote the initial manuscript draft and DM revised the manuscript. All authors contributed to a critical review of the paper (YCS, KHY, AM, SY, DR, MS and DM).

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