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The International Consortium for Quality Research on Dietary Sodium/Salt (TRUE) position statement on the use of 24-hour, spot, and short duration (<24 hours) timed urine collections to assess dietary sodium intake

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Abstract

The International Consortium for Quality Research on Dietary Sodium/Salt (TRUE) is a coalition of intentional and national health and scientific organizations formed because of concerns low-quality research methods were creating controversy regarding dietary salt reduction. One of the main sources of controversy is believed related to errors in estimating sodium intake with urine studies. The recommendations and positions in this manuscript were generated following a series of systematic reviews and analyses by experts in hypertension, nutrition, statistics, and dietary sodium. To assess the population's current 24-hour dietary sodium ingestion, single complete 24-hour urine samples, collected over a series of days from a representative

population sample, were recommended. To accurately estimate usual dietary sodium at the individual level, at least 3 non-consecutive complete 24-hour urine collections obtained over a series of days that reflect the usual short-term variations in dietary pattern were recommended. Multiple 24-hour urine collections over several years were recommended to estimate an individual's usual long-term sodium intake. The role of single spot or short duration timed urine collections in assessing population average sodium intake requires more research. Single or multiple spot or short duration timed urine collections are not recommended for assessing an individual's sodium intake especially in relationship to health outcomes. The recommendations should be applied by scientific review committees, granting agencies, editors and journal reviewers, investigators, policymakers, and those developing and creating dietary sodium recommendations. Low-quality research on dietary sodium/salt should not be funded, conducted, or published.

1 | INTRODUCTION

High intake of dietary sodium is considered one of the leading global health risks, and reducing dietary sodium is estimated to be one of the most cost-effective strategies to improve population health.[1,2] As a result, reducing dietary sodium by 30% is one of nine World Health Assembly-World Health Organization endorsed targets to reduce the global burden of non-communicable disease by 25% by 2025.[3] Based on comprehensive systematic reviews of the evidence, multiple national and international health and scientific governmental, and non-governmental organizations have recommended reducing dietary sodium at the population level.[4] However, there are research studies that associate lowering dietary sodium with harm.[5,6] Concern has been expressed by several national and international health and scientific organizations that the association of reduced dietary sodium with harm results, in part, from the use of inappropriate low-quality research methods.[7] As a consequence, several international health and scientific organizations formed the International Consortium for Quality Research on Dietary Sodium/Salt (TRUE consortium, https://warwick.ac.uk/fac/sci/med/staff/cappuccio/who/true/, accessed March 29, 2019) with a goal of establishing recommended minimum standards for conduct of research on dietary sodium.[8]

This position statement provides recommendations for minimum standards related to the use of 24-hour, spot, or short duration (<24 hours) timed urine collections to assess usual dietary sodium intake in healthy people (A spot urine collection is a single-voided urine collection that is not specifically timed, including untimed first morning voids). This statement does not focus on dietary instruments as the TRUE Consortium and others have developed detailed recommendations related to their use in nutrition research.[9-12] To our knowledge, there is no comprehensive recommendation available for the use of urinary biomarkers in assessing usual sodium intake in nutrition research. In developing the position statement and recommendations, the TRUE consortium formed a scientific committee with expertise in nutrition and specifically dietary sodium, public health, epidemiology, statistics, physiology, and hypertension (https://warwick.ac.uk/fac/sci/med/staff/cappuccio/who/true/, accessed March 29, 2019). Experts who had conflicts of interest with the salt or food industry were excluded. The positions and recommendations in this document are based on a meta-analysis of urinary sodium excretion in healthy populations performed by the TRUE consortium, as well as meta-analyses of studies examining the association between measured 24-hour urinary sodium excretion and urinary sodium excretion estimated using spot and short-term timed urine collections.[13-15] Because many diseases could impact urinary excretion of sodium, the recommendations pertain only to research on healthy individuals and populations. The recommendations were reviewed and approved by consensus of the TRUE expert committee. The manuscript was then reviewed for approval and supported by the organizations listed in Table 1.

One of the major methodologic challenges in research on dietary sodium is accurate assessment of dietary sodium.[10,16] Outside of tightly controlled trials, in most circumstances, individuals' diets vary widely from meal to meal, day to day, and workday to weekend day, and have many other temporal sources of variation related to factors such as seasonal availability of foods, holidays, cultural practices, and climatic change (flood, drought, heat, and cold) causing altered food availability.[16] Small, rigorous studies have directly and carefully measured the sodium content of foods and beverages, and the amount consumed.[13] Such intensive methods are not feasible in studying the health impact of dietary sodium in large, long-term studies conducted in non-institutionalized populations due to the difficulty in measurement of portion sizes and discretionary salt use, errors in self-report, and inaccuracies in food composition databases with respect to sodium concentration.[10,17-19] Hence, other means of assessing sodium intake have evolved.[10,11,16]

TABLE 1 Organizations that support the TRUE Consortium[a] position

British and Irish Hypertension Society
Chinese Regional Office of the World Hypertension League
George Institute for Global Health
Hypertension Canada
International Council of Cardiovascular Prevention and Rehabilitation
International Society of Hypertension
International Society of Nephrology
RESOLVE to save lives
WHO Collaborating Centre on Population Salt Reduction
WHO Collaborating Centre on Nutrition Policy for Chronic Disease Prevention
World Hypertension League

[a]The TRUE Consortium is an abbreviation for "inTernational consoRtium for qUality resEarch on dietary sodium/sodium." The World Health Organization is an observing member. The organizations that have independently supported this position are listed.

Study methodologies to assess dietary sodium may differ depending on the purpose of the research. Some studies are primarily designed to assess the average sodium intake of a population (eg, to assess the overall impact of a population-wide dietary intervention) while others are primarily designed to assess individual sodium consumption (eg, to relate individuals' sodium intake to health outcomes). Estimation of average sodium consumption at the population level is minimally impacted by random error because random high and low individual estimates offset each other. In contrast, random error adds variability when estimating a population distribution and can result in inaccurate estimates at high or low levels of intake (eg, percentiles, prevalence of inadequate, or excess intake). When examining the relationship between individual-level sodium intake and health outcomes, random error will influence the association. Systematic error will affect estimates of sodium consumption for both population averages and individual-level assessments, independent of the sample size. Systematic error can be constant or vary depending on the level of sodium intake or other factors (eg, varying degrees of non-adherence with urine collection). This implies that when assessing population average intake, the prime concern is to minimize systematic error (taking into account that random error can affect percentile and prevalence estimates of high or low intake levels), while research assessing sodium intake in relation to health outcomes of individuals must minimize both random error and systematic error.[9,20]

A further challenge in assessing dietary sodium is related to the time period being assessed (current, short-term [~1 year] and/or long-term intake [years]). Because of temporal variations in sodium intake, sodium excretion from a single 24-hour urine collection does not reflect usual short- or long-term intake in individuals. Between-day variation in sodium intake in an individual can be as high as inter-individual differences in intake.[16] Sodium excretion from a single 24-hour urine collection may not reflect short- and long-term population average intake either, due to seasonal variability in food intake, age-related changes in food intake (eg, in aging populations), as well as population interventions to decrease sodium intake.

2 | EXCRETION OF DIETARY SODIUM IN URINE

Under homeostatic circumstances of constant sodium intake in healthy people, approximately 93% of ingested sodium is excreted in the urine.[13] Similarly, studies in non-institutionalized populations on their usual diets also find that about 90% of sodium is excreted in urine.[13,16] In one small study with limited documentation, ingested sodium was exponentially excreted within 6 hours.[21] Similarly, following acute intravenous administration of 106 mg/kg sodium, most sodium was excreted within 5-10 hours and all within 40 hours.[22] It takes longer to fully excrete ingested sodium when there is an overall change in the usual amount of sodium ingested (ie, a change in homeostasis).[23,24] When there is a significant change in dietary sodium, a new homeostasis requires 2-7 days to be achieved.[13,21,23-26] Even at a constant sodium intake, the individual daily variation in sodium excretion is large and some studies find a weekly cycle in sodium excretion associated with cycles in aldosterone excretion.[27-29]

3 | 24-HOUR URINE COLLECTIONS TO ASSESS AVERAGE POPULATION SODIUM INTAKE

Twenty-four-hour urine collections capture approximately 93% of the current average population sodium intake.[13] Hence, 24-hour urinary sodium can be used to provide a close estimate of current 24-hour dietary sodium in population studies. Assessing average population sodium intake is minimally affected by the random component of day-to-day variation in sodium excretion in individuals as the random over- and underestimates of individual sodium intake are balanced out in calculating the population average. The caveats are that the 24-hour urine collections need to be complete, collected on days that are representative of the usual population pattern of sodium intake (eg, a mixture of weekend and weekdays) and the participants need to be representative of the population in question. If the intent is to assess usual short-term sodium intake in a population, the study design also needs to take into consideration seasonal or cultural variations (if any) in dietary patterns through inclusion of measurements across the time period (eg, a year) and cultural groups of interest. Seasonal variation may affect the extent to which "discretionary" or added salt contributes to total salt consumption in some diets and there may be agricultural or climatic influences on diet that need to be accounted for in the study design. Short-term sodium intake may be used to relate to short-term changes in outcomes such as change in blood pressure. Long-term (>1 year)

estimation of dietary intake also needs to consider changes in diet over time (eg, population interventions to reduce dietary sodium, reduced food intake with age in aging populations). Estimating the long-term sodium intake in a population is usually most relevant for studies assessing the impact of population policies or strategies to reduce dietary sodium, for example, that require stepwise changes in the sodium content of the food supply, or the relationship between dietary sodium and chronic disease outcomes (eg, stroke).

4 | 24-HOUR URINE COLLECTIONS TO ASSESS HEALTHY INDIVIDUAL'S SODIUM INTAKE

Sodium ingestion in individuals varies from day to day, and 24-hour urinary sodium excretion also varies in individuals at a constant sodium intake. Hence, multiple days of 24-hour urine collections are needed to assess an individual's usual sodium intake.[16,30,31] Forty-five to fifty percent of respondents switched tertile of sodium intake when a single 24-hour urine collection was used to estimate long-term sodium intake vs sequential 24-hour urine collections in a study from Amsterdam.[32] The required number of 24-hour urine collections to obtain a stable estimate of usual sodium intake is likely to differ with different dietary patterns, populations, and settings, and has been estimated to be at least 3 non-consecutive days.[27,29,31-39] Weaver et al[29] found that ten 24-hour urine collections were required to have a 75% reliability to estimate an individual's sodium intake when on a constant sodium diet and this number is likely higher when there is substantial day-to-day variation in sodium intake. The strength of the association between dietary sodium and health outcomes is highly influenced by the number of urine collections.[32,38,40] The issues relating to current, short-term, and long-term estimates of sodium intake for populations also apply to individuals. Current sodium intake estimates require multiple 24-hour urine collections that account for usual daily changes in dietary patterns (eg, weekday vs weekend day). Short-term sodium intake estimates for 1 year need to account for annual cyclic changes in diet by the timing of 24-hour urine collections, and long-term sodium intake needs to have 24-hour urine collections taken throughout the study timeframe.

5 | CHALLENGES IN COLLECTING 24-HOUR URINE COLLECTIONS

There are challenges in collecting complete 24-hour urine collections that can reduce their utility in assessing dietary sodium.[10] Study conduct and quality control must be rigorous to ensure complete urine collection.[27] The systematic undercollection of 24-hour urine collections commonly seen in less rigorously conducted studies will underestimate both population and individual sodium intake. Overcollection, which is less common, will do the opposite. There is also considerable respondent burden in collecting 24-hour urines, such that a sizable proportion of potential respondents may decline to enter studies that involve 24-hour urine collection.[10,16] This could lead to incorrect population estimates if some population groups are under- or over-represented (eg, by sex or age group) and a high drop-out rate can lead to an inadequate sample size. Lastly, there may be higher costs and investigator burden related to collecting 24-hour urines in some settings relative to spontaneously voided urine collections. Formulae based on urine creatinine to assess completeness of 24-hour urine collections are not accurate in differentiating incomplete from complete collections especially in studies with a high rate of incomplete 24-hour urine collections.[41]

Twenty-four-hour urine collection studies should consider incorporating an estimation of completeness of the collection using para-aminobenzoic acid (PABA). Urine collections with <80% recovery of PABA should not be used in calculating dietary sodium intake in those under age 70 years, while a threshold of <70% recovery is reasonable in those aged 70 years and above.[42] Studies in which fewer than 80% of the urine collections meet the PABA recovery thresholds should not be used to assess sodium intake. The use of PABA markedly enhances the quality control for a study but adds additional costs, the potential for non-adherence to PABA, as well as increased participant burden, which can reduce participation rates.

6 | USE OF SPOT URINE AND SHORT DURATION TIMED URINE COLLECTIONS TO ASSESS AVERAGE POPULATION SODIUM INTAKE

Estimates of a population's average sodium intake with spot and short duration timed urine collections are not likely to be influenced by random error (each measurement is likely to be randomly above or below the average) but are very likely to be influenced by systematic errors. Several formulae used to estimate 24-hour urine sodium from spot collections have relatively small systematic errors in estimating average population sodium intake; however, some formulae used in different settings result in more substantive systematic error (>400 mg sodium).[14,15] Currently, all commonly used formulae systematically overestimate sodium intake at lower 24-hour urine sodium and underestimate intake at higher 24-hour urine sodium.[14,15,40,43,44] Thus, changes in dietary sodium intake at the population level (both increases and decreases) will be systematically underestimated when assessed by spot urine samples. Concerns have been expressed that changes in temperature/humidity (impacting hydration), and other poorly understood factors that impact the highly variable association of spot and short duration timed collections to 24-hour urine estimates of sodium, may cause inaccuracies in assessing population changes in dietary sodium over time.[45] Further, estimates of the average error in many of the studies assessing the validity of spot and short duration timed urine collections are likely to be impacted by the high rate of incomplete 24-hour urine collections in these studies. A Pan American Health Organization Technical Advisory Group (TAG) on dietary sodium advised caution in using spot and short duration

timed urine collections to assess average population sodium intake.[45] The TAG recommended to only consider using spot and short duration timed urine collections if there was a robust baseline calibration study with 24-hour urine collections. The impact of the systematic error inherent in the use of spot urine collections in assessing changes in population averages over time, as planned in surveillance programs, remains to be established.[44,46] A few studies have examined the average error of multiple spot or short-term timed urine collections for assessing a population average sodium intake. The single study that reported Bland-Altman plots showed underestimates of 24-hour urine sodium at lower 24-hour urine sodium and overestimate at higher 24-hour urine sodium.[47] Other studies have indicated that multiple spot or short-term timed urine collections may provide a more reliable estimate of 24-hour urine sodium and closer associations with 24-hour urine sodium[35,48,49] but this was not the case in all studies.[50]

7 | USE OF SPOT AND SHORT DURATION TIMED URINE COLLECTIONS TO ASSESS USUAL CURRENT HEALTHY INDIVIDUAL'S SODIUM INTAKE

In a systematic review, correlations between 24-hour sodium estimated from spot and 24-hour urine collections were not consistent, with substantial variation from 0.17 to 0.94.[15] Although some investigators have claimed that a high correlation in a validation study indicates the test is valid, this is statistically inappropriate and misleading because correlation coefficients measure relationships rather than concordance of absolute values.[51] When analyzed appropriately, using Bland-Altman plots, a systematic review found all the formulae used to convert sodium in spot urine and short duration timed urine samples to 24-hour urine sodium reported overestimation of 24-hour urine sodium at lower absolute levels of 24-hour urine sodium and underestimation at higher absolute levels of 24-hour sodium. This indicates that formulae based on spot urine collections should not be used to predict 24-hour sodium in an individual or as an estimate of sodium intake in studies of sodium association with health outcomes.[14,43,44] Using a spot urine collection to assess an individual's sodium intake will be influenced by both random and systematic error, and hence, large inaccuracies occur. Indeed, the errors in estimating an individual's 24-hour urine sodium with this technique can exceed 8000 mg, which is greater than an adult's mean daily intake in most populations.[52,53] Further, studies examining spot and short duration timed urine collections have used a single 24-hour urine collection as an indicator of usual current sodium intake for individuals. As previously discussed, multiple 24-hour urine collections are required to reflect usual current intake in individuals. A few studies have investigated the potential for multiple spot urine collections to estimate usual sodium intake as assessed by multiple 24-hour urine collections.[47,54] As is the case for single spot urine collections, multiple spot urine collections underestimate 24-hour urine sodium at lower 24-hour urine sodium and overestimate at higher 24-hour urine sodium and differences between the methods can be as much 7000 mg sodium.[47] Current data do not support using single or multiple spot or short-term timed urine collections to assess individual sodium intake.[47,54,55]

8 | USE OF SPOT AND SHORT DURATION TIMED URINE COLLECTIONS TO ASSESS SODIUM INTAKE AND ITS RELATIONSHIP TO DISEASE

Because sodium intake varies widely between meals, days, and seasons, and because most ingested sodium is exponentially and rapidly excreted within hours when eating a usual diet, there is little scientific rationale to expect the sodium concentration or quantity from a single spot or short duration timed urine collection to reflect current or long-term sodium intake. Sodium concentration in spot and short duration timed urine collections will largely reflect the sodium content of food and beverages consumed within hours of the urine collection.[21] The quantity and concentration of sodium is also influenced by state of hydration, body position, time of day, common substances with natriuretic or diuretic action (eg caffeine), neurohormonal activation (eg early morning rise), and cyclic changes in aldosterone as well as several common diseases and their treatments.[27,56,57] These confounding factors that influence quantity and concentration of sodium in short duration timed and untimed urine collections further weaken the scientific rationale for hypothesizing that short duration urine collections could reflect an individual's long-term sodium consumption.

To partially account for variation in hydration, some investigators have examined the urine sodium in relationship to creatinine. Creatinine is secreted by the renal tubules and less impacted by state of hydration than sodium, which is avidly reabsorbed in the renal tubules when there is dehydration.[58] Changes in the fractional excretion of sodium relative to creatinine are used, clinically, to assess dehydration as a cause of renal dysfunction.[58] A person's hydration status is a confounder in assessing sodium consumption using the ratio of sodium to creatinine in urine. The relationship between sodium and creatinine excretion is also changed by diuretics, such as caffeine, several kidney diseases, and illnesses.[58]

Several formulae have been developed to estimate 24-hour urine sodium from a spot urine sodium collection among adults. Most of these formulae utilize age and sex as variables that are predictive of average sodium intake. On average, sodium intake is lower in females than males, lower in older adults than younger adults, and lower in children than adults. Many formulae also incorporate urine creatinine concentration, potentially to correct for changes in sodium concentration related to urinary dilution/concentration or possibly because creatinine is closely related to muscle mass (and indirectly to physical activity), and hence may relate to food intake.[59,60] Some formulae also incorporate weight, height (or body mass index), and urine potassium (potentially related to sodium-potassium exchange in the renal tubules or to the types of food consumed).[61] Age and sex are strong predictors of death and cardiovascular events. Body mass index has a

complex relationship with health outcomes as both high and low values are major health risks.[62] Further, creatinine (as a reflection of impaired renal function and muscle mass),[63,64] and potassium (either directly or as a marker of diet quality) are also predictive of major health outcomes.[65] The associations between sodium intake estimated by formulae and disease are likely to be affected by the known and strong confounding variables in the formulae. Recently, the use of such formulae has been found to alter the relationship of estimated sodium intake to death compared to an average of multiple days of 24-hour urine sodium collections.[40]

Most of the published validation studies of formulae used to predict 24-hour urine sodium from spot or short duration timed urine collections have had poor quality control.[15] Many of the validation studies have high rates of incomplete 24-hour urine collections and/or had not assessed the completeness of the 24-hour urine collections.[15,66] If the 24-hour urine collections are not complete, there is no valid reference standard for comparison of the spot urine collections, and assessing the average error accurately for the spot urine collections is not possible.[66] Moreover, some studies use "dependent" spot urine collections from the same 24-hour urine collection they are being compared to. This can inflate the correlation between the two collections, especially with high rates of incomplete 24-hour urine collections, as it is in part comparing a sample to itself.[66] Further, when there are high rates of incomplete 24-hour urine collections, common indirect methods of assessing completeness of 24-hour urine collections do not agree on which collections are incomplete [41] and the different methods can alter the estimated 24-hour sodium by twofold.[67] Finally, many of the validation studies have been conducted in healthy normal volunteers whose health characteristics do not reflect those of the individuals in whom the formula is employed.[48,68]

The lack of scientific rationale to support the hypothesis, serious methodological issues in validation studies, incorporation of major confounding risk factors in formulae to estimate 24-hour urine sodium, and systematic differences in error with different levels of dietary sodium have led several to recommend that spot and short duration timed urine collections not be used.[14,45] Finally, these shortcomings create distortions in the associations between estimated salt consumption and health outcomes.[37] The current data do not support using single or multiple spot or short-term timed urine collections to assess sodium intakes in association with health outcomes.

9 | POSITION AND RECOMMENDATIONS ON THE USE OF 24-HOUR URINE COLLECTIONS TO ASSESS DIETARY SODIUM INTAKE

1. Single complete 24-hour urine collections, collected over a series of days that represent the population's usual dietary patterns, provide a reasonably accurate estimate of current 24-hour dietary sodium ingestion in a population, underestimating true intake by about 7% (Table 2).
2. Several days of complete non-consecutive 24-hour urine collections are necessary to accurately reflect an individual's current/usual sodium intake. The number of days of collection required will relate to the inter- and intra-individual variations in sodium intake in the population. At least 3 non-consecutive 24-hour urine collections collected over a series of days that reflect the usual short-term variations in dietary pattern (eg, weekday vs weekend day and usual daily variation in sodium intake) are needed to get a reasonably accurate estimate of usual dietary sodium at the individual level. Multiple 24-hour urine collections over several years are needed for the estimation of an individual´s usual long-term sodium intake.
3. Rigorous attention to quality control, including careful training of research leads, field workers, and study participants, should be in place to ensure a high participation rate and a high rate of complete 24-hour urine collections.

10 | POSITION ON THE USE OF SPOT OR SHORT DURATION TIMED URINE COLLECTIONS (<24 HOURS) TO ASSESS DIETARY SODIUM INTAKE

1. The role of single spot or short duration timed urine collections in assessing population average sodium intake requires more research for a definitive position and should be used cautiously for this purpose (Table 2). Where a single spot or short duration timed urine sample is used to assess average population sodium intake, a simultaneous calibration study with complete 24-hour urine samples should ideally be conducted

TABLE 2 Recommendations for estimating usual dietary sodium using urinary excretion of sodium

Setting	Recommendation
Current average population intake	Single 24-h urine collection in randomly selected individuals over a series of days that reflect the usual population dietary pattern
Current annual population intake	Single 24-h urine collection in randomly selected individuals over a series of days that reflect the usual population dietary pattern over a year
Individuals current usual intake	At least 3 non-consecutive 24-h urine collections collected over a series of days that reflect the usual short-term variations in dietary pattern (eg, weekday vs weekend day and usual daily variation in sodium intake)
Individual's long-term usual intake	Multiple 24-h urine collections over the duration of the long-term study

Note: 24-h urine sodium collections represent approximately 93% of the sodium ingested.

in an adequately large subset to ensure the accuracy of the estimate.

2. Single or multiple spot or short duration timed urine collections are not recommended for assessing an individual's sodium intake especially in relationship to health outcomes.

11 | DISCUSSION

The TRUE Consortium recommends 24-hour urine collections be retained to assess population and individual sodium intake, with a cautious and currently unclear role for spot and short-term timed urine collections to assess population average sodium intake. For individual sodium intake, three and up to ten 24-hour urine collections are needed to obtain a reliable estimate. The important caveats to 24-hour urine collection include that rigorous methods are used to ensure complete urine collection and to assess completeness of the 24-hour urine collections, that the participants are representative of the population being studied, and that the timing of the urine collections meets the needs of the research question (current, annual, or long-term sodium consumption). The Consortium recommends not to use a spot and short-term timed urine collection to assess individual sodium intake.

The TRUE consortium's systematic reviews indicate that low-quality research has been commonly used in assessing dietary sodium. Previous systematic reviews on the use of 24-hour urine collections, food frequency questionnaires, dietary records, and 24-hour diet recall to assess sodium intake found serious methodological issues to be common.[11,13] Few high-quality validation studies were identified in our searches. A priority is to develop minimum methodologic standards for the conduct of validation studies. A regularly updated systematic review of the literature assessing the association of sodium intake to clinical outcomes found the majority of studies could not meet even minimum methodologic criteria.[69-74] The initial TRUE consortium position on blood pressure measurement in research studies was also developed because few research studies used the recommended methods to assess blood pressure.[13] Institutions funding research, journals, and scientists need to carefully assess the validity of the methods used in research relating to dietary sodium to ensure reliable guidance to public health programs.

Increasing evidence relates low-quality research methodology on dietary sodium to findings of "U-shaped," "J-shaped," or "inverse linear" associations between sodium intake and health outcomes. Meta-analyses that use criteria to exclude cohort studies with major methodological weaknesses find positive associations between increasing dietary sodium and cardiovascular events, especially stroke.[75,76] In contrast, meta-analyses that do not exclude studies with major methodological weaknesses find J- or U-shaped associations with dietary sodium and cardiovascular outcomes.[77,78] The importance of research rigor in assessing multiple 24-hour urine collections over time is emphasized in a study conducted by Olde Engberink et al where dietary sodium assessed by a single 24-hour urine collection at baseline had a "U-shaped" relationship cardiovascular disease, with the association at high sodium intake not being different from that at low intake. When Olde Engberink et al[32] assessed multiple 24-hour urine collections over 1-5 years, there were substantially different estimates of individual sodium intake, and the risk of cardiovascular disease increased progressively with intake. Similarly, in the Trials of Hypertension Prevention (TOHP), estimates of sodium intake from an average of multiple 24-hour urine collections had a statistically significant linear relationship with death, while the association was relatively flat, and not statistically significant when sodium intake, was measured by a single 24-hour urine collection.[40] Further, in the TOHP studies, when the Kawasaki equation was used to estimate 24-hour urine sodium from the sodium concentration in 24-hour urine collections, the association with death was not statistically significant and appeared to take on a J-shaped curve. The lack of a credible scientific rationale to relate estimation of dietary sodium using spot urine collections or short-term timed urine collections to usual sodium intake, coupled with numerous confounding factors in the estimation with patient outcomes (including reverse causality in studies using sick participants),[79] systematic and random errors in estimating individual intake and the poor quality of validation studies has led the TRUE Consortium to recommend to not use these collections to estimate individual sodium intake. Although spot or short-term timed urine collections may provide rough estimates of population average sodium consumption, with the current formulae used to estimate 24-hour urine sodium, there is systematic error in estimating the population average with overestimates at lower average population sodium intake and underestimates at higher average 24-hour urine sodium. Further, there is inadequate research to assess the performance of spot urine collections or short-term timed urine collections to monitor changes in sodium intake over time and in different settings (eg, increased temperature).

In developing this position statement, the committee identified several areas where more research is needed. These include the following: (a) "What is the role of spot or short-term timed urine collections in estimating population average sodium intake and its changes over time?"; (b) "How do changes in temperature/humidity, nutrition transition, or long-term dietary changes affect estimation of sodium intake from the different formulae used to estimate 24-hour urine sodium?"; (c) "Can multiple spot or timed urine collections accurately estimate usual sodium intake in an individual and/or in a population?"; (d) "How do age, sex, ethnicity, and setting affect estimation of sodium intake from the different spot urine formulae?"; (e) "Will any or all the formulae used to estimate 24-hour urine sodium alter the relationship of sodium intake to outcomes?"; (f) "How many 24-hour urine sodium collections are needed to accurately assess usual sodium intake in an individual and how does this change with different dietary patterns?"; (g) "How can 24-hour urine collections best be assessed for completeness (How do different indirect measures of complete urine collection relate to the use of PABA to assess completeness)?"; "What range of PABA recovery best reflects complete urine collection?"; Can adjustments to complete collection be made based on less than complete PABA recovery?"; (h) Can spot or timed

urine collections detect small but public health-relevant changes in average population salt consumption?"; and (i) "What is the rate (eg, half-life) of urinary excretion of ingested sodium when people are eating their usual diet?".

Using the best current evidence, high dietary sodium intake has been stated to be a leading risk for death and disability globally, with reducing dietary sodium being one of the most cost-effective mechanisms to improve population health.[2,80] However, some research finds reducing dietary sodium to be associated with harm.[77] The TRUE consortium and others have expressed concern that low-quality research methods, including inaccurate assessment of dietary sodium and not accounting for confounding health risks (ie, use of formulae and spot or short-term timed urine collections), have caused some of the controversy around reducing dietary sodium.[11,13,15,46,66,81,82] Systematic review of the use of dietary records, food recall, and food frequency questionnaires has led the TRUE Consortium to recommend against using those methods for assessing sodium intake in individuals. Studies on dietary sodium need to be done rigorously and reproducibly with appropriate methods to further scientific knowledge and support public health action. In contrast, low-quality research can generate false controversy, and misleading results thus confusing policymakers and the public with a strong potential to harm the ongoing public health efforts to reduce cardiovascular disease burden globally. The recommendations are intended to guide scientific review committees, granting agencies, editors and journal reviewers, investigators, policymakers, and those developing and creating dietary sodium recommendations. Low-quality research on important public health topics should not be funded, conducted, or published.

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CONFLICT OF INTEREST

NRCC was a paid consultant to the Novartis Foundation (2016-2017) to support their program to improve hypertension control in low-to-middle–income country cities that included travel support for site visits and a contract to develop a survey. NRCC has provided paid consultative advice on accurate blood pressure assessment to Midway Corporation (2017) and is an unpaid member of World Action on Salt and Health (WASH). FPC: Member of Consensus Action on Salt & Health (CASH), WASH, UK Health Forum, Advisor to the World Health Organization, Trustee, and President of the British and Irish Hypertension Society (Registered UK Charity No: 287635). FJH is a member of Consensus Action on Salt & Health (CASH) and World Action on Salt & Health (WASH). Both CASH and WASH are non-profit charitable organizations, and FJH does not receive any financial support from CASH or WASH. GAM is Chairman of Blood Pressure UK (BPUK), Chairman of CASH, WASH, and Action on Sugar (AoS). BPUK, CASH, WASH, and AoS are non-profit charitable organizations. GAM does not receive any financial support from any of these organizations. MT, PW, ML, MEC, MW, and RM have nothing to disclose.

DISCLAIMER

The findings and conclusions expressed in review paper are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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