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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Effects of Dietary Sodium and Potassium Intake on Chronic Disease Outcomes and Related Risk Factors.

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of *Effects of Dietary Sodium and Potassium Intake on Chronic Disease Outcomes and Related Risk Factors*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: *Submission Deadline* on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES:

E-mail submissions: SEADS@epc-src.org.

Print submissions:

Mailing Address:

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Scientific Resource Center

ATTN: Scientific Information Packet Coordinator

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FOR FURTHER INFORMATION CONTACT:

Ryan McKenna, Telephone: 503-220-8262 ext. 51723 or Email: SEADS@epc-src.org.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Effects of Dietary Sodium and Potassium Intake on Chronic Disease Outcomes and Related Risk Factors*.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Effects of Dietary Sodium and Potassium Intake on Chronic Disease Outcomes and Related Risk Factors*, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at:

<https://www.effectivehealthcare.AHRQ.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=2428>

This is to notify the public that the EPC Program would find the following information on *Effects of Dietary Sodium and Potassium Intake on Chronic Disease Outcomes and Related Risk Factors* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.
 - *For completed studies that do not have results on ClinicalTrials.gov*, please provide a summary, including the following elements: study number; study period; design, methodology; indication and diagnosis; proper use instructions; inclusion and exclusion criteria; primary and secondary outcomes; baseline characteristics; number of patients screened, eligible, enrolled, lost to follow up, withdrawn, and analyzed; as well as effectiveness and efficacy, and safety results.

- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: <https://www.effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/>.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions

Sodium

1. Among adults and children of all age groups (including both sexes and pregnant and lactating women), what is the effect (benefits and harms) of interventions to reduce dietary sodium intake on blood pressure at the time of the study and in later life?
 - I. Do other minerals (e.g., potassium, calcium, magnesium) modify the effect of sodium?
 - II. Among subpopulations defined by sex, race/ethnicity, age (children, adolescents, young adults, older adults, elderly), and for women (pregnancy and lactation).
 - III. Among subpopulations defined by hypertension, diabetes, and obesity health status.
2. Among adults and children, what is the association between dietary sodium intake and blood pressure?
 - I. Among subpopulations defined by sex, race/ethnicity and age (children, adolescents, young adults, older adults, elderly).
 - II. Among subpopulations defined by hypertension, diabetes, and obesity health status.
3. Among adults, what is the effect (benefits and harms) of interventions to reduce dietary sodium intake on [cardiovascular disease \(CVD\)](#) and kidney disease morbidity and mortality and on total mortality?
 - I. Do other minerals (e.g., potassium, calcium, magnesium) modify the effect of sodium?
 - II. Among subpopulations defined by sex, race/ethnicity, age (adults, older adults, elderly), and for women (pregnancy and lactation).

- III. Among subpopulations defined by hypertension, diabetes, obesity and renal health status.
- 4. Among adults, what is the association between dietary sodium intake and CVD, coronary heart disease (CHD), stroke and kidney disease morbidity and mortality and between dietary sodium intake and total mortality?
 - I. Do other minerals (e.g., potassium, calcium, magnesium) modify the association with sodium?
 - II. Among subpopulations defined by sex, race/ethnicity, age (adults, older adults, elderly), and for women (pregnancy and lactation).
 - III. Among subpopulations defined by hypertension, diabetes, obesity and renal health status.

Potassium

- 5. Among children and adults, what is the effect of interventions to increase potassium intake on blood pressure and kidney stone formation?
 - I. Do other minerals (e.g., sodium, calcium, magnesium) modify the effect of potassium?
 - II. Among subpopulations defined by sex, race/ethnicity, age (children, adolescents, young adults, older adults, elderly), and for women (pregnancy and lactation).
 - III. Among subpopulations defined by hypertension, diabetes, obesity and renal health status.
- 6. Among children and adults, what is the association between potassium intake and blood pressure and kidney stone formation?

- I. Among subpopulations defined by sex, race/ethnicity, and age (children, adolescents, young adults, older adults, elderly).
 - II. Among subpopulations defined by hypertension, diabetes, and obesity health status.
7. Among adults, what is the effect of interventions aimed at increasing potassium intake on CVD, and kidney disease morbidity and mortality, and total mortality?
- I. Do other minerals modify the effect of potassium (e.g., sodium, calcium, magnesium)?
 - II. Among subpopulations defined by sex, race/ethnicity, age (young adults, older adults, elderly), and for women (pregnancy and lactation).
 - III. Among subpopulations defined by hypertension, diabetes, obesity and renal health status.
8. Among adults, what is the association between dietary potassium intake and CVD, CHD, stroke and kidney disease morbidity and mortality and between dietary potassium and total mortality?
- I. Do other minerals (e.g., sodium, calcium, magnesium) modify the association with potassium?
 - II. Among subpopulations defined by sex, race/ethnicity, age (young adults, older adults, elderly), and for women (pregnancy and lactation).
 - III. Among subpopulations defined by hypertension, diabetes, and obesity health status.

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

Key Question 1

I. Population

- A. Studies in human participants will be eligible for inclusion in the review, with the exception of studies exclusively reporting on patients with end stage renal disease, heart failure, HIV, or cancer.

II. Interventions

- A. Studies evaluating interventions to reduce dietary sodium intake that specify the oral consumption from food or supplements of quantified amounts of sodium and sodium chloride (salt) or sodium-to-potassium ratio will be eligible, with the exception of trial arms in which participants demonstrate a weight change of +/- 3% or more. Interventions simultaneously addressing sodium and potassium intake that document sodium/potassium ratio are eligible; all other multicomponent interventions in which the effect of sodium reduction cannot be disaggregated from other intervention components will be excluded.

III. Comparators

- A. Studies comparing interventions to placebo or control diets will be eligible. Studies comparing an experimental diet to usual diet, studies comparing levels of sodium intake, or studies that alter sodium/potassium ratio in other ways will be included if they control for other nutrient levels.

IV. Outcomes

- A. Studies reporting on blood pressure outcomes (e.g., systolic blood pressure, diastolic blood pressure, rate of hypertensive/non-hypertensive participants, incident hypertension, percent of participants at blood pressure goal, and change in blood pressure) will be eligible.

V. Timing

- A. Studies reporting on an intervention period of at least four weeks will be eligible.

VI. Setting

- A. Studies in outpatient settings will be eligible.

VII. Study design

- A. Parallel RCTs and cross-over RCTs with a washout period of two weeks or more will be eligible.

Key Question 2

I. Population

- A. Studies in community-dwelling (non-institutionalized) human participants will be eligible for inclusion in the review with the exception of studies exclusively reporting on patients with pre-existing conditions specific to the clinical outcome of interest, as well as studies exclusively reporting on patients with end stage renal disease, heart failure, HIV, or cancer.

II. Exposure

- A. Studies that measure the intake (oral consumption from food or supplements of quantified amounts of sodium and sodium chloride [salt] or sodium-to-potassium ratio) with validated measures or that use biomarker values to assess sodium level (at least one 24-hour urinary analysis with or without reported quality control measure, chemical analysis of diet with intervention/exposure adherence measure, composition of salt substitute with intervention/exposure adherence measure, and food diaries with reported validation [adherence check, electronic prompts]) will be eligible. Observational studies that report a

weight change of +/- 3% or more (in any exposure group) among adults; multicomponent studies that do not properly control for confounders; and studies relying only on serum sodium levels, composition of salt substitute without intervention/exposure adherence measure, food diaries without reported validation, use of a published food frequency questionnaire, or partial or spot urine without reported prediction equation will be excluded.

III. Comparator

- A. Studies comparing groups with different documented sodium intake or biomarker values for sodium will be eligible. Studies where differences in sodium intake or values are confounded with alteration of other nutrient levels will be excluded.

IV. Outcomes

- A. Studies reporting on blood pressure outcomes (e.g., systolic blood pressure, diastolic blood pressure, rate of hypertensive /non-hypertensive participants, incident hypertension, percent of participants at blood pressure goal, change in blood pressure) will be eligible. Studies that do not report baseline blood pressure status will be excluded.

V. Timing

- A. Studies reporting on an intervention period of at least four weeks will be eligible.

VI. Setting

- A. Studies in community-dwelling participants will be eligible.

VII. Study design

- A. Prospective cohort studies and nested case-control studies, where at least two groups are compared based on measured sodium intake or biomarker values will be eligible. Retrospective

studies, case series, cross-sectional studies or surveys, and case reports will be excluded.

Key Question 3

I. Population

- A. Studies in human adults will be eligible for inclusion in the review. Studies exclusively reporting on patients with end stage renal disease, heart failure, HIV, or cancer will be excluded.

II. Intervention

- A. Studies evaluating interventions to reduce dietary sodium intake that specify the oral consumption from food or supplements of quantified amounts of sodium and sodium chloride (salt) or sodium-to-potassium ratio will be eligible. Studies with trial arms in which participants demonstrate a weight change of +/- 3% or more will be excluded. Interventions simultaneously addressing sodium and potassium intake with documents sodium/potassium ratio are eligible. All other multicomponent interventions in which the effect of sodium reduction cannot be disaggregated from other intervention components will be excluded.

III. Comparators

- A. Studies comparing interventions to placebo or control diets will be eligible. Studies comparing an experimental diet to usual diet, studies comparing levels of sodium intake, or studies that alter sodium/potassium ratio in other ways will be included if they control for other nutrient levels.

IV. Outcomes

- A. Studies reporting on mortality (all-cause, CVD, CHD, or renal); cardiovascular disease morbidity, including acute coronary

syndrome (unstable angina and myocardial infarction), stroke, myocardial infarction (ST-segment elevation myocardial infarction [STEMI] and non-ST elevation myocardial infarction [NSTEMI]), requiring coronary revascularization procedures (angioplasty, coronary stent placement, coronary artery bypass), other atherosclerotic revascularization procedures (carotid endarterectomy), left ventricular hypertrophy, hospitalization for heart failure, hospitalization for any cause of coronary heart disease or cardiovascular disease, or combined CVD morbidity and mortality; or reporting on renal function intermediary and clinical outcomes including creatinine clearance (CrCl), serum creatinine (SCr), glomerular filtration rate (GFR), end stage renal disease, chronic kidney disease (CKD), albuminuria or proteinuria (including urine albumin-to-creatinine ratio, urine albumin dipstick level, urine protein-to-creatinine ratio, albumin excretion rate), kidney stone incidence, or acute kidney injury will be eligible.

V. Timing

- A. Only interventions of two years or longer will be included for kidney disease outcomes; only interventions of three months or longer will be included for cardiovascular disease outcomes; all other studies need to report on an intervention period of at least four weeks to be eligible.

VI. Setting

- A. Studies in outpatient settings will be eligible.

VII. Study design

- A. Parallel RCTs and cross-over RCTs with a washout period of two weeks or more will be eligible.

Key Question 4

I. Population

- A. Studies in community-dwelling (non-institutionalized) adults will be eligible for inclusion in the review with the exception of studies exclusively reporting on patients with pre-existing conditions specific to the clinical outcomes of interest, as well as studies exclusively reporting on patients with end stage renal disease, heart failure, HIV, or cancer.

II. Exposure

- A. Studies that measure the intake (oral consumption from food or supplements of quantified amounts of sodium and sodium chloride [salt] or sodium-to-potassium ratio) with validated measures or use biomarker values to assess sodium level (at least one 24-hour urinary analysis with or without reported quality control measure, chemical analysis of diet with intervention/exposure adherence measure, composition of salt substitute with intervention/exposure adherence measure, and food diaries with reported validation [adherence check, electronic prompts]) will be eligible. Observational studies that report a weight change of +/- 3% or more (in any exposure group) among adults; multicomponent studies that do not properly control for confounders; and studies relying only on serum sodium levels, composition of salt substitute without intervention/exposure adherence measure, food diaries without reported validation, use of a published food frequency questionnaire, or partial or spot urine without reported prediction equation will be excluded.

III. Comparator

- A. Studies comparing groups with different documented sodium intake or biomarker values for sodium will be eligible. Studies where differences in sodium intake or values are confounded with alteration of other nutrient levels will be excluded.

IV. Outcomes

- A. Studies reporting on mortality (all-cause, CVD, CHD, or renal); cardiovascular mortality; cardiovascular disease morbidity, including coronary heart disease (CHD), acute coronary syndrome (unstable angina and myocardial infarction), stroke, myocardial infarction (ST-segment elevation myocardial infarction [STEMI] and non-ST elevation myocardial infarction [NSTEMI]), requiring coronary revascularization procedures (angioplasty, coronary stent placement, coronary artery bypass), other atherosclerotic revascularization procedures (carotid endarterectomy), left ventricular hypertrophy, hospitalization for heart failure, or hospitalization for any cause of coronary heart disease or cardiovascular disease, or combined CVD morbidity and mortality; or reporting on renal function intermediary and clinical outcomes including creatinine clearance (CrCl), serum creatinine (SCr), glomerular filtration rate (GFR), end stage renal disease, chronic kidney disease (CKD), albuminuria/ proteinuria (including, urine albumin-to-creatinine ratio, urine albumin dipstick level, urine protein-to-creatinine ratio, albumin excretion rate), acute kidney injury will be eligible. Studies that do not report baseline data for the outcomes of interest will be excluded.

V. Timing

- A. Studies reporting exclusively on kidney disease outcomes need to report follow up periods of at least two years, studies

reporting exclusively on cardiovascular disease outcomes or stroke need to report on follow up periods of at least 12 months duration; studies reporting on other outcomes need to evaluate exposure lasting at least four weeks to be eligible.

VI. Setting

A. Studies in community-dwelling participants will be eligible.

VII. Study design

A. Prospective cohort studies and nested case-control studies, where at least two groups are compared based on measured sodium intake or biomarker values will be eligible. Retrospective studies, case series, cross-sectional studies or surveys, and case reports will be excluded.

Key Question 5

I. Population

A. Studies in human participants will be eligible for inclusion in the review; studies exclusively reporting on patients with end stage renal disease, heart failure, HIV, or cancer will be excluded.

II. Interventions

A. Studies evaluating interventions to increase dietary potassium intake that specify the oral consumption from food or supplements of quantified amounts of potassium, potassium supplements, salt substitutes such as potassium chloride, or sodium-to-potassium ratio will be eligible, with the exception of trial arms in which participants demonstrate a weight change of $\pm 3\%$ or more among adults. Interventions simultaneously addressing sodium and potassium intake with documents sodium/potassium ratio are eligible; all other multicomponent

interventions in which the effect of sodium reduction cannot be disaggregated from other intervention components will be excluded.

III. Comparators

- A. Studies comparing interventions to placebo or control diets will be eligible. Studies comparing an experimental diet to usual diet, studies comparing levels of potassium intake, or studies that alter sodium/potassium ratio in other ways will be included if they control for other nutrient levels.

IV. Outcomes

- A. Studies reporting on blood pressure outcomes (e.g., systolic blood pressure, diastolic blood pressure, rate of hypertensive/non-hypertensive participants, hypertension incidence, percent of participants at blood pressure goal, change in blood pressure) and incident kidney stones or kidney stone regrowth will be eligible.

V. Timing

- A. Studies reporting exclusively on kidney stone formation need to report on an intervention period of two years; all other studies need to report on an intervention period of at least four weeks to be eligible.

VI. Setting

- A. Studies in outpatient settings will be eligible.

VII. Study design

- A. Parallel RCTs and cross-over RCTs with a washout period of two weeks or more will be eligible.

Key Question 6

I. Population

- A. Studies in community-dwelling (non-institutionalized) human participants will be eligible for inclusion in the review; studies reporting exclusively on patients with pre-existing conditions specific to the clinical outcomes of interest, as well as studies exclusively reporting on patients with end stage renal disease, heart failure, HIV, or cancer will be excluded.

II. Exposure

- A. Studies that measure intake (oral consumption from food or supplements of quantified amounts of potassium, potassium supplements, salt substitutes such as potassium chloride, or sodium-to-potassium ratio) with validated measures or use biomarkers values to assess potassium level (at least one 24-hour urinary analysis with or without reported quality control measure, chemical analysis of diet with intervention/exposure adherence measure, composition of potassium supplement with intervention/exposure adherence measure, use of a published food frequency questionnaire, and food diaries) will be eligible. Observational studies that report a weight change of +/- 3% or more (in any exposure group) among adults; multicomponent studies that do not properly control for confounders; and studies measuring potassium intake by reporting chemical analysis of diet without intervention/exposure adherence measures, composition of potassium supplement without intervention/exposure measure, or serum potassium will be excluded.

III. Comparator

- A. Studies comparing groups with different documented potassium intake, serum potassium levels, or urinary potassium excretion

will be eligible. Studies where differences in potassium intake or values are confounded with alteration of other nutrient levels will be excluded.

IV. Outcomes

- A. Studies reporting on blood pressure outcomes (e.g., systolic blood pressure, diastolic blood pressure, rate of hypertensive/non-hypertensive participants, hypertension incidence, percent of participants at blood pressure goal, change in blood pressure), and kidney stone incident or kidney stone regrowth will be eligible. Studies that do not report baseline blood pressure status and the presence or absence of kidney stones will be excluded.

V. Timing

- A. Studies exclusively reporting on kidney stone formation need to follow participants for at least five years; all other studies need to report on exposure of at least four weeks to be eligible.

VI. Setting

- A. Studies in community-dwelling participants will be eligible.

VII. Study design

- A. Prospective cohort studies and nested case-control studies, where at least two groups are compared based on measured potassium intake or biomarker values will be eligible. Retrospective studies, case series, cross-sectional studies or surveys, and case reports will be excluded.

Key Question 7

I. Population

- A. Studies in adults will be eligible for inclusion in the review; studies reporting exclusively on patients with heart failure, end stage renal disease, HIV, or cancer will be excluded.

II. Interventions

- A. Studies evaluating interventions to increase dietary potassium intake that specify the oral consumption from food or supplements of quantified amounts of potassium, potassium supplements, salt substitutes such as potassium chloride, or sodium-to-potassium ratio will be eligible, with the exception of trial arms in which participants demonstrate a weight change of +/- 3% or more. Interventions simultaneously addressing sodium and potassium intake with documents sodium/potassium ratio are eligible; all other multicomponent interventions in which the effect of sodium reduction cannot be disaggregated from other intervention components will be excluded.

III. Comparators

- A. Studies comparing interventions to placebo or control diets will be eligible. Studies comparing an experimental diet to usual diet, studies comparing levels of potassium intake, or studies that alter sodium/potassium ratio in other ways will be included if they control for other nutrient levels.

IV. Outcomes

- A. Studies reporting on mortality (all-cause, CVD, CHD, or renal); cardiovascular disease morbidity, including acute coronary syndrome (unstable angina and myocardial infarction), stroke, myocardial infarction (ST-segment elevation myocardial infarction [STEMI] and non-ST elevation myocardial infarction [NSTEMI]), requiring coronary revascularization procedures (angioplasty, coronary stent placement, coronary artery bypass),

other atherosclerotic revascularization procedures (carotid endarterectomy), left ventricular hypertrophy, hospitalization for heart failure, or hospitalization for any cause of coronary heart disease or cardiovascular disease, or combined CVD morbidity and mortality; or reporting on renal function intermediary and clinical outcomes including creatinine clearance (CrCl), serum creatinine (SCr), glomerular filtration rate (GFR), end stage renal disease, chronic kidney disease (CKD), albuminuria or proteinuria (including urine albumin-to-creatinine ratio, urine albumin dipstick level, urine protein-to-creatinine ratio, albumin excretion rate), kidney stone incidence, or acute kidney injury will be eligible.

V. Timing

- A. Studies reporting exclusively on kidney disease outcomes need to report on an intervention period of two years, studies reporting on cardiovascular disease or stroke need to report on an intervention period of three months; all other studies need to report on an intervention period of at least four weeks to be eligible.

VI. Setting

- A. Studies in outpatient settings will be eligible.

VII. Study design

- A. Parallel RCTs and cross-over RCTs with a washout period of two weeks or more will be eligible.

Key Question 8

I. Population

- A. Studies in community-dwelling (non-institutionalized) adults will be eligible for inclusion in the review with the exception of studies exclusively reporting on patients with pre-existing conditions specific to the clinical outcomes of interest, as well as studies exclusively reporting on patients with end stage renal disease, heart failure, HIV, or cancer.

II. Exposure

- A. Studies that measure intake (oral consumption from food or supplements of quantified amounts of potassium, potassium supplements, salt substitutes such as potassium chloride, or sodium-to-potassium ratio) with validated measures or use biomarkers values to assess potassium level (at least one 24-hour urinary analysis with or without reported quality control measure, chemical analysis of diet with intervention/exposure adherence measure, composition of potassium supplement with intervention/exposure adherence measure, use of a published food frequency questionnaire, and food diaries) will be eligible. Observational studies that report a weight change of +/- 3% or more (in any exposure group) among adults; multicomponent studies that do not properly control for confounders; and studies measuring potassium intake by reporting chemical analysis of diet without intervention/exposure adherence measures, composition of potassium supplement without intervention/exposure measure, or serum potassium will be excluded.

III. Comparator

- A. Studies comparing groups with different documented potassium intake, serum potassium levels, or urinary potassium excretion will be eligible. Studies where differences in potassium intake or

values are confounded with alteration of other nutrient levels will be excluded.

IV. Outcomes

A. Studies reporting on mortality (all-cause, CVD, CHD, or renal); cardiovascular disease morbidity, including coronary heart disease (CHD), acute coronary syndrome (unstable angina and myocardial infarction), stroke, myocardial infarction (ST-segment elevation myocardial infarction [STEMI] and non-ST elevation myocardial infarction [NSTEMI]), requiring coronary revascularization procedures (angioplasty, coronary stent placement, coronary artery bypass), other atherosclerotic revascularization procedures (carotid endarterectomy), left ventricular hypertrophy, hospitalization for heart failure, or hospitalization for any cause of coronary heart disease or cardiovascular disease, or combined CVD morbidity and mortality; or reporting on renal function intermediary and clinical outcomes including creatinine clearance (CrCl), serum creatinine (SCr), glomerular filtration rate (GFR), end stage renal disease, chronic kidney disease (CKD), albuminuria/ proteinuria (including urine albumin-to-creatinine ratio, urine albumin dipstick level, urine protein-to-creatinine ratio, albumin excretion rate), kidney stone incidence, or acute kidney injury will be eligible. Studies that do not report baseline data on the outcomes of interest will be excluded.

V. Timing

A. Studies reporting exclusively on kidney stone formation need to follow participants for at least five years, studies reporting exclusively on kidney disease need to follow participants for at least two years, studies reporting exclusively on cardiovascular

disease or stroke need to follow patients for at least 12 months; all other studies need to report on an exposure period of at least four weeks to be eligible.

VI. Setting

A. Studies in community-dwelling participants will be eligible.

VII. Study design

A. Prospective cohort studies and nested case-control studies, where at least two groups are compared based on measured potassium intake or biomarker values will be eligible. Retrospective studies, case series, cross-sectional studies or surveys, and case reports will be excluded.

Sharon B. Arnold

Acting AHRQ Director

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