Sodium Working Group

Cross-cutting Topics of Dietary Guidance and Public Health Importance
Scope

To describe:

- the relationship between sodium intake, blood pressure, and cardiovascular disease
- how sodium recommendations may be influenced by the interaction of sodium and potassium
- strategies to promote recommended intake of sodium
Invited Experts

Individuals invited by the SC, usually on a one time basis, to provide their expertise to inform the SC’s work. Invited experts do not participate in decisions at the SC level.

Consultant SC Members

Individuals sought by the SC to participate in SC discussions and decisions on an ongoing basis but are not members of the full DGAC. Like DGAC members, consultants complete training and have been reviewed and cleared through a formal process within the Federal government.
Experts and Consultants

Invited Experts (Sept to Nov 2014)
None

Consultant SC Members
None
Questions Addressed Today

1. What is the relationship between sodium intake and blood pressure in children?
2. What is the relationship between sodium intake and blood pressure in adults?
3. What is the relationship between sodium intake and cardiovascular disease?
4. What is the interrelationship of sodium and potassium on BP and CVD outcomes?
5. What individual strategies can be used to promote recommended intake of sodium? (*Implications*)
6. What policies and environmental (e.g., reformulation, menu labeling) strategies can be used to promote recommended intake of sodium? (*Implications*)
What is the relationship between sodium intake and blood pressure in children?

NEL Systematic Review
(2010 DGAC + update)
Sodium and Blood Pressure in Children
Sources of Evidence

• The 2010 DGAC conducted a systematic review on the relationship between sodium intake and blood pressure in children from birth to age 18 years, examining studies published from January 1970 to May 2009.

• The 2015 DGAC updated the systematic review done by the 2010 DGAC with 2 newly published studies.
A moderate body of evidence has documented that as sodium intake decreases, so does blood pressure in children, birth to 18 years of age.

DGAC Grade: Moderate
What is the relationship between sodium intake and blood pressure in adults?

Existing Reports
Sodium and Blood Pressure in Adults
Source of Evidence

• 2013 American Heart Association/American College of Cardiology Guideline on Lifestyle Management to Reduce Cardiovascular Risk
The committee concurs with the 2013 AHA/ACC Lifestyle report which advises adults who would benefit from blood pressure lowering to:

- “Lower sodium intake”
AHA/ACC Grade: Strong

The committee concurs with the 2013 AHA/ACC Lifestyle report which advises adults who would benefit from blood pressure lowering to:

- “Consume no more than 2,400 mg of sodium/d;
- Further reduction of sodium intake to 1,500 mg/d can result in even greater reduction in BP; and
- Even without achieving these goals, reducing sodium intake by at least 1,000 mg/d lowers BP.”
AHA/ACC Grade: Moderate

The committee concurs with the 2013 AHA/ACC Lifestyle report which advises adults who would benefit from blood pressure lowering to:

- “Combine the DASH dietary pattern with lower sodium intake.”
AHA/ACC Grade: Strong
For blood pressure lowering, high levels of sodium intake should be reduced and healthful U.S. dietary patterns should be combined with lower sodium intake if necessary.

Achievement of the recommendations to reduce sodium intake requires an emphasis on policies and population-based strategies. These include:

- FDA taking action to modify the generally recognized as safe (GRAS) status of sodium
- Food product reformulation to achieve progressive reduction in sodium content of foods
- Incentives to encourage health systems to provide preventive nutrition services that encourage healthy dietary patterns
- Public-private-community partnerships

Strategies that complement policies and support consumers to make dietary behavior changes are also needed. These include:

- Nutrition services and comprehensive lifestyle intervention by multi-disciplinary teams (AHA/ACC)
- Enhanced nutrition labeling and point of purchase sodium information
- Diet planning tools that include sodium as an area of focus

Although the evidence on potassium and blood pressure is limited, we recognize that potassium intake is suboptimal and encourage increased potassium intake through potassium-rich foods.
What is the relationship between sodium intake and cardiovascular disease?

NEL Systematic Review Update
(IOM, 2013 and AHA/ACC, 2013 + NEL update)
Analytical Framework: Sodium and Cardiovascular Disease

**Target Population**
Children and adults, aged 2 years and older

**Intervention/Exposure**
Sodium intake

**Comparator**
Different levels of sodium intake

**Endpoint Health Outcomes**
- Myocardial infarction
- Stroke
- Coronary heart disease
- CVD-related mortality
- Incidence of hypertension
- Congestive heart failure

**Potential Confounders**
- Total energy intake
- BMI
- Age
- Race/ethnicity
- Sex
- SES

**Systematic Review Questions:**
- What is the relationship between sodium intake and risk of cardiovascular disease?
Sodium and Cardiovascular Disease Literature Search: Inclusion/Exclusion Criteria

**Date Range:**
- Published between January 2013 and September 2014 (in English in a peer-reviewed journal)

**Study Design:**
- Randomized or non-randomized controlled trial, or prospective cohort study

**Study Subjects:**
- Children and adults aged 2 years and older
- From countries with high or very high human development (per the 2012 Human Development Index) (if a study included subjects from multiple countries with differing Human Development Index ratings, the study was included)
- Healthy or at elevated chronic disease risk

**Intervention/Exposure:**
- Sodium intake

**Outcome:**
- Myocardial infarction, stroke, coronary heart disease, CVD-related mortality, incidence of hypertension, and congestive heart failure
Sodium and Cardiovascular Disease Literature Search Results

Articles identified through database searching (n=1111) (PubMed, Embase, Cochrane, CINAHL)

Articles screened (Title) (n=1111)

Articles screened (Abstract) (n=55)

Full-text articles reviewed for eligibility (n=7)

Studies included in systematic review (4)

Articles excluded (n=1056)

Articles screened (Abstract) (n=55)

Articles excluded (n=48)

Full-text articles excluded (n=3)
Sodium and Cardiovascular Disease
Description of the Evidence

• The 2015 DGAC updated systematic reviews done by the IOM and NHLBI, and identified 4 prospective cohort studies:
  – Studies were done in adults from the US, Netherlands, UK, and from 17 countries around the world
  – Two studies used multiple 24-h urinary samples, and two used a single urine sample to estimate sodium excretion
  – Two studies found that higher sodium intake was associated with higher CVD risk
  – Two studies found either no association or an inverse association between low sodium intake and risk of CVD. However, these studies had limitations that make interpretation of the results challenging.

• The 2015 DGAC considered the findings from these four studies and determined that changes were not warranted to the IOM and NHLBI conclusion statements.
Sodium and Cardiovascular Disease

Draft Conclusion Statement

The 2015 DGAC concurs with the Institute of Medicine (IOM), which concluded that although the reviewed evidence on associations between sodium intake and direct health outcomes has methodological flaws and limitations, when considered collectively, it indicates a positive relationship between higher levels of sodium intake and risk of cardiovascular disease (CVD). This evidence is consistent with existing evidence on blood pressure as a surrogate indicator of CVD risk.

**IOM Grade**: Grade not determined, outside the statement of task

**DGAC Grade**: Moderate

The 2015 DGAC concurs with the IOM conclusion that evidence from studies on direct health outcomes is inconsistent and insufficient to conclude that lowering sodium intakes below 2,300 mg per day either increases or decreases risk of CVD outcomes (including stroke and CVD mortality) or all-cause mortality in the general U.S. population.

**IOM Grade**: Grade not determined, outside the statement of task

**DGAC Grade**: Grade not assignable
Sodium and Cardiovascular Disease

Draft Conclusion Statement

The 2015 DGAC concurs with the National Heart, Lung, and Blood Institute (NHLBI), which concluded that a reduction in sodium intake by approximately 1,000 mg/day reduces CVD events by about 30 percent and that higher dietary sodium intake is associated with a greater risk for fatal and nonfatal stroke and CVD.

NHLBI Strength of Evidence: Low
DGAC Grade: Limited

The 2015 DGAC concurs with the NHLBI conclusion that evidence is not sufficient to determine the association between sodium intake and the development of heart failure.

NHLBI Strength of Evidence: Not assigned due to insufficient evidence
DGAC Grade: Not Assignable
Sodium and Cardiovascular Disease

Draft Implications Statement

- To reduce risk for CVD, high levels of sodium intake should be reduced and healthful U.S. dietary patterns should be combined with lower sodium intake if necessary.
- Because of the strong link between blood pressure and CVD, achievement of the recommendations to reduce sodium intake requires an emphasis on policies and population-based strategies. These include:
  - FDA taking action to modify the generally recognized as safe (GRAS) status of sodium
  - Food product reformulation to achieve progressive reduction in sodium content of foods
  - Incentives to encourage health systems to provide preventive nutrition services that encourage healthy dietary patterns
  - Public-private-community partnerships
- Also due to the strong link between blood pressure and CVD, strategies that complement policies and support consumers to make dietary behavior changes are also needed. These include:
  - Nutrition services and comprehensive lifestyle intervention by multi-disciplinary teams (AHA/ACC)
  - Enhanced nutrition labeling and point of purchase sodium information
  - Diet planning tools that include sodium as an area of focus
- Although the evidence on potassium and CVD is limited, we recognize that potassium intake is suboptimal and encourage increased potassium intake
What is the interrelationship of sodium and potassium on BP and CVD outcomes?

Existing Reports
Sodium and Potassium Source of Evidence

• NHLBI Lifestyle Interventions to Reduce Cardiovascular Risk: Systematic Evidence Review from the Lifestyle Work Group, Evidence Report
The DGAC concurs with the NHLBI Lifestyle Work Group that:

“Evidence is not sufficient to determine whether increasing dietary potassium intake lowers BP.”

**NHLBI Strength of Evidence:** *Not assigned due to insufficient evidence*  
**DGAC Grade:** *Not Assignable*

“In observational studies with appropriate adjustments (e.g., BP, sodium intake, etc.), higher dietary potassium intake is associated with lower risk for stroke.”

**NHLBI Strength of Evidence:** *Low*  
**DGAC Grade:** *Limited*

“Evidence is not sufficient to determine an association between dietary potassium intake and CHD, heart failure, and cardiovascular mortality.”

**NHLBI Strength of Evidence:** *Not assigned due to insufficient evidence*  
**DGAC Grade:** *Not Assignable*
Sodium Working Group

Cross-cutting Topics of Dietary Guidance and Public Health Importance

Reminder: DGAC members, please state your name before speaking.
# NEL Grading Rubric

<table>
<thead>
<tr>
<th>Elements</th>
<th>Grade I: Strong</th>
<th>Grade II: Moderate</th>
<th>Grade III: Limited</th>
<th>Grade IV: Grade Not Assignable</th>
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<tbody>
<tr>
<td><strong>Quality</strong> (as determined using the NEL BAT)</td>
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<tr>
<td>• Scientific rigor and validity</td>
<td>Studies of strong design</td>
<td>Studies of strong design with minor methodological concerns OR only studies of weaker study design for question</td>
<td>Studies of weak design for answering the question OR inconclusive findings due to design flaws, bias, or execution problems</td>
<td>Serious design flaws, bias, or execution problems across the body of evidence</td>
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<tr>
<td>• Consider study design and execution</td>
<td>Free from design flaws, bias, and execution problems</td>
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<tr>
<td></td>
<td>Several good quality studies</td>
<td>Several studies by independent investigators</td>
<td>Limited number of studies</td>
<td>Available studies do not directly answer the question OR no studies available</td>
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<td></td>
<td>Large number of subjects studied</td>
<td>Doubts about adequacy of sample size to avoid Type I and Type II error</td>
<td>Low number of subjects studied and/or inadequate sample size within studies</td>
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<td></td>
<td>Studies have sufficiently large sample size for adequate statistical power</td>
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<tr>
<td><strong>Quantity</strong></td>
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<tr>
<td>• Number of studies</td>
<td>Findings generally consistent in direction and size of effect or degree of association, and statistical significance with very minor exceptions</td>
<td>Some inconsistency in results across studies in direction and size of effect, degree of association, or statistical significance</td>
<td>Unexplained inconsistency among results from different studies</td>
<td>Independent variables and/or outcomes are too disparate to synthesize OR single small study unconfirmed by other studies</td>
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<tr>
<td>• Number of subjects in studies</td>
<td>Studied outcome relates directly to the question</td>
<td>Some study outcomes relate to the question indirectly</td>
<td>Most studied outcomes relate to the question indirectly</td>
<td>Studied outcomes relate to the question indirectly</td>
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<td></td>
<td>Size of effect is clinically meaningful</td>
<td>Some doubt about the clinical significance of the effect</td>
<td>Size of effect is small or lacks clinical significance</td>
<td>Size of effect cannot be determined</td>
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<tr>
<td><strong>Impact</strong></td>
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<td>• Directness of studied outcomes</td>
<td>Studied population, intervention and outcomes are free from serious doubts about generalizability</td>
<td>Minor doubts about generalizability</td>
<td>Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied</td>
<td>Highly unlikely that the studied population, intervention AND/OR outcomes are generalizable to the population of interest</td>
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<tr>
<td>• Magnitude of effect</td>
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<td><strong>Generalizability</strong> to the U.S. population of interest</td>
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