Considerations for a Sodium/Potassium DRI review

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DRI Nutrient Nomination Process

2013-2014 DRI Nutrient Review Nomination and Prioritization Process
Joint CAN/US Decision on Priority Nutrient(s) by Federal DRI Committees

- Significant, new, relevant data
- Relevance to public health
- Consideration of methodological issues

26 nominations

11 nutrients/nutrient groups evaluated

Prioritized nutrients
- Omega-3 fatty acids
- Sodium/Potassium
- Magnesium
- Vitamin E
Using Chronic Disease Endpoints for Setting DRIs

  - 26 nominations
  - 11 nutrients/nutrient groups evaluated
  - Prioritized nutrients: Omega-3 fatty acids, Sodium/Potassium, Magnesium, Vitamin E

Before a review, need guiding principles to use chronic disease endpoints for setting DRI values

- **2014-2016 Expert Working Group**: to develop options for using chronic disease endpoints for setting DRIs

- **2016-2017 NASEM Committee**: for Guiding Principles for Basing DRIs on Chronic Disease Values
Options for basing Dietary Reference Intakes (DRIs) on chronic disease endpoints: report from a joint US-/Canadian-sponsored working group


— Government directed-Expert working group – Dec 2014
— Workshop – March 2015
— Report - January 2017
— Critically evaluated key scientific issues involved in using CD endpoints for setting DRIs
— Provided options for whether and/or how CD endpoints can be used in the setting of DRI values.
— Not a consensus report and not recommendations

NASEM Guiding Principles for using CD Endpoints August 2017

• *Options Report* provided the foundation for developing principles for basing DRIs on chronic disease endpoints
Selection of sodium/potassium for review

2013-2014 DRI Nutrient Review Nomination and Prioritization Process
Joint Decision on Priority Nutrient(s) by Federal DRI Committees

2014-2016 Expert Working Group to develop options for using chronic disease endpoints for setting DRIs

2016-2017 NASEM Committee for Guiding Principles for Basing DRIs on Chronic Disease Values

2016-2017 AHRQ Systematic Review on Sodium and Potassium

Prioritized nutrients
Omega-3 fatty acids
Sodium/Potassium
Magnesium
Vitamin E

2017-2019 NASEM Committee for DRI Review of Sodium and Potassium

26 nominations
11 nutrients/nutrient groups evaluated
Sodium/potassium review

- AHRQ review available for public review in December/January
- Will be first DRI review to apply the new Guiding Principles

http://nationalacademies.org/hmd/activities/nutrition/reviewdriforsodiumandpotassium.aspx
Rationale – Sodium (Na) DRI Review

• New reports/evidence since 2004
  • NASEM (IOM) reports, 2010, 2013
    • NOT systematic reviews, NOT DRIs
  • Federally-sponsored evidence reviews¹,²
  • Other systematic reviews/studies

• Varying conclusions on implications
  • Optimal sodium intake levels
  • National strategies for sodium reduction

• Evaluation/potential use of observational evidence
  • Long-term sodium intake and chronic disease end points

Rationale – Potassium (K) DRI Review

• **Na/K inextricably-linked**
  - Biology
  - Physiology
  - Functional outcomes

• **Joint Na/K DRI review efficient**

• **Unclear health effects of different K forms/uses**
  - Food reformulation for sodium reduction (e.g., KCl, KHCO3)
  - Potassium salts sold as salt substitutes (e.g., KCl)
  - Addition as an ingredient in foods - other purposes
    (e.g., potassium benzoate, C7H5KO2, “to protect taste”)

Review of the Dietary Reference Intakes (DRI) for Sodium (Na) and Potassium (K)

“An ad hoc committee will undertake a study to assess current relevant data and update, as appropriate, the DRIs for sodium and potassium intake.”
Statement of Task

- Review evidence on indicators of inadequacy and potential effects of low sodium and potassium intakes and on indicators of excess intake.

- Consider systematic evidenced-based reviews and carefully document the approach used to select reviews and conduct any of its own literature reviews of original studies and systematic reviews.

- Review and describe, as appropriate, dietary sources (e.g., foods, beverages, supplements, antacids, and water).

- Update indicators on which to base DRIs and update the DRI values for each age, gender, and life stage group, using the DRI risk assessment approach and drawing on the DRI guiding principles for inclusion of chronic disease endpoints.

- Identify research gaps to address the uncertainties identified in the process of deriving the reference values and evaluating their public health implications.
Available evidence: AHRQ review

**Na Key Questions:**
- 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?
  - CVD and kidney disease morbidity and mortality and on total mortality?
- What is the **association** between dietary sodium intake and:
  - blood pressure?
  - CVD, CHD, stroke and kidney disease morbidity and mortality?
  - total mortality?

**K Key Questions**
- What is the **effect** of interventions to increase potassium intake on:
  - blood pressure and kidney stone formation?
  - CVD, and kidney disease morbidity and mortality, and total mortality?
- What is the **association** between potassium intake and:
  - blood pressure and kidney stone formation?
  - CVD, CHD, stroke and kidney disease morbidity and mortality?
  - total mortality?

https://effectivehealthcare.ahrq.gov/topics/sodium-potassium/
Available evidence: Other sources

- The committee can consider other relevant sources of evidence to support the review.

Taylor CL, 2008, Figure 2-2, Reproduced in NASEM Guiding Principles Report, 2017
Use of Chronic Disease Endpoints
Assumptions of the EAR/UL Approach

• “Essentiality” of the substance
• Evidence of causality and dose response
• Threshold for adequacy and adverse effects
• Relevant population
• Biomarkers on causal pathway
• Nature of the evidence dictates the absolute nature of the risk

• These don’t always apply to nutrient-chronic disease (CD) relationships
NASEM Guiding Principles for using CD Endpoints

1. How to determine whether specific levels of nutrient (or other food substances (NOFSs)) intake can ameliorate CD risk

2. How to develop DRIs based on CD outcomes
Selecting Indicators and Judging the Evidence

- **CD endpoint:**
  - Acceptable diagnostic criteria or qualified surrogate biomarkers on the causal pathway
  - Use only a single outcome indicator on causal pathway

- **Intake measurement:** Random and systematic errors/biases of exposure assessment considered

- **Intake-response indicators:** Use a single outcome indicator on the causal pathway

- **Judging the evidence:** Use GRADE system; causal and intake-response relationships based on *at least* moderate certainty

DRI Values Based on Chronic Disease Endpoints

• **CD DRI:**
  • A range rather than a single number; Eg. Range of beneficial (increased/decreased) intakes
  • If data support relationships with multiple diseases, a DRI could be set for each disease

• **UL:**
  • Not based on CD endpoints
  • If an increased CD Risk occurs above the traditional UL, no CD DRI is required because avoiding intakes >UL will avoid CD risk

• **Risk/benefit overlap:** Explicit and transparent descriptions of health risk/benefit should be described.

• **Extrapolation:** Only to similar populations

Sponsors

• United States
  • CDC
  • FDA
  • NIH
  • USDA

• Canada
  • Health Canada
  • Public Health Agency of Canada