

Activities to Reduce Sodium Intake in the US: Overview

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Conflict of Interest Disclosure

I have no conflict of interest to report in relation to this presentation (ILSI funded travel)

I retired from the Food & Drug Administration in 2006; I am not speaking on behalf of FDA

Tell the Story... so far

THEME 1 → Much will be ... and must be ... learned
THEME 2 → We are at first steps of an *organized* process

- ▶ The US Sodium "History" 1969+
- ▶ 2016 – FDA Voluntary Draft Sodium Reduction Targets for Food Industry
 - ▶ Development of Draft Targets
 - ▶ Technical Challenges
- ▶ Sorting the Science for Public Health
 - ▶ Questions about "too little" sodium
- ▶ Review of Sodium and Potassium Reference Values (DRI)
- ▶ Data and Research Gaps

Sodium History: Many Have Tried

US & Related Public Health Initiatives, 1969-2010

	1969-1970	1971-1972	1973-1974	1975-1976	1977-1978	1979-1980	1981-1982	1983-1984	1985-1986	1987-1988	1989-1990	1991-1992	1993-1994	1995-1996	1997-1998	1999-2000	2001-2002	2003-2004	2005-2006	2007-2008	2009-2010	
White House	R																					
U.S. Senate		R																				
HHS (Surgeon General)						R				R						I	I					
HHS (Public Health)						I																
HHS (NHLBI)		A											R	R/I	R			R	R	A		
USDA/HHS						R			R		R									R		
FDA				A		R	I/A	A					A	→							I/A	
USDA													A	A				I			A/I	
CDC																						I
State/Local Gov't-Non-Gov't Organization Partnership																					A	A
NRC/IOM	R					R					R										R	R
WHO											R								R			
AHA			R						R	R				R	R	R				R	R	
AMA						R														R	R	
ADA																					R	
APHA																	R					
AICR/WCRF															R						R	
WASH																					A	→
WHL/WASH																					A	→

A=action; I=initiative; R=recommendations

Sodium History

- ▶ 1969 White House Conference on Food & Nutrition
 - ▶ High sodium intake = national issue of concern
- ▶ Numerous initiatives followed
 - ▶ Federal government
 - ▶ State and local agencies
 - ▶ Scientific bodies and health organizations
 - ▶ Voluntary industry programs*
- ▶ 2005 Dietary reference value for sodium (IOM = Institute of Medicine)
 - ▶ 1,500 mg/d Adequate Intake
 - ▶ 2,300 mg/d Tolerable Upper Level
- ▶ 1980-2015 Dietary Guidelines for Americans: Sodium intake reduction

* Campbell's Soup, ConAgra, General Mills, Kraft, Nestle, Pepsi, Sara Lee, Unilever

Limited Success

- ▶ No Reduction in Intake 1969+:
 - ▶ Instructing consumers to select lower-sodium foods
 - ▶ Availability of “niche” products
 - ▶ Food industry voluntary efforts faced obstacles – lacked a “level playing ground”
- ▶ Challenges
 - ▶ Involves almost entire food system
 - ▶ Salt has desirable and useful purposes
 - ▶ “Preference” for “salt taste”
- ▶ What to Do?
 - ▶ IOM **2010**: *Strategies to Reduce Sodium Intake in the US*
 - ▶ Must involve entire food supply
 - ▶ Need level playing field
 - ▶ New York City *National Salt Reduction Initiative* as “laboratory”

Sodium: Where We Are Today

- ▶ **CURRENT INTAKE:** Average US Sodium Intake = ~ **3,400** mg/day
- ▶ **RECOMMENDED TARGET INTAKE:** **2,300** mg/day (2015 Dietary Guidelines for Americans)
- ▶ **SOURCES OF SODIUM in US:** Most (**over 70%**) from commercially processed and prepared foods -- not salt shaker
 - ▶ Difficult for individuals to control sodium intake
 - ▶ Despite some companies reducing sodium in certain foods, many foods continue to contribute large amounts of sodium
- ▶ **SCIENCE:**
 - ▶ Totality of evidence supports lowering sodium consumption from current levels

I. US FDA 2016 -- Draft Guidance

Voluntary Sodium Reduction Targets for Food Industry

- ▶ **Goal:** Facilitate dialogue with food industry
 - ▶ Level the playing field and establish common goals
 - ▶ Sequential; Gradual; Back-and-forth learning process
- ▶ **Focus:** Packaged and prepared foods (including restaurants)
 - ▶ *Not salt added by consumers; Not sodium naturally occurring*
- ▶ **Approach:** Establish Draft Sodium Targets for 150 food categories
- ▶ **Participation:** Voluntary participation by food industry
- ▶ **Assessment:** Monitoring of US food supply and food categories

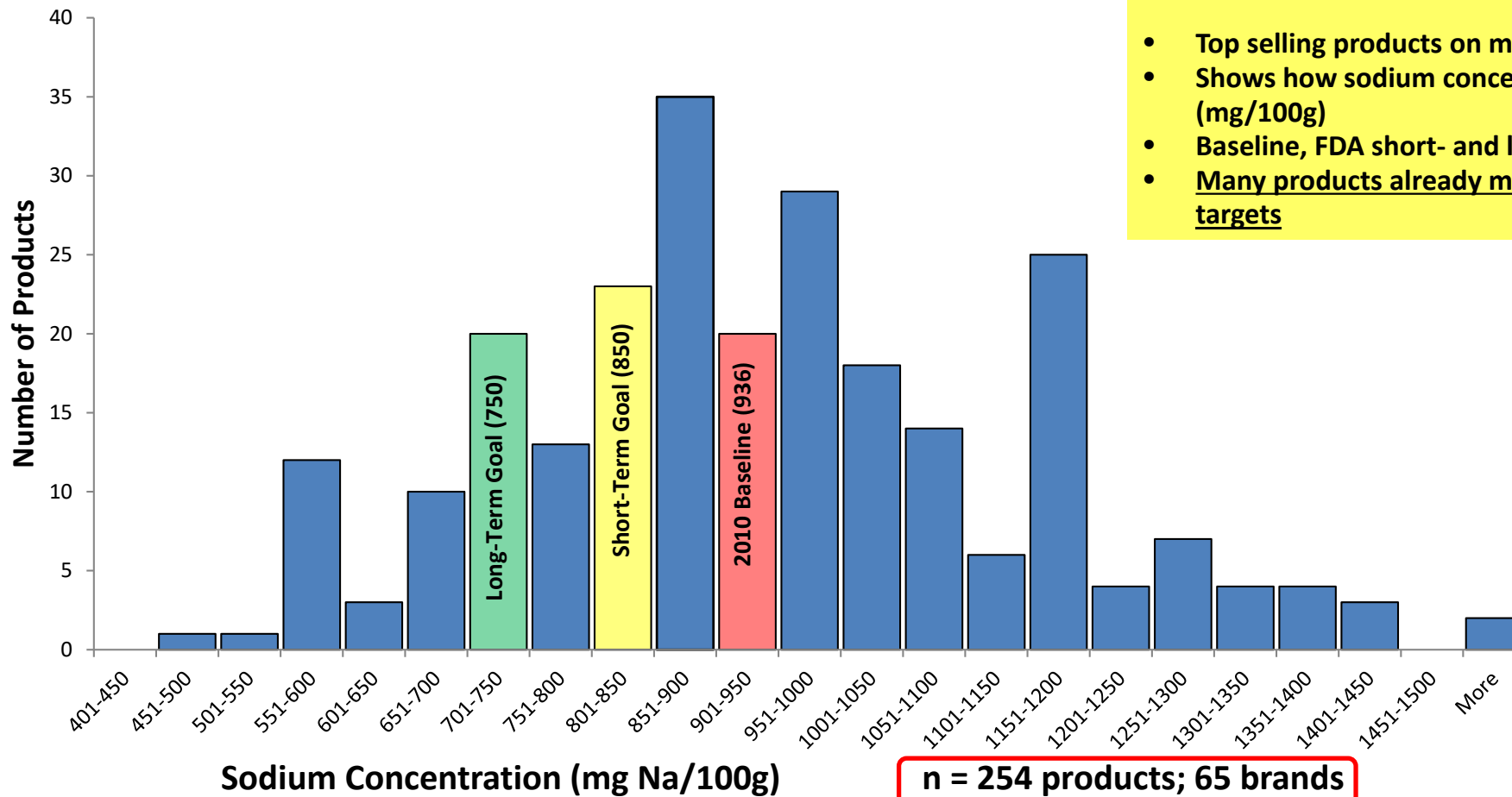
Development of Voluntary Draft Sodium Targets

- ▶ On basis of 150 food categories
- ▶ Baseline establishes starting point for each food category
 - ▶ Estimates of current level of sodium in the food category
 - ▶ Food label and restaurant data – 2010
 - ▶ Average weighted by sales volume – best sellers
- ▶ Draft targets for each food category
 - ▶ Used food intake predictions from model based on national food intake surveys mapped to sodium food categories
 - ▶ 2-year Target: To support 3,000 mg/d population average
 - ▶ Exploratory and informative
 - ▶ 10-year Target: To support 2,300 mg/d population average
 - ▶ Also, provide an “upper bound” for each category

Examples for 5 Snack Food Categories

Examples of Food Categories in Major Category " <u>Snacks</u> "	Baseline mg/100g (pkg)	2-year Target mg/100g	10-year Target mg/100g	Upper Bound mg/100g 2 yr\10yr
Unflavored potato & vegetable chips	585	500	250	650 \ 480
Flavored potato & vegetable chips	774	630	380	830 \ 630
Unflavored grain chips	438	390	300	510 \ 410
Flavored grain chips	674	590	450	750 \ 610
Puffed corn snacks	1075	870	550	1190 \ 900

Sample Category: Precooked Sausage



- Top selling products on market
- Shows how sodium concentrations compare (mg/100g)
- Baseline, FDA short- and long-term targets overlaid
- Many products already meeting short- and long-term targets

Note: Data on the number of products was obtained from Nielsen. Sodium concentration values were calculated from sodium values on nutrition labels obtained from Gladson and Mintel. <https://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm253316.htm>

Manufacturer How To

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- ▶ Food manufacturer may find it helpful to consider:
 - ▶ “Is my product below the upper bound?”
 - ▶ “Can my products get closer to the draft targets? Which ones and how?”
 - ▶ “Does my product contribute to overall sodium reduction?”
- ▶ Draft voluntary guidance does NOT recommend specific methods or technologies
 - ▶ Dependent upon manufacturers’ efforts and innovations
 - ▶ Build on existing methods and technologies; pursue new as needed
- ▶ Gradual, efficient, sustainable voluntary reduction
 - ▶ Seeking dialogue and innovation

Industry Comments to Draft Guidance

- ▶ ~200 comments in 2016
- ▶ Some categories should be adjusted / methodology unclear
- ▶ 2 years too short, extend to 4 years
 - ▶ Technological challenges, need time for new technologies
- ▶ FDA should consider a process to address marketplace shifts
- ▶ Innovation takes time, resources, and collaboration

Industry approach to reducing sodium	Factors relevant to reducing sodium
<ol style="list-style-type: none">1. Identify sodium target2. Deconstruct food into components3. Identify sources of sodium in each ingredient4. Determine functional role of sodium-containing ingredients5. Reformulate and test prototype6. Conduct sensory testing7. Conduct processing validation for food safety8. Conduct shelf-life testing	<ul style="list-style-type: none">• Controlling bacterial growth• Controlling spoilage, shelf-life• Conducting appropriate process validation studies• Finding appropriate salt substitutes• Maintaining product texture & color• Promoting gluten development• Controlling and preserving flavor interactions• Containing costs

Will Reduction to Targets Have Impact?

Modeled changes in US sodium intake from reducing sodium concentrations of commercially processed and prepared foods to meet voluntary standards established in North America: NHANES

Mary E Cogswell,¹ Sheena M Patel,¹ Keming Yuan,¹ Cathleen Gillespie,¹ WenYen Juan,² Christine J Curtis,³ Michel Vigneault,⁴ Jenifer Clapp,³ Paula Roach,⁴ Alanna Moshfegh,⁵ Jaspreet Ahuja,⁶ Pamela Pehrsson,⁶ Lauren Brookmire,² and Robert Merritt¹

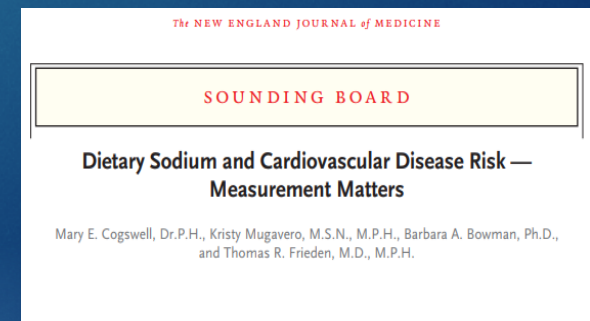
- ▶ Meaningful reductions could occur with widespread implementation
- ▶ Based on 2-year targets:
 - ▶ Intake Estimates:
 - ▶ 3,417 mg/d → 2,802 – 2,719 mg/d (persons >1y)
 - ▶ % Exceeding 2,300 mg/d:
 - ▶ 88% → 71% (persons >19+y)

II. Sorting the Science for Public Health

- ▶ **(1) Science for Population-based Public Health Action**
 - ▶ ↓Sodium Intake → ↓High Blood Pressure
 - ▶ High Blood Pressure = Accepted predictor of risk for health outcomes
 - ▶ [? Direct effect of sodium intake on measurable health outcomes ?]

- ▶ **(2) Major focus: Moving current intake toward 2,300 mg/d**

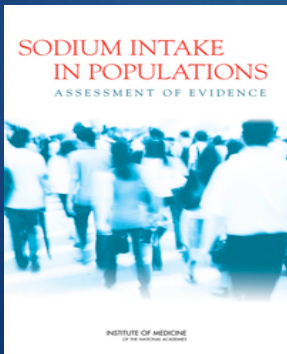
- ▶ **(3) Emerging Issue: Effect of Intakes below 2,300 mg/d [1,500 mg/d]**
 - ▶ J-shape risk curve for intake vs CVD
 - ▶ CVD Risk for patients with congestive heart failure
 - ▶ CVD Risk for 55y+ High blood pressure
 - ▶ Sodium 'set point' or 'appetite' (3600-3700 mg/d)
 - ▶ Conclusions controversial -- ?confounded data and systematic bias



II. Sorting the Science for Public Health

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- ▶ (4) IOM Report 2013 “Sodium Intake In Populations: Assessment of Evidence”
 - ▶ Task: Compare safety and efficacy of sodium intakes in range of 1,500 to 2,300 mg/d
 - ▶ On basis of health outcomes, not blood pressure (more controversy)
 - ▶ Conclusion: Data did not allow question to be answered
 - ▶ Studies on health outcomes inconsistent and insufficient
 - ▶ Unclear whether going **below 2,300** mg/d increases OR decreases risk of CVD, stroke, all-cause mortality
 - ▶ Data cannot be used to justify 1,500 mg/d for general population
 - ▶ Likewise, risk cannot be demonstrated generally for intakes at 1,500 mg/d
 - ▶ Diseased Sub-groups (congestive heart failure, kidney disease, diabetes) **may** have risk with these lower intakes
 - ▶ Too many inconsistencies in data to be certain
 - ▶ Noted: Evidence for direct health outcomes is consistent with population-based efforts to lower sodium intake **below 3,400** mg/d



III. Reviewing Sodium Reference Values (US & Canada)

- ▶ 2005 Sodium Reference Value = “Tolerable Upper Level” 2,300 mg/d
“Adequate Intake” 1,500 mg/d
- ▶ Request National Academies* **convene committee** to review and update as necessary reference values for sodium & potassium
 - ▶ Initiate review in early Fall 2017 - Final report within 14 months
 - ▶ Expectation: Reference values in context of reduction of chronic disease
- ▶ AHRQ** conducting **systematic review of sodium & potassium** to assist committee’s evaluation – objective array of data indicating quality
 - ▶ Complete by Fall 2017
 - ▶ “TOTALITY OF THE EVIDENCE”
 - ▶ Adults & Children; Effects on blood pressure and health outcomes

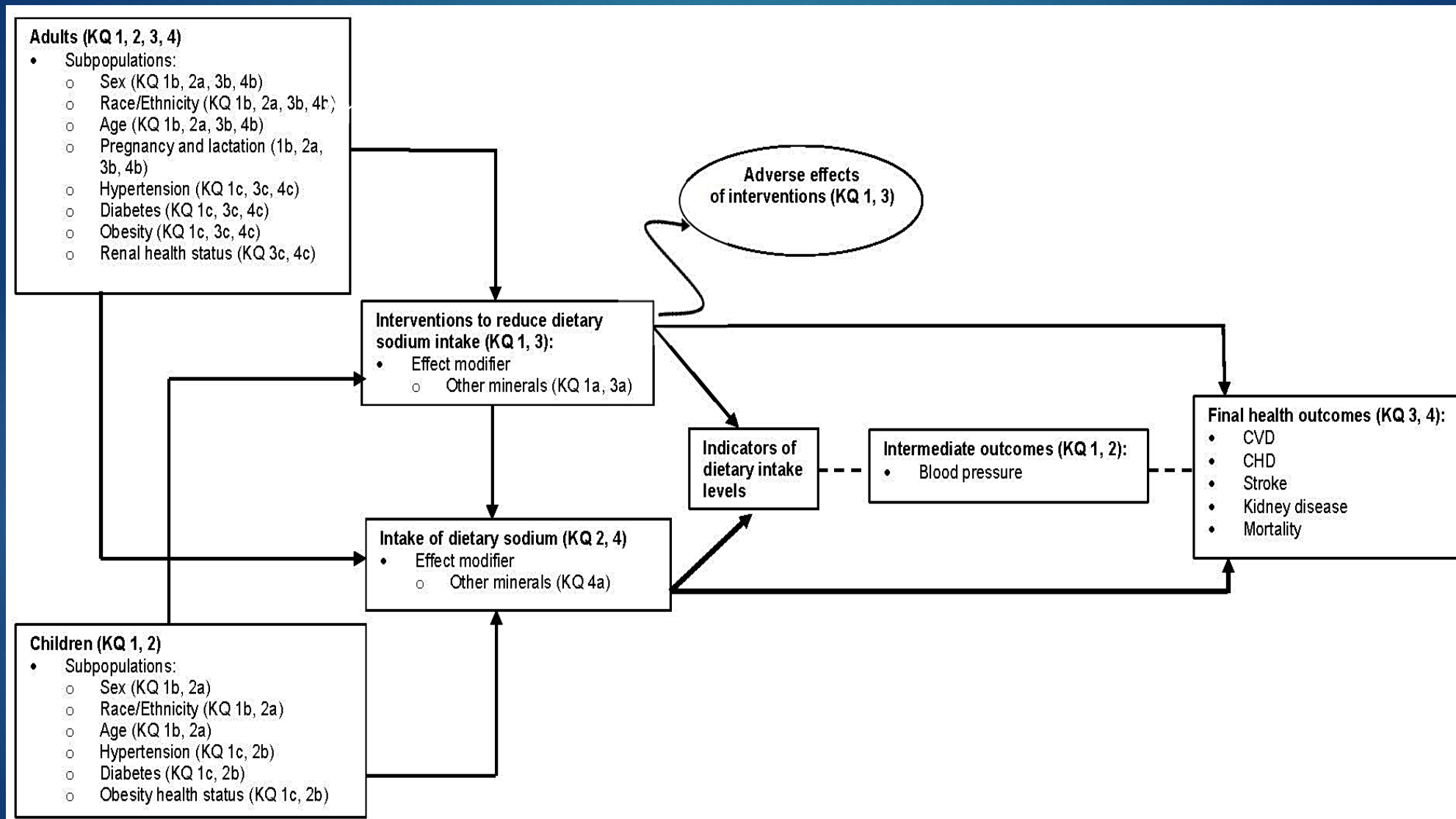


* Health & Medicine Division of The National Academies (formerly IOM)

** AHRQ = Agency for Healthcare Research & Quality, US HHS Dept
<https://effectivehealthcare.ahrq.gov/topics/sodium-potassium/research-protocol/>

Analytic Framework for AHRQ Systematic Review 2017

“Effects of Dietary Sodium and Potassium Intake on Chronic Disease Outcomes and Related Risk Factors”



IV. Research Needs Moving Forward

- ▶ **Better understanding of salt taste***
 - ▶ How does it develop? Relevance of early exposure?
 - ▶ Biological mechanisms? How do preferences change?
 - ▶ Differences between gradual reduction and abrupt reduction?
 - ▶ Nature of compensation and “adding salt back to food”?
 - ▶ Measurement of changes in salt preference
- ▶ **Sodium reduction in food**
 - ▶ New methods and technologies to achieve palatability
 - ▶ Develop processing methods to create similar physical properties viz sodium → salt substitutes
 - ▶ Clarify minimal levels of sodium to ensure safety of product
- ▶ **Interface with consumer:** Research on communication, messaging, acceptance
- ▶ **Sodium Intake:** Measurement methodologies – *Until this information can be accurately obtained, it is difficult to move forward on the questions of benefits and harms*
- ▶ **Sodium interaction with diet** Today’s program
 - ▶ Growing interest in other dietary factors: Dietary patterns related to calcium, magnesium, potassium; Na:K ratios

* From Gary Beauchamp, Monell Chemical Senses Center, 2017

Questions?

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NEXT

- >Sodium Activities in the Americas
- >Sodium and Potassium in the Diet: Intake and Ratios
- <Modeling Relationship of Sodium and Other Minerals



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