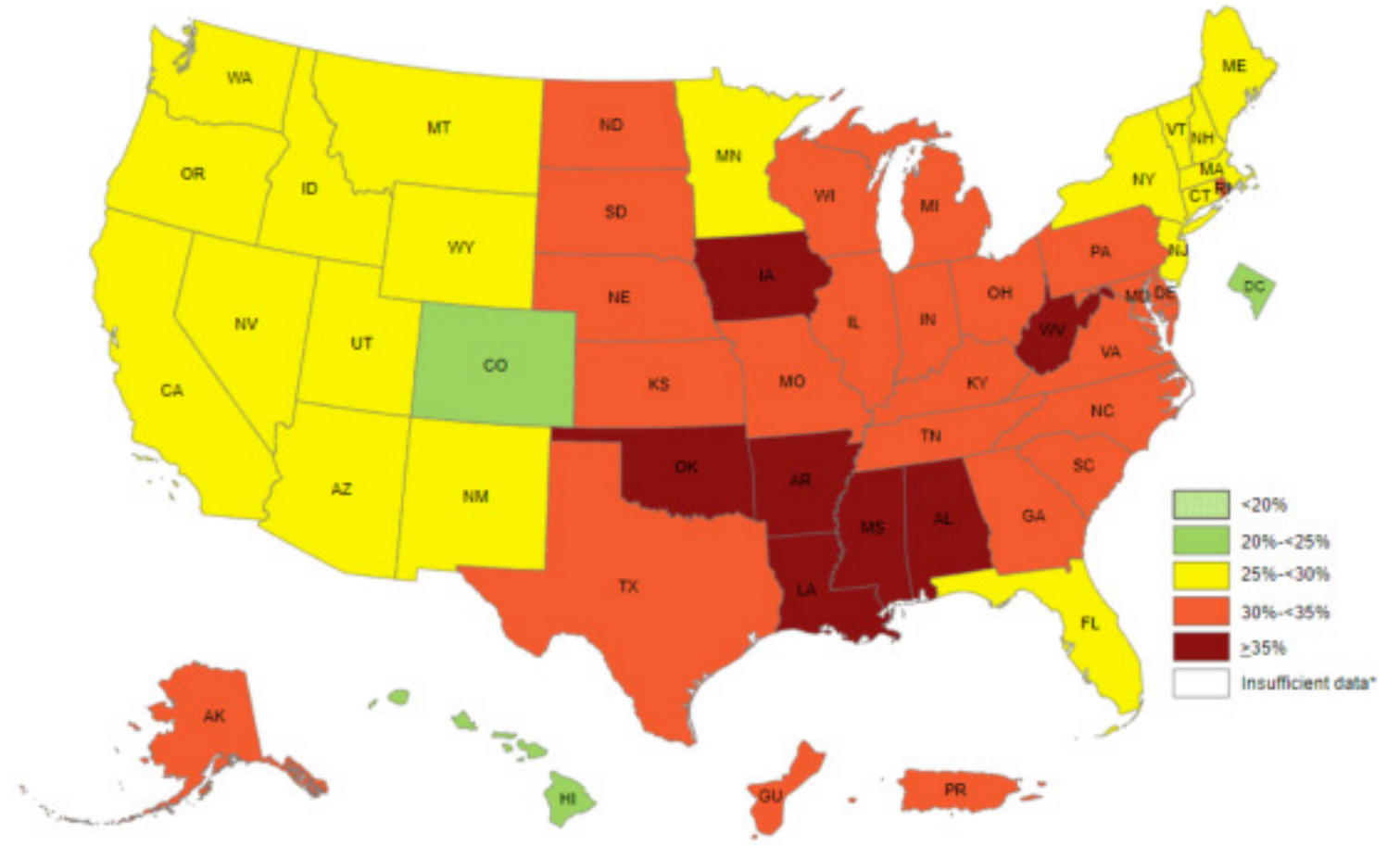


# PRACTICALITY OF THE USAGE OF MEDICAL FOODS TO ASSURE COMPLIANCE & MEET NUTRITIONAL REQUIREMENTS: HEALTHCARE PROVIDERS PERSPECTIVES ON THREE DISEASE STATES...**ESRD**

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Chief Science Officer  
Research, International and Scientific Affairs  
Academy of Nutrition and Dietetics

# OBESITY RATES 2017

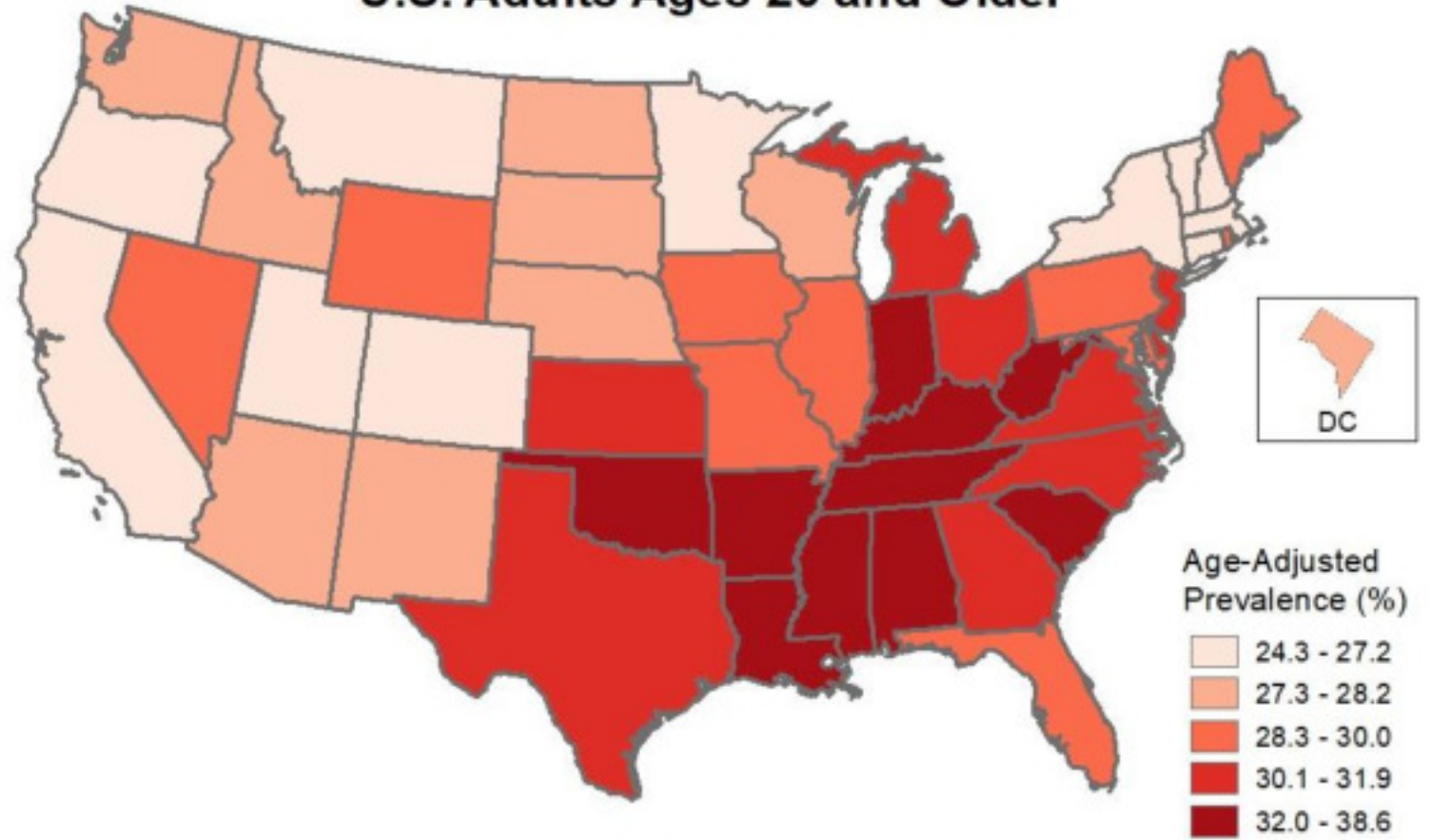


Source: [Behavioral Risk Factor Surveillance System](#)

\*Sample size <50 or the relative standard error (dividing the standard error by the prevalence) ≥ 30%

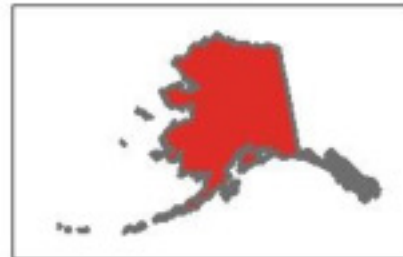
# HYPERTENSION

## Prevalence of Hypertension, 2017 U.S. Adults Ages 20 and Older



Data Source:  
BRFSS - Behavioral Risk Factor Surveillance System, CDC.

Self-report: "Have you ever been told by a doctor, nurse, or other health care professional that you have high blood pressure?"  
Excludes women who reported being told only during pregnancy and respondents who reported they had been told that their blood pressure was borderline high or pre-hypertensive.





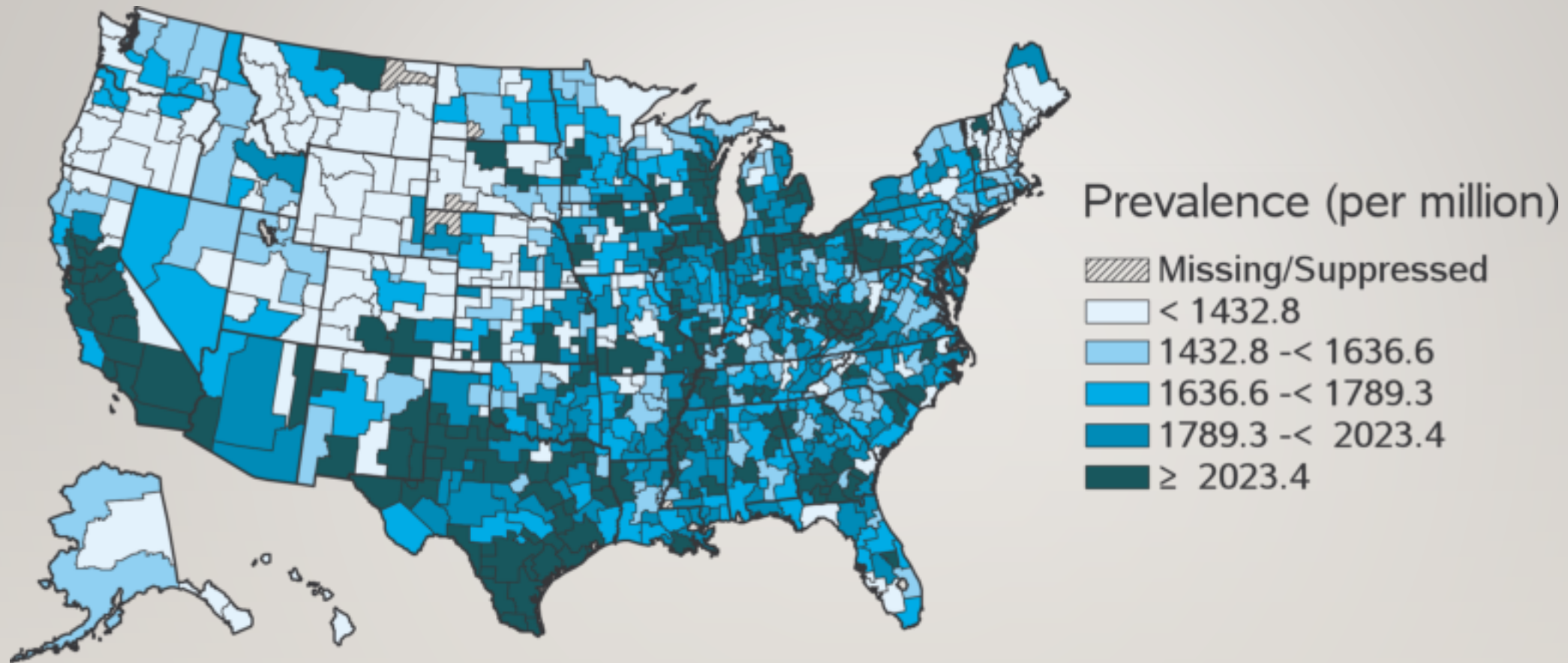
# Global Prevalence of Chronic Kidney Disease Among Adults Aged 65+



Source: <http://thelancet.com/pb/assets/raw/pbassets/raw/lanet/campaigns/kidney/chronic-kidney-disease-facts.jpg>  
99-18-32856-01-76 | © Siemens Healthcare Diagnostics Inc., 2018

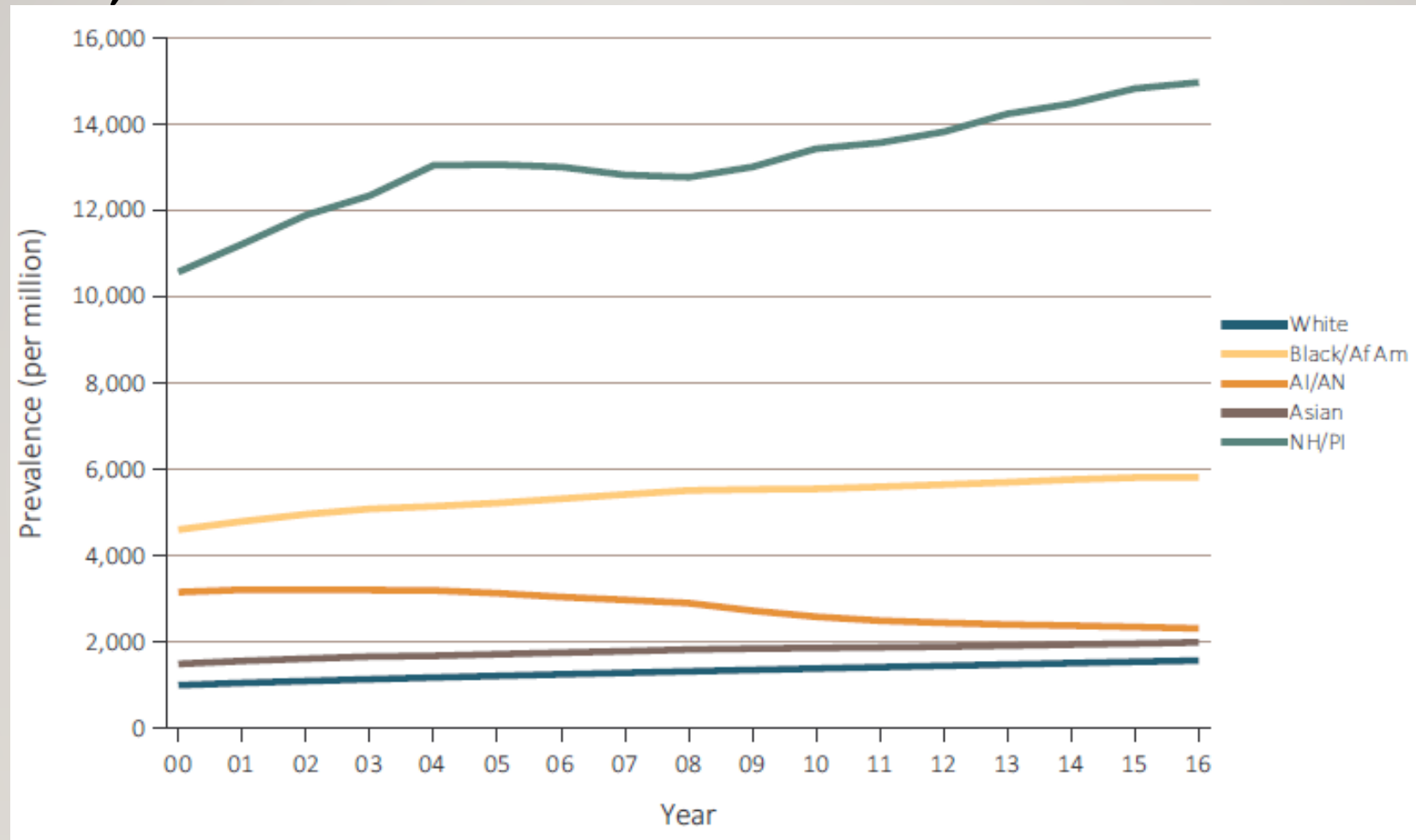
GLOBAL  
PREVALENCE

# MAP OF THE STANDARDIZED PREVALENCE OF ESRD IN THE U.S. POPULATION, 2012-2016\*



*Data Source: Special analyses, USRDS ESRD Database. Standardized to the age-sex-race distribution of the 2011 US population. Special analyses exclude unknown age, sex, HSA and unknown/other race. \*Four Health Service Areas were suppressed because the ratio of crude rate to standardized rate or standardized rate to crude rate was greater than 3. Values for cells with 10 or fewer patients are suppressed. Abbreviation: ESRD, end-stage renal disease.*

# TRENDS IN THE STANDARDIZED PREVALENCE OF ESRD, BY RACE, IN THE U.S. POPULATION, 2000-2016

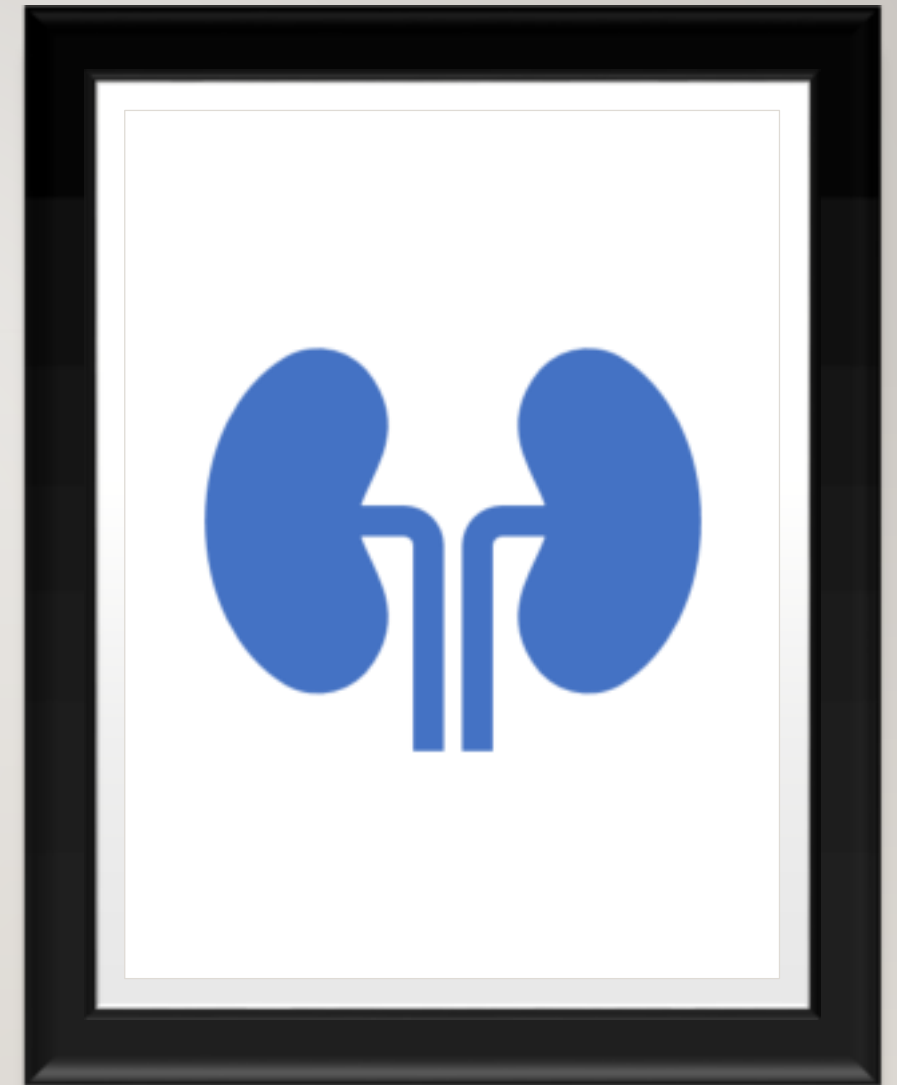


Data Source: Special analyses, USRDS ESRD Database. Point prevalence on December 31 of each year. Standardized to the age-sex distribution of the 2011 US population. Special analyses exclude unknown age, sex, and unknown/other race. Abbreviations NH/PI: Native Hawaiian/Pacific Islander; AI/AN: Americans Indian/Alaska Natives; ESRD, end-stage renal disease.

# IS THERE EVIDENCE THAT THE QUALITY OF DIETS OF PATIENTS WITH CKD IS POOR?

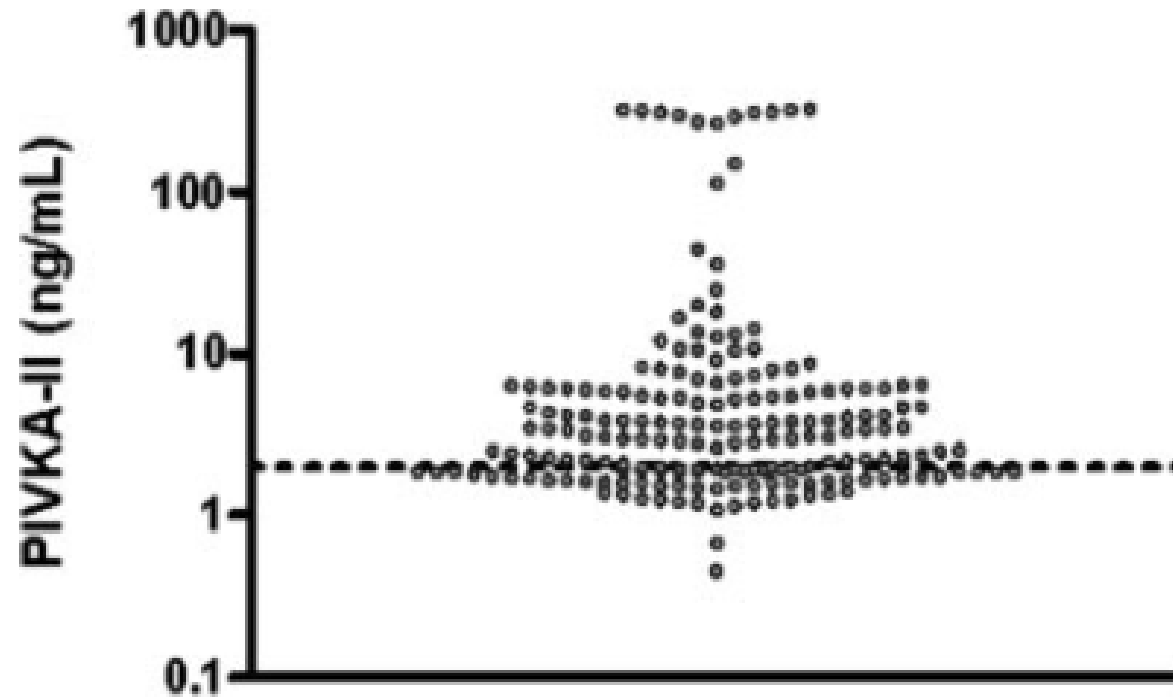
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8/30/2019





# EVIDENCE FOR DEFICIENCY IN HD:VITAMIN K



**Figure 1.** Dialysis patients are deficient in vitamin K. Distribution of PIVKA-II in hemodialysis patients. According to the upper limit of the normal range (dotted line, 2 ng/ml<sup>30</sup>), 64% of dialysis patients display vitamin K deficiency (as indicated by increased PIVKA-II levels).



# EVIDENCE FOR DEFICIENCY IN HD: INTERVENTION STUDY WITH VITAMIN K(2)

Table 2. Circulating dephosphorylated-uncarboxylated-MGP (pmol/L)

	Treatment group (MK-7) (N = 165)		
	360 µg (n = 59)	720 µg (n = 53)	1080 µg (n = 53)
Baseline	2872 (123–7539)	2897 (500–7567)	3206 (857–7337)
After treatment	2306 (105–6618)	1935 (130–6132)	1719 (116–6047)
% Change	17 <sup>a</sup>	33 <sup>a</sup>	46 <sup>a</sup>

Circulating dephosphorylated-uncarboxylated MGP values are presented as mean (range).

<sup>a</sup>P < 0.001.

Linear dose response of dp-uncarboxylated MGP to Vitamin K

Caluwe et al NDT 2014

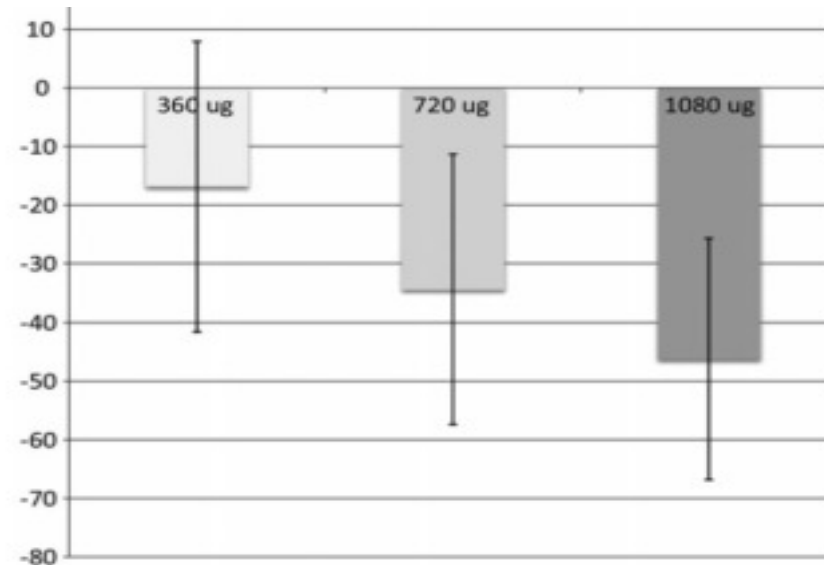
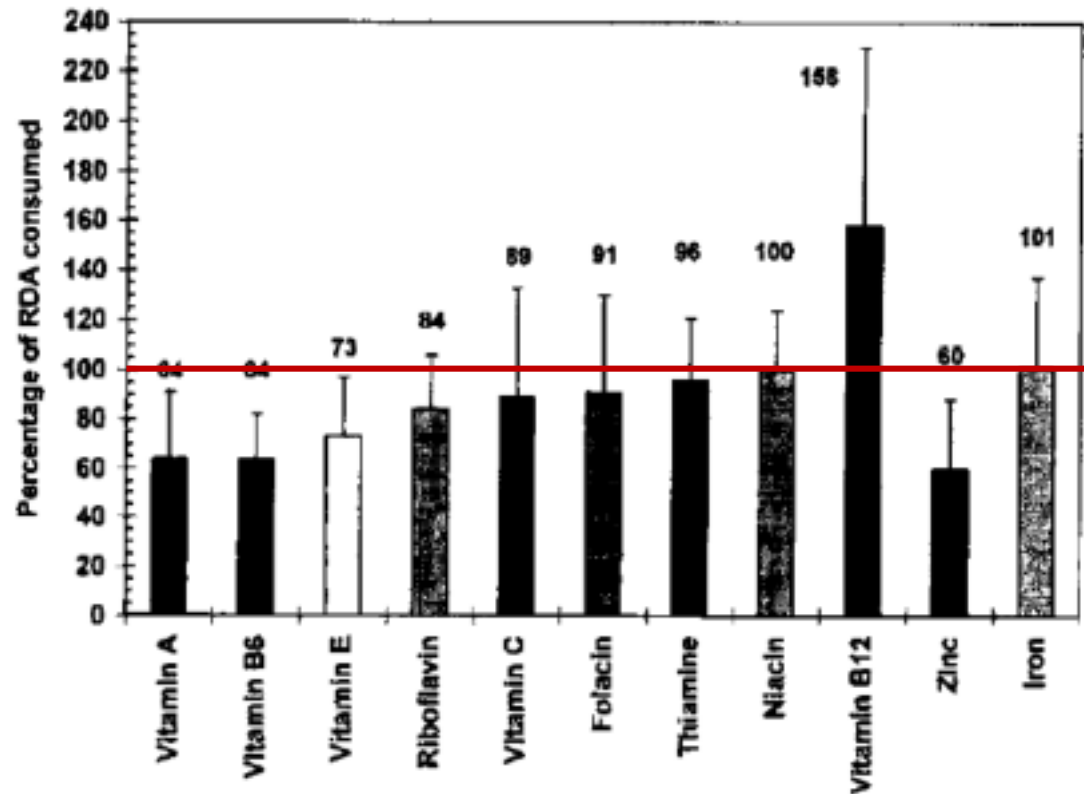


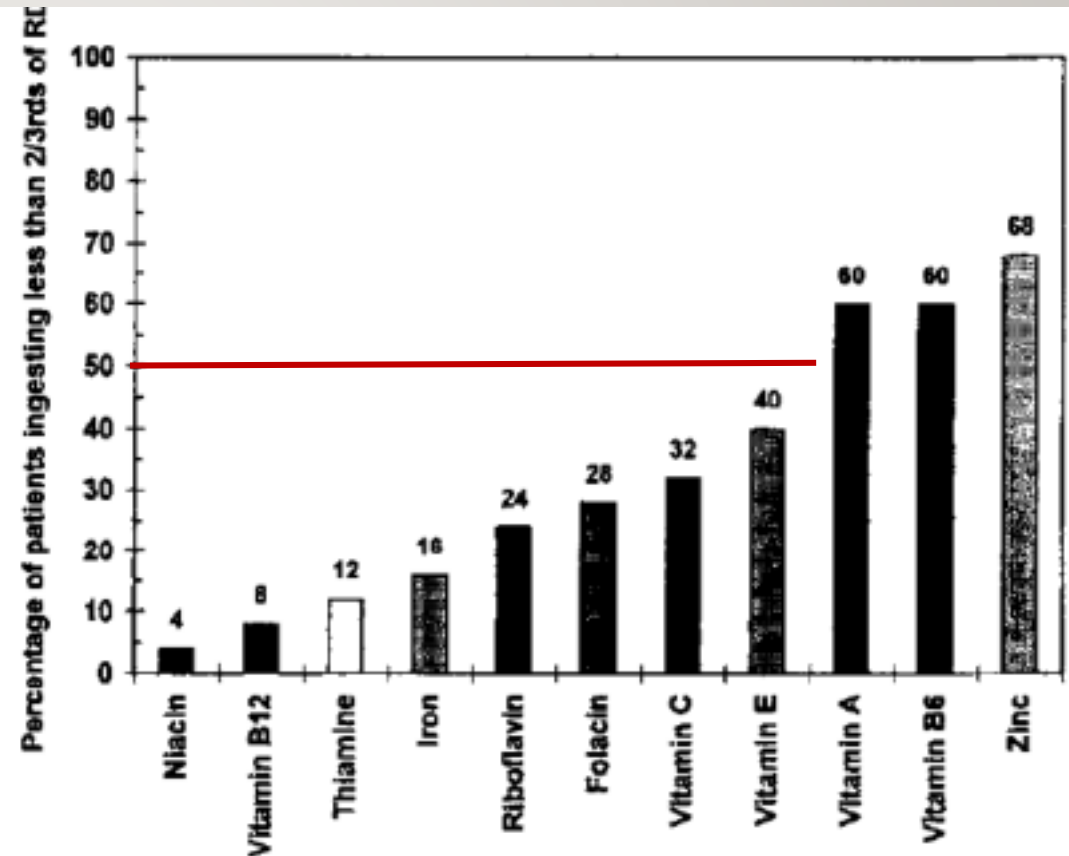
FIGURE 2: Relative decrease (%) in circulating dp-uc-MGP levels after 8 weeks of supplementation with different doses of MK-7. Data represent mean ± standard deviation. The decrease was statistically significant in every treatment group (P < 0.001).

## Intake of Vitamins and Minerals in Stable Hemodialysis Patients as Determined by 9-Day Food Records

Michael V. Rocco, MD, MS,\* Diane Poole, RD,† Patsy Poindexter, LPN,‡  
Jean Jordan, LPN,§ and John M. Burkart, MD,¶



**Figure 1.** Percentage of RDA consumed by chronic hemodialysis patients for selected vitamins and minerals.



**Figure 2.** Percent of patients consuming less than two thirds of the RDA for selected vitamins and minerals.

**Table 2. Daily Intake of Macronutrients and Proportion of Individuals Within Recommended Targets**

Macronutrients	Daily Intake	N (%) Within Target Values		Daily Recommendations	
Calorie density, kcal/kg*†	24.8 ± 7.5	10 (11)*	14 (15)†	30-35 kcal/kg*	30-40 kcal/kg†
Protein density, g/kg*†	1.1 ± 0.4	32 (41)*	49 (54)†	≥1.2 g/kg*	≥1.1 g/kg†
Total fat‡§, g	68.8 ± 29.3		43 (47)		25%-35% energy
Saturated fat	22.6 ± 10.9		7 (8)		<7% energy
MUFA	28.9 ± 12.3		14 (15)		>20% energy
PUFA	12 ± 8.2		10 (11)		>10% energy
Cholesterol‡§, mg	257 ± 127		39 (43)		<200 mg
Carbohydrates§, g	189 ± 70		76 (84.5)		≥130 g
Fiber§, g	16.6 ± 6.2		21 (22)		>20 g

Only parameter with >50% meeting = carbohydrates



**Table 3. Daily Intake of Micronutrients and Proportion of Individuals Within Recommended Targets**

Macronutrients	Daily Intake, mg	N (%) Within Target Values	Daily Recommendations
<b>Minerals*</b>			
Phosphorus	1104 ± 316	18 (20)	800-1000 mg
Calcium	710 ± 268	31 (34)	500-800 mg
Sodium	2308 ± 910	15 (15)	2000-2300 mg
Potassium	2609 ± 716	43 (47)	1950-2730 mg
Iron	9.1 ± 3.1	90 (99)	8 mg ♂/15 mg ♀
Magnesium†	230 ± 66	2 (2)	19-30 y (400 mg ♂/310 mg ♀)
			>30 y (420 mg ♂/320 mg ♀)
Zinc	7 ± 2.5	89 (98)	10-15 mg ♂/8-12 mg ♀
<b>Hydrosoluble vitamins†</b>			
Thiamine (B <sub>1</sub> )	1.1 ± 0.4	26 (29)	≥1.3 mg ♂/≥1.1 mg ♀
Riboflavin (B <sub>2</sub> )	1.5 ± 0.5	11 (12)	19-50 y (≥1.3 mg)
			>50 y (≥1.7 mg ♂/≥1.5 mg ♀)
Niacin (B <sub>3</sub> )	16.1 ± 6.5	41 (45)	≥16 mg ♂/≥14 mg ♀
Folate (B <sub>9</sub> )	180 ± 74	1 (1.1)	≥400 µg
Cobalamin (B <sub>12</sub> )	4.7 ± 6.3	66 (75.5)	≥2.4 µg
Ascorbic acid (C)	59 ± 41	17 (19)	≥90 mg ♂/≥75 mg ♀
<b>Liposoluble vitamins†</b>			
Vitamin A	771 ± 909	21 (23)	≥900 µg RAE
			♂/≥700 µg RAE ♀
Cholecalciferol (D)	1.5 ± 1.7	0 (0)	19-50 y 5 µg
			51-70 y 10 µg
			>70 y 15 µg
α-Tocopherol (E)	7.4 ± 3.5	2 (2)	≥15 mg

Nutrients that >50% are meeting = iron, zinc and B12





# DIET/NUTRIENT ADEQUACY KEY POINTS

## ➤ Deficiency has been identified and replenishment is needed

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- ✓ Evidence exists that certain nutrients have been documented to be either suboptimal or frankly deficient in patients with CKD

## ➤ Diet is sub-optimal to support adequacy of key nutrients

- ✓ Evidence exists that a substantial percentage of patients with CKD consume a diet that is low in multiple nutrients (macro and micro)

## ➤ Clinical condition causes an increased need in single or multiple nutrients

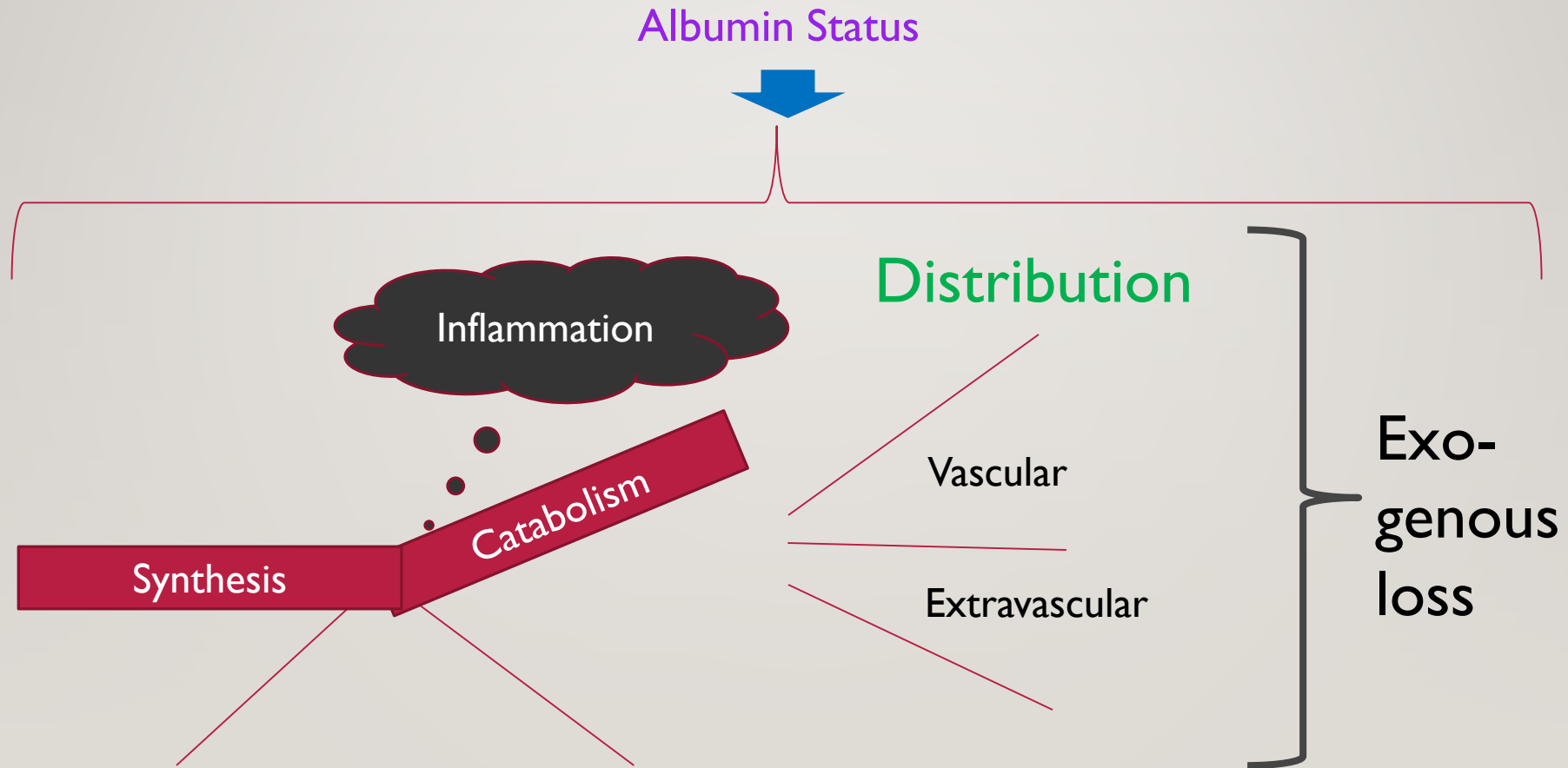
- ✓ Evidence exists that the medical condition of chronic kidney disease alters the metabolism of at least one nutrient leading to increased needs



# INTERVENTIONS WITH ONS...CONSIDERATION AND EFFECTIVENESS

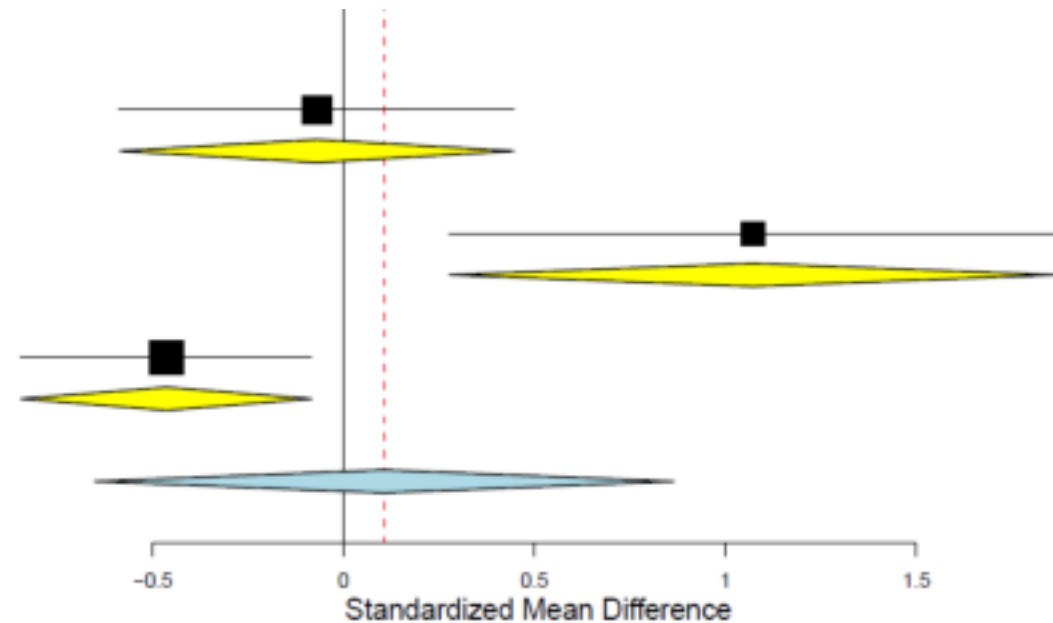


# MOST CURRENT STUDIES, USED ALBUMIN STATUS AS THE CRITERIA FOR MALNUTRITION



# Protein Intake as an outcome with ONS Interventions

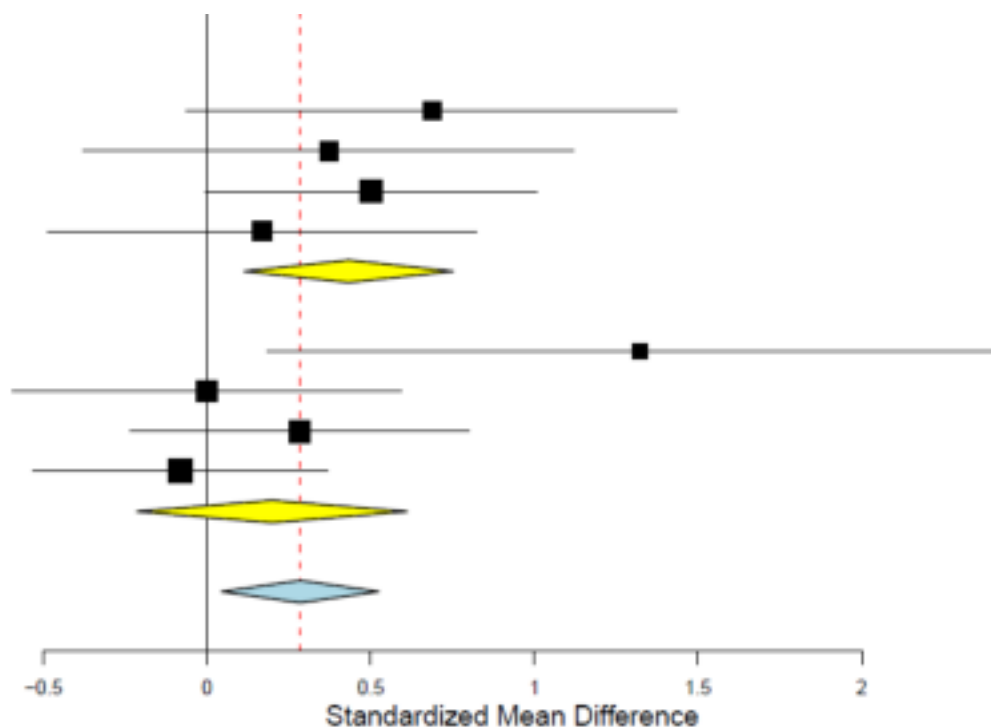
Studies	Estimate (95% C.I.)
Fouque-Protein	-0.070 (-0.586, 0.447)
Subgroup Protein Energy (I <sup>2</sup> =NA , P=NA)	-0.070 (-0.586, 0.447)
Gonzalez-Espinoza-Protein	1.071 (0.277, 1.865)
Subgroup Protein (I <sup>2</sup> =NA , P=NA)	1.071 (0.277, 1.865)
Wu-Protein	-0.464 (-0.844, -0.083)
Subgroup Energy (I <sup>2</sup> =NA , P=NA)	-0.464 (-0.844, -0.083)
Overall (I <sup>2</sup> =83.05 % , P=0.003)	0.107 (-0.652, 0.865)



Statistically significant

# PNA/PCR Outcome with Oral Nutrition Supplement (ONS) Interventions

Studies	Estimate (95% C.I.)
Bolasco-ePCR	0.687 (-0.063, 1.436)
Gonzalez-Espinoza-nPNA	0.372 (-0.377, 1.121)
Moretti Group I-nPCR	0.502 (-0.003, 1.008)
Moretti Group II-nPCR	0.168 (-0.486, 0.823)
<b>Subgroup Protein (I<sup>2</sup>=0 % , P=0.761)</b>	<b>0.433 (0.113, 0.752)</b>
Calegari-PCR	1.322 (0.186, 2.458)
Teixido-Planas-nPNA	0.000 (-0.593, 0.593)
Sezer-nPCR	0.283 (-0.234, 0.800)
Fouque-nPNA	-0.082 (-0.534, 0.370)
<b>Subgroup Protein Energy (I<sup>2</sup>=46.37 % , P=0.133)</b>	<b>0.199 (-0.215, 0.612)</b>
<b>Overall (I<sup>2</sup>=18.5 % , P=0.284)</b>	<b>0.285 (0.044, 0.525)</b>

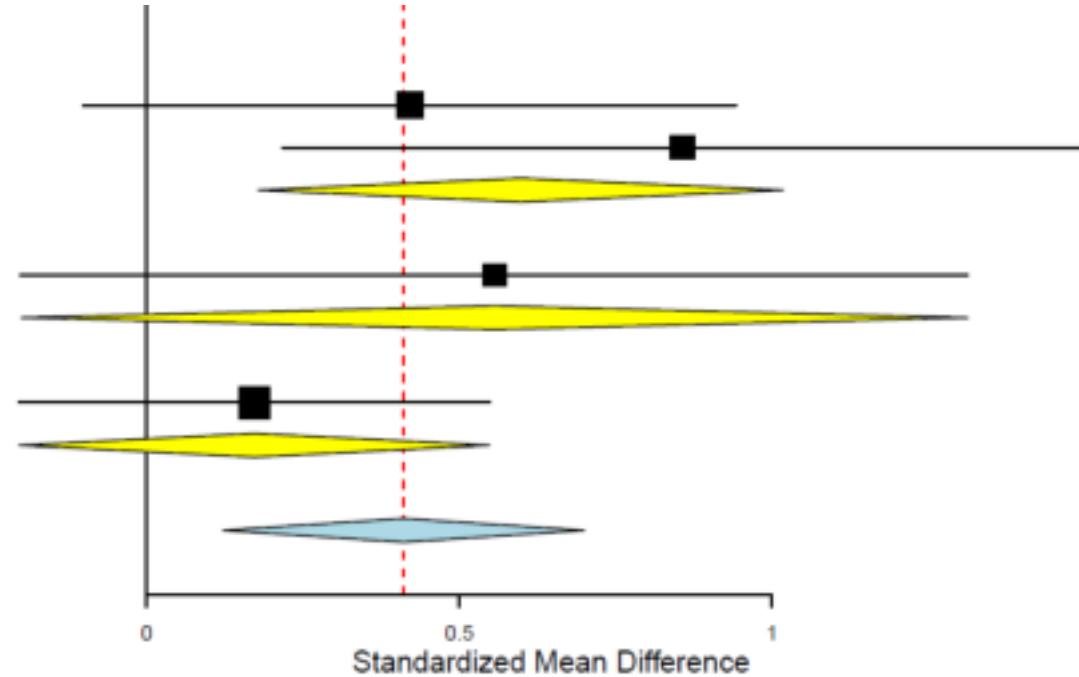


Not statistically significant



## Energy Intake by Population and ONS

Studies	Estimate (95% C.I.)
Fouque-Energy	0.421 (-0.101, 0.943)
Hung-Energy	0.857 (0.217, 1.497)
<b>Subgroup HD (I<sup>2</sup>=6.75 % , P=0.300)</b>	<b>0.598 (0.178, 1.018)</b>
Gonzalez-Espinoza-Energy	0.556 (-0.200, 1.313)
<b>Subgroup PD (I<sup>2</sup>=NA , P=NA)</b>	<b>0.556 (-0.200, 1.313)</b>
Wu-Energy	0.172 (-0.204, 0.549)
<b>Subgroup Pre-dialysis (I<sup>2</sup>=NA , P=NA)</b>	<b>0.172 (-0.204, 0.549)</b>
<b>Overall (I<sup>2</sup>=15.09 % , P=0.316)</b>	<b>0.411 (0.122, 0.700)</b>

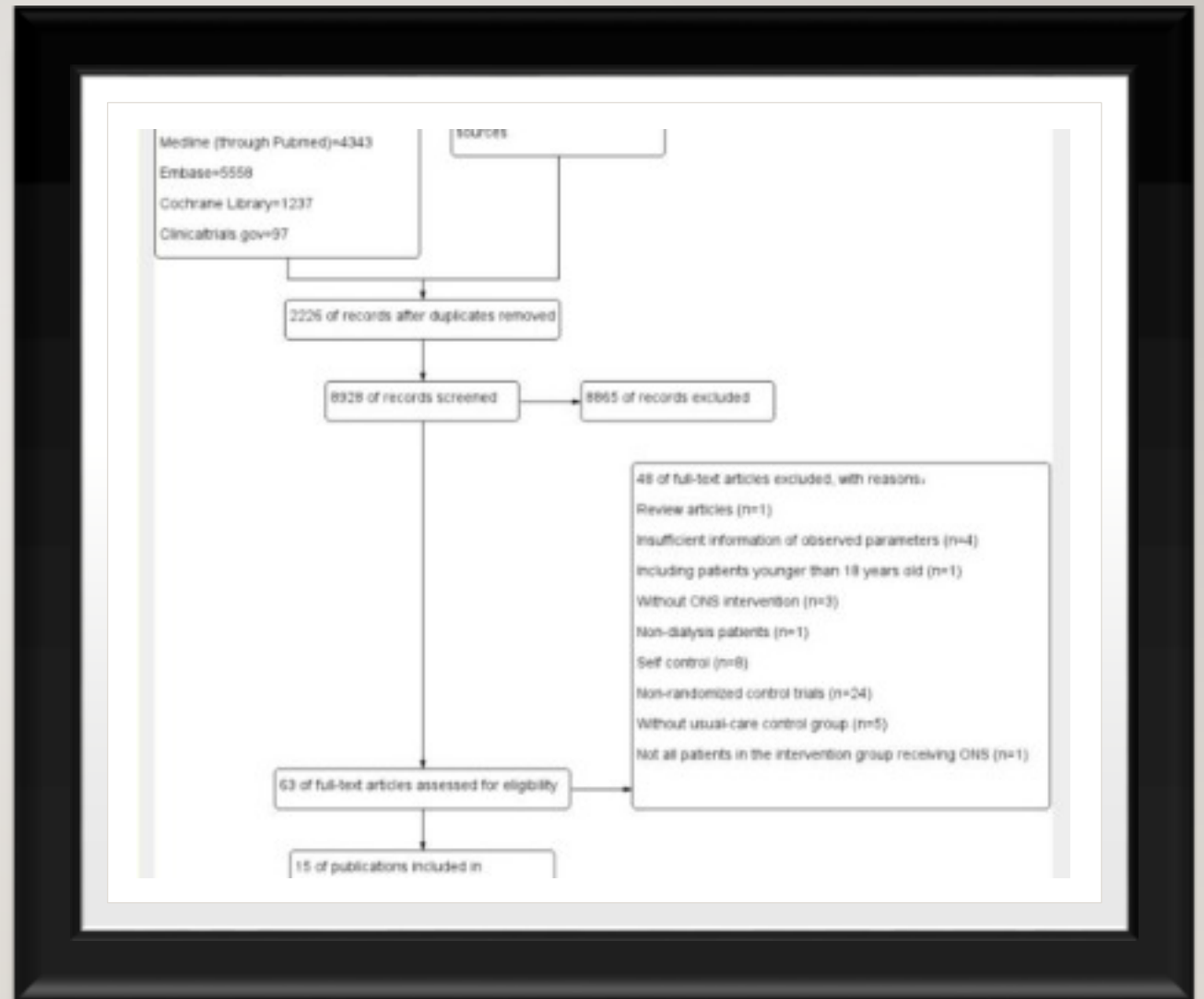


Not statistically significant

LIU P, MA F, WANG Q AND  
HE S, PLOS ONE, 2018

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The Effects of oral  
nutrition supplements in  
patients with maintenance  
dialysis therapy: A  
Systematic Review and  
Meta-analysis of  
Randomized Clinical Trials



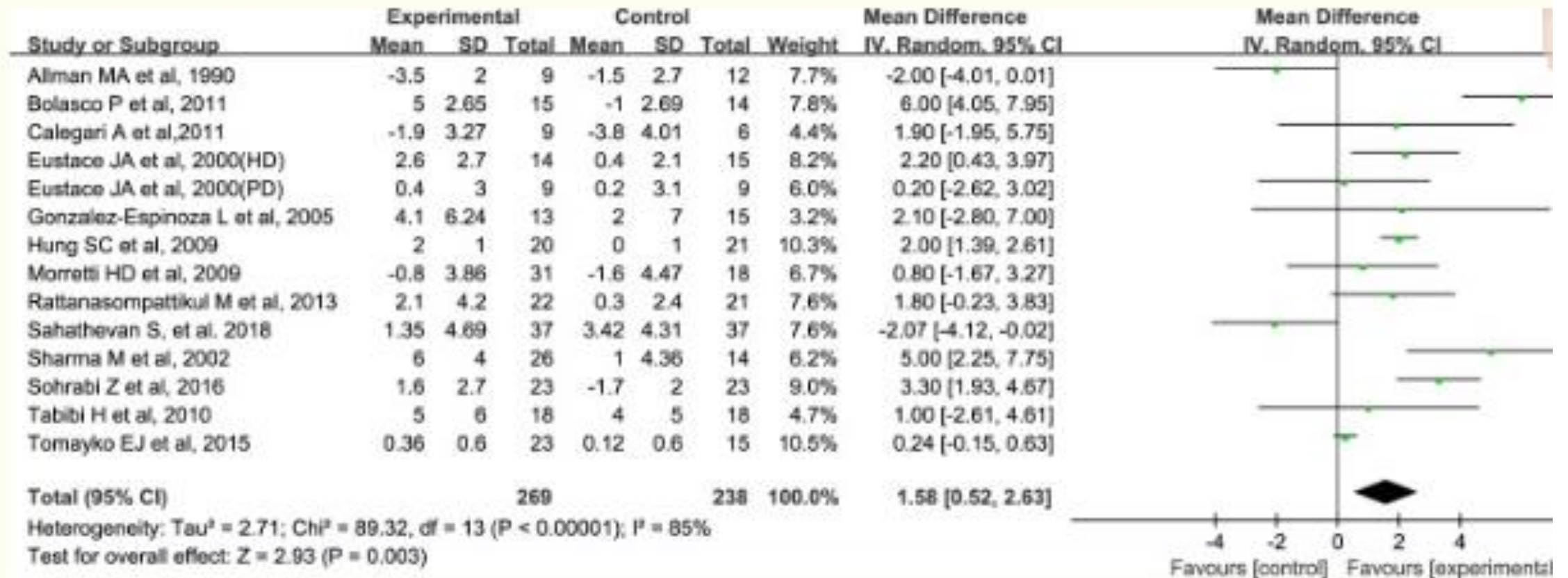


Fig 2

Forest plots depicting the effect of ONS on serum albumin level.

Conclusion: “Evidence of very-low quality suggests that short-term oral nutritional supplements with energy or protein/AA were found to be associated with increased ALBUMIN level, esp. in those who receive HD.

More high-quality & large RCTs, particularly those involving the observation of mortality and/or quality of life, are needed to validated our findings in a long-term way.