DOPPS

Dialysis Outcomes and Practice Patterns Study

NKF DOPPS WebEx

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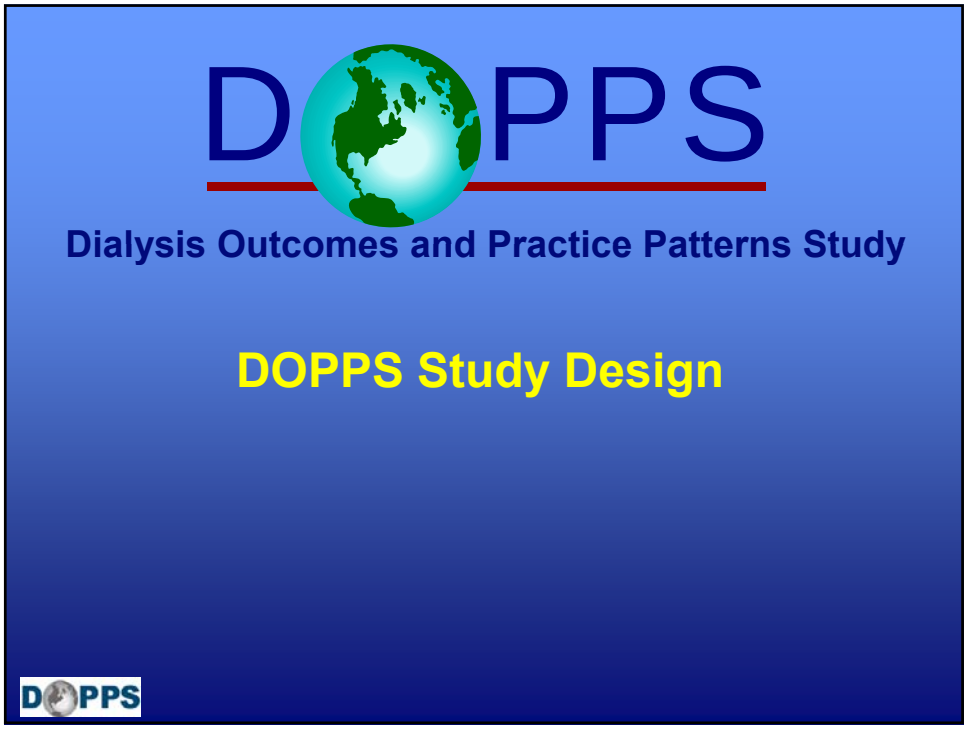
Web Conference
June 17, 2010

Agenda

1. DOPPS study design
2. DOPPS data collection
3. DOPPS nutritional studies: prior results
4. Future research opportunities in DOPPS



Dialysis Outcomes and Practice Patterns Study (DOPPS)

- International prospective cohort study of hemodialysis patients and HD unit practices
- Uniform international data collection
- Goal: Identify HD practice patterns associated with improved patient outcomes (adjusted for patient mix)
- Major outcomes: mortality, hospitalization, vascular access, quality of life
- DOPPS is supported by scientific research grants from Amgen (since 1996), Kyowa Hakko Kirin (since 1999, in Japan), Genzyme (since 2009), and Abbott (since 2009) without restrictions on publications
- Coordinated by the Arbor Research Collaborative for Health (Ann Arbor, MI USA)

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A Decade of DOPPS

	DOPPS 1	DOPPS 2	DOPPS 3	DOPPS 4**
Years:	1996-2001	2002-2004	2005-2008	2009-2011
Countries*:	7	12	12	12
Facilities:	308	322	300	382
Census Pts:	>50,000	>43,000	>50,000	>54,000
Sample Pts:	>17,000	>12,800	>11,300	>15,000
Focus:	Cross-sectional, longitudinal, representative Comorbidities, medications, labs, QoL			
Additions:	cross-sections annually	+ incident & depression	+ process of care & nutrition	+3x/yr cross-sections, special study "modules"
Outcomes:	Quality of Life, Events, Hospitalizations, Mortality			

* Japan, US, Europe (France, Germany, Italy, Spain, UK) + Australia, Belgium, Canada, New Zealand, Sweden

** Includes oversampling of small, rural, independent facilities in US

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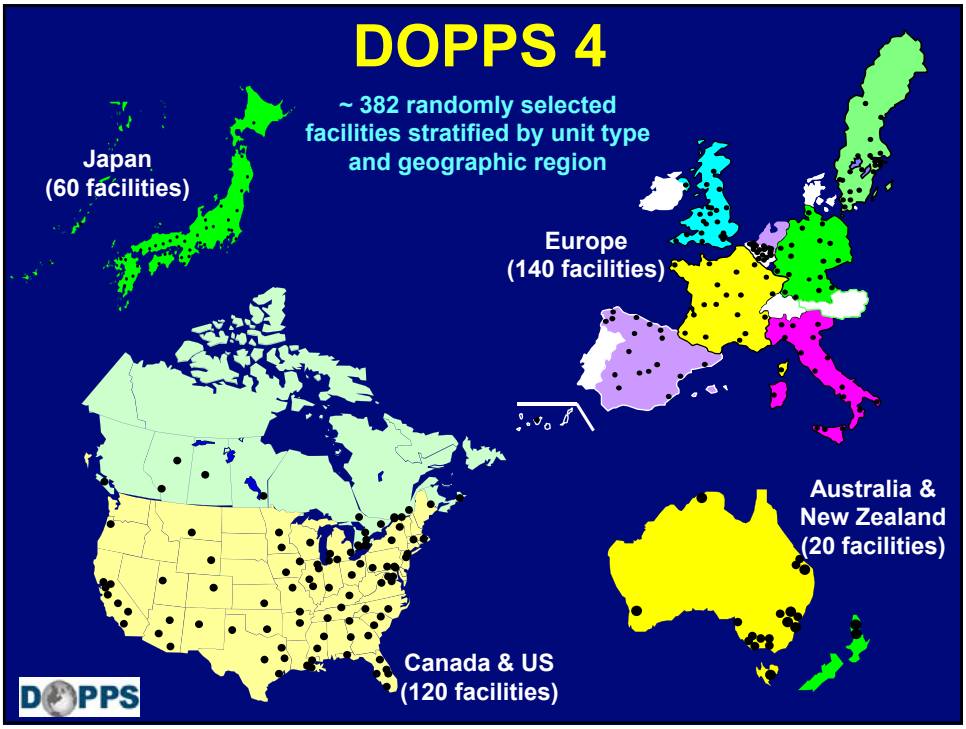
~ 382 randomly selected facilities stratified by unit type and geographic region



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DOPPS Sampling Protocol

Goal: A representative sample of dialysis facilities and patients from each country

Methodology

- Randomized selection among all facilities
- Exclude small facilities (< 25 in- center HD pts, affects ≤ 5% of HD patients in a country)
- Random selection stratified to ensure proportional representation by geographic region and facility types within each country

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What is Unique About DOPPS?

- Nationally representative, 12 countries
- Uniform data collection
- In depth assessment of comorbidities, practices, lab values, and medications
- Timeliness of the data
- Longitudinal data, time trends

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DOPPS
Framework for Hypotheses

Patient Demographics

+

Patient Comorbidities

+

Practice Patterns

} Patient Outcomes

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Selected Practice Patterns

- Administrative
- Anemia Rx
- Dialysis practice
- Cardiovascular risk
- Mineral metabolism
- Physician
- Nursing and technician
- Nutritional
- Social services
- Vascular access

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Dialysis Outcomes and Practice Patterns Study

Data Collection Overview

DOPPS Data Collection

- The DOPPS use a number of study instruments to gather detailed data on facilities and patients:
  - Cumulative Hemodialysis Census, demographic and outcomes data fro all chronic HD patients in a facility during the study
  - Medical Questionnaire, baseline medical information
  - Interval Summary, longitudinal data, monthly laboratory data
  - Patient Questionnaire, patient-reported data (e.g., QoL)
  - Termination Form
  - Unit Practices Survey and Medical Directors Survey, providing detailed facility practice information
- Selected details are provided on the following slides.

DOPPS Nutrition-Related Data

- For each patient, data on pre- and post-dialysis weight are collected for three consecutive HD sessions during the reporting interval
- Nutritional indicators collected monthly: total protein, s. albumin, creatinine, BUN, nPCR, phosphorus & lipid panel
- Question on undernourished or cachectic appearance
- Data on oral nutritional supplement use, intradialytic parenteral nutrition and multi-vitamin prescription collected every four months
- Prior DOPPS special nutrition study in the US and Japan collected patient self-administered food frequency questionnaires (FFQ)

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DOPPS Nutrition-Related Papers (1)

- Mortality Risk in Hemodialysis Patients and Changes in Nutritional Indicators: The Dialysis Outcomes and Practice Patterns Study. Pifer TB et al. KI 2002
- Kidney Disease Outcomes Quality Initiative (K/DOQI) and Dialysis Outcomes and Practice Patterns Study (DOPPS): Nutrition Guidelines, Indicators, and Practices. Combe et al. AJKD 2004
- Hemodialysis Prescription, Adherence, and Nutritional Indicators in Five European Countries: Results from the Dialysis Outcomes and Practice Patterns Study (DOPPS). Hecking et al. NDT 2004

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DOPPS Nutrition-Related Papers (2)

- Lack of Appetite in Haemodialysis Patients-Associations with Patient Characteristics, Indicators of Nutritional Status and Outcomes in the International DOPPS. Lopes et al. NDT 2007
- Independent and Joint Associations of Nutritional Status Indicators With Mortality Risk Among Chronic Hemodialysis Patients in the Dialysis Outcomes and Practice Patterns Study (DOPPS). Lopes et al. JRN 2010

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More DOPPS publications and slide downloads are available at:

www.dopps.org

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Dialysis Outcomes and Practice Patterns Study

Kidney Disease Outcomes Quality Initiative (K/DOQI) and Dialysis Outcomes and Practice Patterns Study (DOPPS): Nutrition Guidelines, Indicators, and Practices

Combe C, McCullough KP, Asano Y, Ginsberg N, Maroni BJ, Pifer TB

American Journal of Kidney Diseases 44 (Suppl 2):S39-S46, 2004

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Serum Albumin

- Patients with serum albumin concentrations <3.5 g/dL had 1.38 times the mortality risk of patients with higher concentrations, even after controlling for demographics and comorbid conditions.
- Patients had higher mortality risks following a six-month period with a decline in serum albumin concentration, supporting the recommendation to measure ESRD patients' serum albumin regularly.

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Combe C et al. *Am J Kidney Dis* 44 (Suppl 2):S39-S46, 2004

Modified Subjective Global Assessment (mSGA)

- The DOPPS found wide and significant differences among countries in the proportions of both moderately and severely malnourished ESRD patients[1] (Table 1).
- In the US, severely malnourished ESRD patients had a 25% higher mortality risk (after adjustment for demographics and comorbid factors) than patients with normal mSGA scores (Table 2).

[1] Based on a mSGA determined using DOPPS data on caregiver responses to questions about patient weight loss and physical appearance and on patient responses to questions about appetite, nausea, energy level, and disease burden.

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Combe C et al. *Am J Kidney Dis* 44 (Suppl 2):S39-S46, 2004

Serum Creatinine

- In the US and Europe, the DOPPS found mortality risk to be inversely associated with baseline serum creatinine concentration (60%-70% higher for patients with serum creatinine levels in the lowest quartile than those in the quartile with the highest level).
- Mortality risk was also higher following a decrease in serum creatinine concentration over a six-month period.
- Because there is no clear threshold value for serum creatinine concentration, serial measurements remain highly useful for measuring nutritional status and predicting outcomes.

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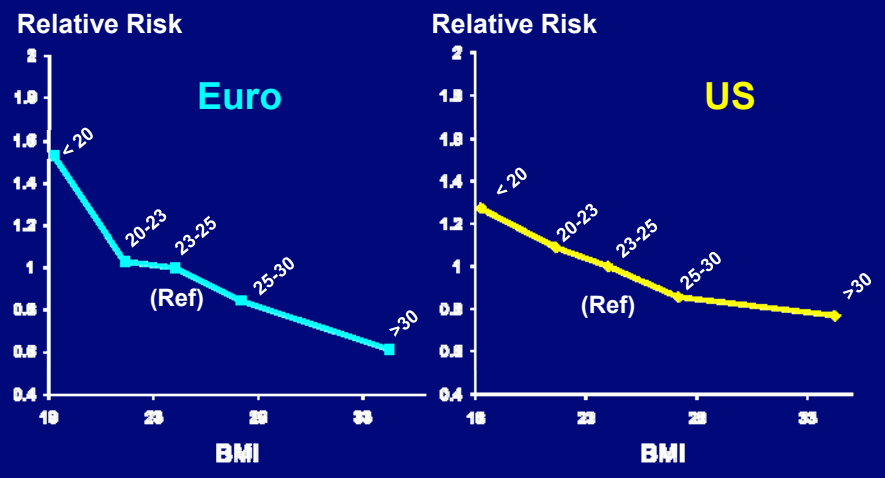
Combe C et al. *Am J Kidney Dis* 44 (Suppl 2):S39-S46, 2004

Figure 1. Mortality versus BMI, Euro- and US-DOPPS



Adjusted for demographics, comorbidity, and albumin (left truncated models). Reprinted from Leavey et al, *Nephrol Dial Transplant* 16:2386-2394, 2001.

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Combe C et al. *Am J Kidney Dis* 44 (Suppl 2):S39-S46, 2004

Conclusion

- DOPPS findings on various nutritional indicators highlight the importance of routinely assessing nutritional status using multiple parameters. Monitoring nutritional status with a variety of means and in accordance with clinical practice guidelines can help predict outcomes and improve patient care.

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Combe C et al. *Am J Kidney Dis* 44 (Suppl 2):S39-S46, 2004

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Dialysis Outcomes and Practice Patterns Study

Lack of Appetite in Haemodialysis Patients- Associations with Patient Characteristics, Indicators of Nutritional Status and Outcomes in the International DOPPS

Lopes A, Elder S, Ginsberg N, Andreucci V, Cruz J, Fukahara S, Mapes D, Saito A, Pisoni R, Saran R, Port F

Nephrology Dialysis Transplantation 22: 3538-3546, 2007

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Introduction

- Malnutrition highly prevalent and strongly associated with higher mortality risk in haemodialysis (HD) patients
- Low food intake contributes to this malnutrition
- Early identification of patients with eating behaviour disturbances could improve HD outcomes
- Use of food frequency questionnaires and food diaries not practical in clinical setting
- Data from DOPPS I and II used to explore relationship between single lack of appetite question and nutritional status, inflammatory markers morbidity, and mortality

DOPPS

Lopes AA et al. *Nephrol Dial Transplant* 23: 3538–3546, 2007

Methods [1]

- **Sample: 14 406 patients from 12 countries enrolled in DOPPS I and II**

- **Variables of interest:**
  - **Lack of appetite**
    - KDQOL-SF: 'To what extent were you bothered during the last four weeks by lack of appetite'
  - **Nutritional status**
    - BMI, serum albumin, serum creatinine, normalized protein catabolic rate
  - **Depression**
    - 'Have you felt so down in the dumps that nothing could cheer you up?' (KDQOL-SF)
    - 'Have you felt downhearted and blue' (KDQOL-SF)
    - 10 item Center for Epidemiological Studies Depression Screening Index (CES-D)
  - **Inflammation**
    - Neutrophil and white blood cell counts

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Lopes AA et al. *Nephrol Dial Transplant* 23: 3538–3546, 2007

Prevalent patient characteristics by categories of bothered by lack of appetite

Characteristic	Bothered by lack of appetite-Mean (±SD) or %					
	None n=7606	Somewhat n=3354	Moderately n=1919	Very much n=985	Extremely n=542	P-value*
Nutritional indicators						
Albumin (g/dl)	3.80 (0.43)	3.75 (0.42)	3.73 (0.51)	3.65 (0.48)	3.65 (0.47)	<0.0001
Creatinine (mg/dl)	10.3 (3.2)	9.9 (3.1)	9.2 (2.9)	8.9 (2.8)	8.9 (3.0)	<0.0001
nPCR (g/kg/day)	1.08 (0.24)	1.03 (0.24)	1.01 (0.25)	1.00 (0.26)	0.99 (0.24)	<0.0001
BMI (kg/m^2)	24.1 (5.3)	23.8 (5.6)	24.2 (5.4)	23.6 (5.0)	23.3 (5.7)	<0.0001
White blood cell (x 10^3/mm^3)	6.7 (2.2)	6.8 (2.4)	7.1 (2.4)	7.2 (2.6)	7.3 (2.4)	0.001
Neutrophils (x 10^3/mm^3)	4.3 (1.9)	4.4 (2.0)	4.6 (2.0)	4.8 (2.4)	4.8 (1.9)	0.001
spKt/V	1.39 (0.29)	1.41 (0.30)	1.41 (0.30)	1.44 (0.30)	1.43 (0.29)	0.001
Treatment time	236 (40)	231 (42)	227 (39)	231 (46)	228 (50)	<0.002
Years on dialysis	5.5 (5.7)	5.4 (5.6)	5.0 (5.3)	5.0 (5.4)	4.9 (5.2)	0.91

* P-value for trend across degree that the patients were bothered by lack of appetite; for Kt/V the P-value trend from somewhat to extremely bothered was not significant-P=0.42 (DOPPS I and II)

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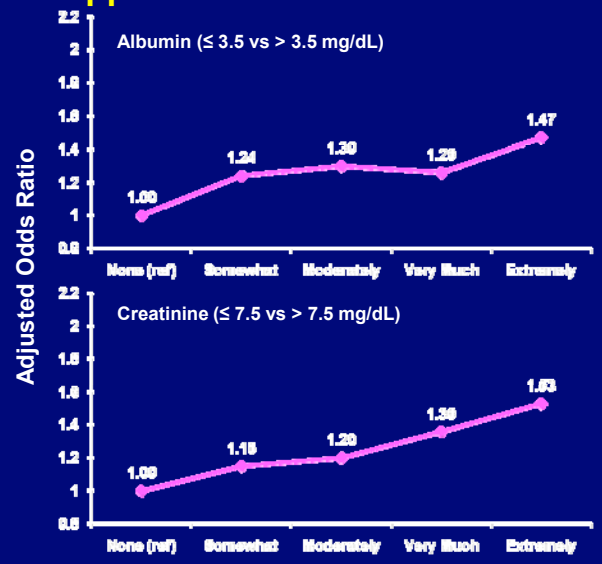
Lopes AA et al. *Nephrol Dial Transplant* 23: 3538–3546, 2007

Association between being bothered by lack of appetite and indicators of nutritional status [1]



P-values < 0.03 for all data points compared to their respective references

Odds ratios are adjusted for facility clustering, age, sex, black race, years on dialysis, 14 summary comorbid conditions and country; *n*=14 406 (DOPPS I and II)

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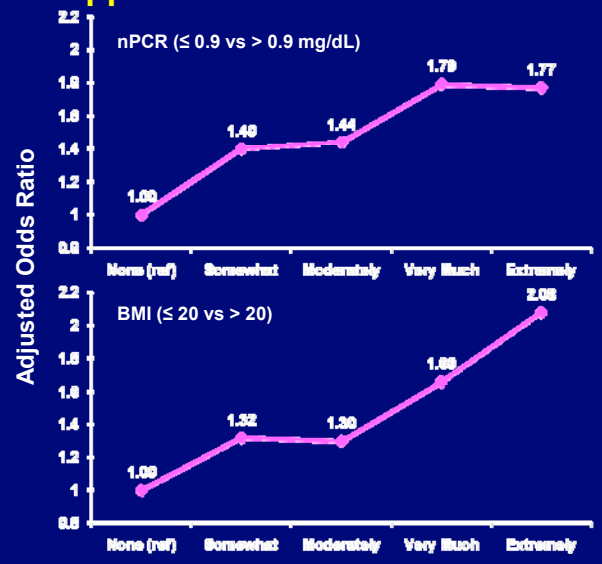
Lopes AA et al. *Nephrol Dial Transplant* 23: 3538–3546, 2007

Association between being bothered by lack of appetite and indicators of nutritional status [2]



P-values < 0.03 for all data points compared to their respective references

Odds ratios are adjusted for facility clustering, age, sex, black race, years on dialysis, 14 summary comorbid conditions and country; *n*=14 406 (DOPPS I and II)

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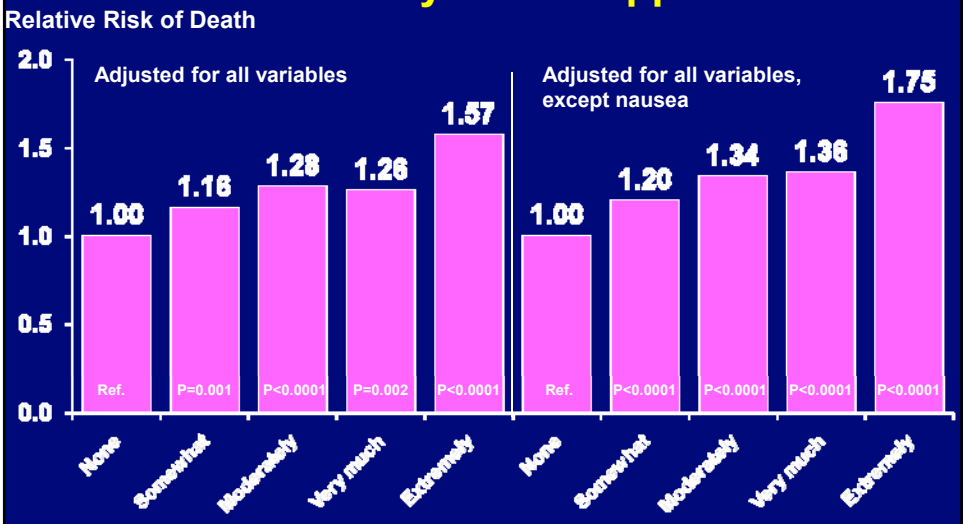
Lopes AA et al. *Nephrol Dial Transplant* 23: 3538–3546, 2007

Relative risk of death by degree of being bothered by lack of appetite



Cox models stratified by country and adjusted for facility clustering, age, sex, race, years on dialysis, physician-diagnosed depression and 13 comorbid conditions; n=14 399 (DOPPS I and II)

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Lopes AA et al. *Nephrol Dial Transplant* 23: 3538–3546, 2007

Conclusion

- **Being bothered by lack of appetite is a dose-dependent, significant predictor of hospitalization and mortality**
  - **RR (mortality) = 2.23 (1.90-2.62)**
  - **RR (hospitalization) = 1.33 (1.19-1.48)**

  Comparing patients extremely bothered by lack of appetite vs. patients not bothered at all
- **Depression, nutritional status markers, and inflammation markers were all independently associated with higher odds of being bothered by lack of appetite**
- **A single question about lack of appetite helps identify HD patients with poorer nutrition status, inflammation, depression, and higher risks of hospitalization and death**
- **The possible beneficial effect of longer HD on appetite should be further explored**
- **Country differences in lack of appetite deserve further study**

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Lopes AA et al. *Nephrol Dial Transplant* 23: 3538–3546, 2007

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Dialysis Outcomes and Practice Patterns Study

Independent and Joint Associations of Nutritional Status Indicators With Mortality Risk Among Chronic Hemodialysis Patients in the Dialysis Outcomes and Practice Patterns Study (DOPPS)

Lopes AA, Bragg-Gresham JL, Elder SJ, Ginsberg N, Goodkin DA, Pifer TB, Lameire N, Marshall M, Asano Y, Akizawa T, Pisoni RL, Young EW, Port FK

Journal of Renal Nutrition 2010 Jan 6 [epub ahead of print]

DOPPS

Introduction

- Serum albumin, serum creatinine, body mass index (BMI), and normalized protein catabolic rate (nPCR) have been used to assess nutritional status of hemodialysis patients
- Kidney Disease Outcomes Quality Initiative (KDOQI) asserts that none of these measures provides complete evaluation of nutritional status
- KDOQI therefore recommends evaluation of multiple parameters

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Lopes, AA et al. *J Ren Nutr* Vol, 2010 Jan [Epub]

Table 3: AOR of the associations between patient characteristics and baseline indicators of nutritional status in DOPPS I, II, and III [1]

	Creatinine ≤7.5 vs >7.5 mg/dL (n=36,071)	Albumin ≤3.5 vs >3.5 g/dL (n=32,443)	BMI ≤22 vs >22 Kg/m^2 (n=34,242)	nPCR <1.0 vs ≥1.0 g/kg/day (n=23,172)	Cachectic Yes vs No (n=36,747)
Age 45-64 (vs <45 years)	1.53**	1.24**	0.64**	1.02	1.23*
Age ≥65 (vs <45 years)	2.92**	1.54**	0.70**	1.51**	1.64**
Male (vs female)	0.51**	0.79**	0.85**	1.03	0.94
Black (vs other)	0.36**	0.98	0.87*	1.32**	1.06
Black (vs other) only in the United States	0.37**	1.01	0.86*	1.30**	1.06
Married (vs not married)	0.89*	1.02	0.81**	0.99	0.79**
Living Alone (vs with spouse/friends)	0.96	0.93	1.03	1.05	0.95
In nursing home (vs with spouse/friends)	1.60**	1.30**	1.26*	0.96	1.25*
Dietitian (yes/no)	0.95	0.85**	1.00	1.00	0.87*
Eat independently (yes vs no)	0.62**	0.59**	0.82*	0.91	0.39**
Kt/V ≤1.2 (vs >1.2)	0.97	1.01	0.61**	2.69**	1.00

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Lopes, AA et al. *J Ren Nutr* Vol, 2010 Jan [Epub]

Table 3: AOR of the associations between patient characteristics and baseline indicators of nutritional status in DOPPS I, II, and III [3]

	Creatinine ≤7.5 vs >7.5 mg/dL (n=36,071)	Albumin ≤3.5 vs >3.5 g/dL (n=32,443)	BMI ≤22 vs >22 Kg/m^2 (n=34,242)	nPCR <1.0 vs ≥1.0 g/kg/day (n=23,172)	Cachectic Yes vs No (n=36,747)
Comorbidities (yes vs no)					
Diabetes mellitus (DM) – All	1.84**	1.30**	0.46**	1.07*	0.72**
DM – Age at ESRD start <35 yr	2.22**	1.92**	0.78*	1.31	1.21
DM – Age at ESRD start 35-44 yr	1.93**	1.72**	0.67**	1.33*	0.87
DM – Age at ESRD start ≥45 yr	1.78**	1.22**	0.43**	1.02	0.7**

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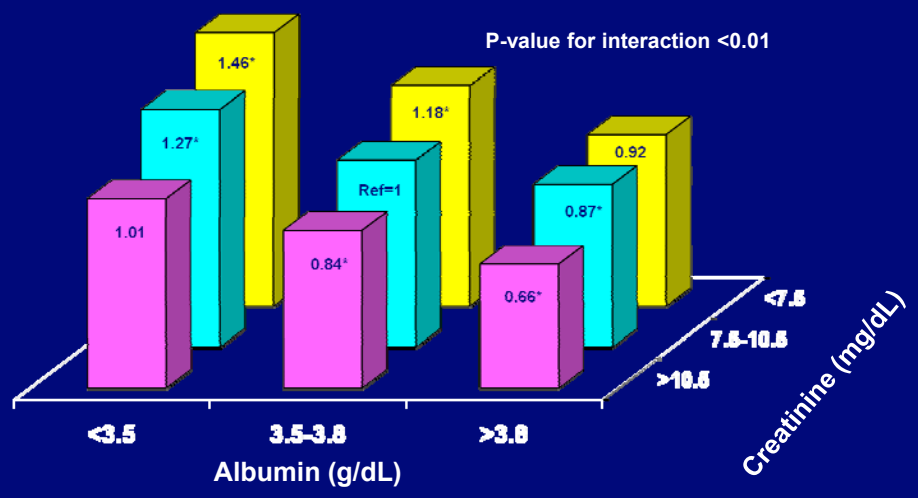
Lopes, AA et al. *J Ren Nutr* Vol, 2010 Jan [Epub]

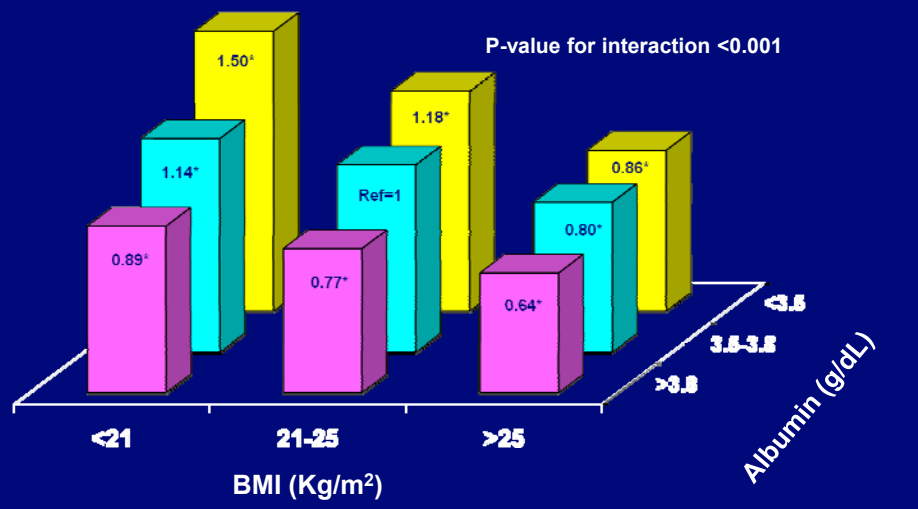
Figure 2a: The relative risks of all-cause mortality due to the joint effects of creatinine and albumin



*p<0.05 as compared with the referent group; ref = referent group; BMI=body mass index
Relative risks were adjusted for age, sex, race, vintage, 14 summary comorbidities, neutrophil/lymphocyte ratio and dialysis by catheter

Lopes, AA et al. *J Ren Nutr* Vol, 2010 Jan [Epub]

Figure 2b: The relative risks of all-cause mortality due to the joint effects of BMI and albumin



*p<0.05 as compared with the referent group; ref = referent group; BMI=body mass index
Relative risks were adjusted for age, sex, race, vintage, 14 summary comorbidities, neutrophil/lymphocyte ratio and dialysis by catheter

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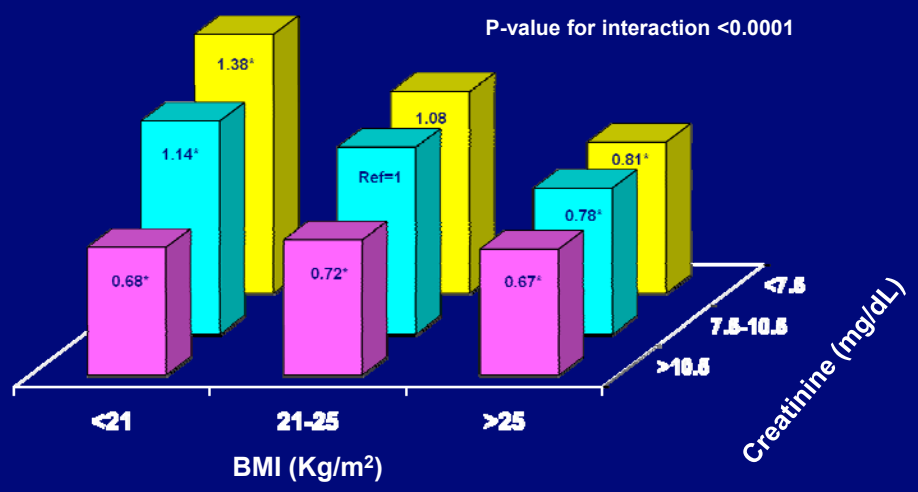
Figure 2c: The relative risks of all-cause mortality due to the joint effects of BMI and creatinine



*p<0.05 as compared with the referent group; ref = referent group; BMI=body mass index
Relative risks were adjusted for age, sex, race, vintage, 14 summary comorbidities, neutrophil/lymphocyte ratio and dialysis by catheter

Lopes, AA et al. *J Ren Nutr* Vol, 2010 Jan [Epub]

Conclusions

- There are important variations by country and patient characteristics in nutritional status indicators
- The joint effects of nutritional indicators on mortality indicate the need to use multiple measurements when assessing the nutritional status of hemodialysis patients
- A greater emphasis on nutritional interventions may improve survival among hemodialysis patients

Lopes, AA et al. *J Ren Nutr* Vol, 2010 Jan [Epub]

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Dialysis Outcomes and Practice Patterns Study

Nutrition-Related Questions in the Current Phase of DOPPS

DOPPS UPS Dietitian Section

- The Unit Practice Survey (UPS) assesses the facility practices related to nursing, patient care, social services and dietary practices
- Dietary section should be completed by the facility dietitian
- If your unit participates in DOPPS, please be aware that you will be asked to answer this section

Examples of Nutrition-Related Questions

H-1	Do you have a dietitian assigned to patients in your unit? 1: Yes-1 or more, totaling <20 hrs per week [skip to question H-3] 2: Yes-1 or more totaling 20-40 hrs per week [skip to question H-3] 3: Yes-2 or more totaling ≥40 hrs per week [skip to question H-3] 4: No
H-60	In how many dialysis units do you work as a dietitian? 1: One 2: Two 3: Three 4: More than three
H-61	How many hemodialysis patients are you responsible for (include patients from all dialysis units where you work as a dietitian)? 1: <50 2: 50-100 3: 101-150 4: 151-200 5: >200

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Examples of Nutrition-Related Questions

For the following services, please indicate if they are offered at your unit.		
H-7	Meal service offered during the HD session	1: Yes 2: No
H-8	Recipes for a dialysis patient's diet	1: Yes 2: No
H-9	Diagrams of portion size	1: Yes 2: No
H-10	Exercise program during the hemodialysis session	1: Yes 2: No
H-11	Exercise program not during the hemodialysis session	1: Yes 2: No
H-12	Oral nutritional supplements administered during the HD session	1: Yes 2: No
H-13	Are oral nutrition supplements for home use prescribed at your unit?	1: Yes 2: No [skip column (A) in next 2 tables]
H-14	Is Intradialytic Parenteral Nutrition (IDPN) prescribed at your unit?	1: Yes 2: No [skip column (B) in next 2 tables]

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Examples of Nutrition-Related Questions

Is there a cut-off value for the following measures at which you typically begin prescribing (A) oral nutritional supplements or (B) Intradialytic Parenteral Nutrition (IDPN) for your chronic HD patients (answer both columns for each measure if applicable)

		(A) Oral nutritional supplements	(B) Intradialytic Parenteral Nutrition
H-15	Serum albumin	1: Yes _____ g/dL 2: No	1: Yes _____ g/dL 2: No
H-16	BMI	1: Yes _____ kg/m^2 2: No	1: Yes _____ kg/m^2 2: No
H-17	Unintentional large weight loss (e.g. ≥ 5% of estimated dry weight [EDW])	1: Yes _____ ☐ kg ☐ % 2: No	1: Yes _____ ☐ kg ☐ % 2: No
H-18	Other (please specify)	1: Yes _____ 2: No	1: Yes _____ 2: No

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Examples of Nutrition-Related Questions

How often are the following clinical indicators typically used at your unit to assess a patient's nutrition status?

		1: At least every month	2: At least every 3 months	3: At least every 6 months	4: At least every year	5: Less often than every year or never
H-23	Subjective Global Assessment (SGA)	1	2	3	4	5
H-24	Body Mass Index (BMI)	1	2	3	4	5
H-25	Serum albumin	1	2	3	4	5
H-26	Pre-albumin	1	2	3	4	5
H-27	Creatinine	1	2	3	4	5
H-28	Potassium	1	2	3	4	5
H-29	C-reactive protein levels	1	2	3	4	5
H-30	Neutrophil to lymphocyte ratio	1	2	3	4	5
H-31	Protein catabolic rate (PCR or nPCR)	1	2	3	4	5
H-32	Is a diet prescription written for each patient in the unit?				1: Yes 2: No [Skip to H-34]	

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Examples of Nutrition-Related Questions

For patients with the following conditions does the dietitian (or other provider responsible for nutritional management in your unit) typically conduct a special dietary assessment?

		1: Never	2: Seldom	3: About half the time	4: Usually	5: Always
H-36	Serum potassium 5.0 to 5.4 mEq/L	1	2	3	4	5
H-37	Serum potassium 5.5 to 5.9 mEq/L	1	2	3	4	5
H-38	Serum potassium ≥ 6.0 mEq/L	1	2	3	4	5
H-39	Serum albumin < 3.2 g/L	1	2	3	4	5
H-40	Serum albumin < 3.5 g/L	1	2	3	4	5
H-41	Serum albumin < 3.8 g/L	1	2	3	4	5
H-42	Serum albumin < 4.0 g/L	1	2	3	4	5
H-43	Serum phosphate 5.0 to 5.4 mg/dL	1	2	3	4	5
H-44	Serum phosphate 5.5 to 5.9 mg/dL	1	2	3	4	5
H-45	Serum phosphate ≥ 6.0 mg/dL	1	2	3	4	5

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Possible Collaborations between CRN and DOPPS

- Analyses of data collected in prior DOPPS phases
  - E.g. ongoing analyses on dietitian-patient ratio
- Potential for additional questions for future DOPPS phases
- Proposals for ancillary studies

DOPPS

Developing a Short Tool for Nutritional Status Screening in HD Patients: the ESRD Dietary Intake Evaluation Tool (ESRD DIET)

PI: Sylvia Ramirez

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DOPPS ESRD-DIET

- Aims:
  1. To develop a clinically useful brief dietary intake questionnaire for use in the dialysis population.
  2. To evaluate the performance of the ESRD DIET against the Willett SFFQ for validity, comparability, & reproducibility.
  3. To compare the ability of the ESRD DIET to the Willett SFFQ for identifying dietary patterns and associated intermediate markers of nutrition.
- ESRD DIET is meant to be a clinically useful screening tool for dietary intake rather than a research tool (e.g. Block FFQ or Willett FFQ)

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ESRD-DIET Study Design

- Patient subjects (600) will come from a sample of 25 dialysis facilities where facility dietitians have expressed interest in participating in the study (note Council of Renal Nutrition support)
- Questionnaire Development and Pre-testing (questionnaire components based on prior DOPPS pilot study, methodology similar to Prime Screen in general population)
- Questionnaire Administration: two administrations of the Willett SFFQ (once at baseline and at a second time point six months later) and four replicates of the ESRD DIET (four weeks before and four weeks after the SFFQ)
- We seek your support in facilitating questionnaire administration to DOPPS patients

DOPPS