

## **Major Kidney Clinical Research Studies and Projects Inventory\***

### **Overcoming Barriers to Adequate Delivery of Hemodialysis**

#### **Overcoming Nutritional Barriers in Hemodialysis Patients**

#### **Overcoming Barriers to Adequate Delivery of Hemodialysis**

##### **1. Administrative Data**

(a) Name of study/research project and acronym:

Overcoming Barriers to Adequate Delivery of Hemodialysis

(b) Type of study/research project:

Randomized clinical trial

(c) Funding status:

Previously funded as R01; project now completed

(d) Recruitment status:

Recruitment completed

(e) For studies/project currently recruiting, indicate total sample size/number currently enrolled, anticipated period of recruitment:

Not applicable

(f) Data coordinating center principal investigator contact information:

Ash Sehgal, M.D.  
Division of Nephrology  
2500 MetroHealth Drive  
Cleveland, OH 44109  
*Phone:* 216-778-7728  
*Fax:* 216-778-3945  
*E-mail:* axs81@po.cwru.edu

(g) Number of recruiting sites, list of principal investigators at recruiting sites, and contact information:

Not applicable

(h) List of principal investigators at central laboratories/facilities (identify type of central facility) and contact information:

Not applicable

(i) Roster of Data and Safety Monitoring Board/Scientific Advisory Committee or other oversight committee(s):

Andy Levey, M.D.; Johanna Dwyer, R.D.; Kate Propert, Ph.D.; Mike Rocco, M.D.

(i) Private-sector support (type of support, e.g., financial, donation of drugs/placebo, etc.):

None

**2. Study Design (for completed studies, a copy of the primary publication can substitute for information below):**

*For details of study design see*

Sehgal AR, Leon JB, Siminoff LA, Singer ME, Bunosky LM, Cebul RD.  
Improving the quality of hemodialysis treatment: A community-based randomized controlled trial to overcome patient-specific barriers. *JAMA* 2002;287:1961-1967.

**3. Data and Biological Sample Resources**

(a) Biological samples collected in ongoing studies/research projects (specify the type of sample-blood, urine, etc., the amount, and the point in the study when samples were collected, e.g., baseline visit #1, baseline visit #2, follow-up visit #1-specify months after randomization/study entry,):

None

(b) Biological samples currently in storage from completed trials (grid showing sample collection time, type of sample, amount, and number of study participants sample was collected from, and physical location of where the samples are stored):

Not applicable.

(c) Brief summary of typical informed consent provisions (template informed consent form acceptable), including major variables in participant consents, if applicable (e.g., “use for other studies or not”, “allow genetic studies or not.”) Does consent include use of samples in other studies that are not part of the main study?

Data only to be used for specified project. No biological samples.

(d) Data collected (grid of data collection by time/clinic visit with specificity on the type of information collected (e.g., quality of life with SF-MOS 36, measurement of kidney function by GFR, serum creatinine measurement, etc.)

Dialysis dose, barriers to adequate dose, demographic and medical characteristics collected monthly.

(e) Any provisions for distributing resources outside of the study? What is the sharing plan?

No.

#### **4. Ancillary Studies**

(a) Process and contact person (name, address, phone, fax, and e mail address) for application to perform ancillary studies:

No ancillary studies done.

(b) List of ancillary studies approved, completed and ongoing (including source of funding and amount):

No ancillary studies done.

#### **5. List of Publications and Presentations (full citations, also note manuscripts in progress)**

Sehgal AR. Improving hemodialysis patient outcomes: A step-by-step approach. *Seminars in Dialysis*. 2002;15:35-37.

Sehgal AR. What is the best treatment for end stage renal disease? *American Journal of Medicine*. 2002;112:735-736.

Alexander GC, Sehgal AR. Variation in access to kidney transplantation across dialysis facilities: Using process of care measures for quality improvement. *American Journal of Kidney Diseases*. 2002;40:824-831.

Sehgal AR, Leon JB, Siminoff LA, Singer ME, Bunosky LM, Cebul RD. Improving the quality of hemodialysis treatment: A community-based randomized controlled trial to overcome patient-specific barriers. *Journal of the American Medical Association*. 2002;287:1961-1967.

O'Connor A, Leon JB, Sehgal AR. The relative predictive ability of four different measures of hemodialysis dose. *American Journal of Kidney Diseases*. In press.

Flauto R, Leon JB, Sehgal AR. The provision and outcomes of diabetic care of hemodialysis patients. *American Journal of Kidney Diseases*. In press.

*Nephrology Nursing Journal*. In press.

## **Overcoming Nutritional Barriers in Hemodialysis Patients**

### **1. Administrative Data**

(a) Name of study/research project and acronym:

Overcoming Nutritional Barriers in Hemodialysis Patients

(b) Type of study/research project:

Randomized clinical trial

(c) Funding status:

R01; project in progress

(d) Recruitment status:

Recruitment in progress

(e) For studies/project currently recruiting, indicate total sample size/number currently enrolled, anticipated period of recruitment:

Approximately 100 subjects enrolled so far; anticipate recruiting for 1 more year

(f) Data coordinating center principal investigator contact information:

Ash Sehgal, M.D.  
Division of Nephrology  
2500 MetroHealth Drive  
Cleveland, OH 44109  
*Phone:* 216-778-7728

*Fax:* 216-778-3945

*E-mail:* axs81@po.cwru.edu

(g) Number of recruiting sites, list of principal investigators at recruiting sites, and contact information:

Not applicable

(h) List of principal investigators at central laboratories/facilities (identify type of central facility) and contact information:

Not applicable

(i) Roster of Data and Safety Monitoring Board/Scientific Advisory Committee or other oversight committee(s):

Johanna Dwyer, R.D.; Kate Propert, Ph.D.; Mike Rocco, M.D.; Judith Beto, R.D.

(j) Private-sector support (type of support, e.g., financial, donation of drugs/placebo, etc.):

None

**2. Study Design (for completed studies- a copy of the primary publication can substitute for information below)**

(a) Objective:

To determine if addressing nutritional barriers improves nutritional status of hemodialysis patients

(b) Study design:

Randomized controlled trial

(c) Major inclusion criteria:

- Low albumin
- On dialysis at least 9 months

(d) Major exclusion criteria:

- Mentally incompetent

- Terminal illness

(e) Description of the intervention(s):

Education and feedback about nutritional barriers

(f) Baseline/eligibility visit schedule (number of visits, major assessments):

One visit to assess baseline barriers

(g) Follow-up contact schedule (frequency, type of visit/phone, in-clinic, major assessments):

Monthly meetings in dialysis facility

(h) Primary outcome, secondary outcomes:

Change in albumin; change in specific nutritional barriers

(i) Brief summary of power estimates used to justify sample size/duration, including critical assumptions (i.e., effect size estimates, estimated event rates or rate of change in outcome measure):

Assume 50% of intervention patients will improve compared to 25% of control patients. To account for nesting of subjects within facilities, will need total of 270 subjects.

(j) Web site:

None

### **3. Data and Biological Sample Resources**

(a) Biological samples collected in ongoing studies/research projects (specify the type of sample, e.g., blood, urine, etc., the amount, and the point in the study when samples were collected, e.g., baseline visit #1, baseline visit #2, follow-up visit #1; specify months after randomization/study entry):

5 cc of blood every 3 months during the 12-month long trial (to check albumin level).

(b) Biological samples currently in storage from completed trials (grid showing sample collection time, type of sample, amount, and number of study participants sample was collected from, and physical location of where the samples are stored):

Not applicable

(c) Brief summary of typical informed consent provisions (template informed consent form acceptable), including major variables in participant consents, if applicable (e.g., “use for other studies or not”, “allow genetic studies or not.”) Does consent include use of samples in other studies that are not part of the main study?

Data only to be used for specified project. Biological samples (blood) only to be used for specified project.

(d) Data collected (grid of data collection by time/clinic visit with specificity on the type of information collected, e.g., quality of life with SF-MOS 36, measurement of kidney function by GFR, serum creatinine measurement, etc.):

Nutritional status, barriers to adequate nutrition, demographic and medical characteristics collected monthly.

(e) Any provisions for distributing resources outside of the study? What is the sharing plan?

No

#### **4. Ancillary Studies**

(a) Process and contact person (name, address, phone, fax, and e mail address) for application to perform ancillary studies:

No ancillary studies

(b) List of ancillary studies approved, completed and ongoing (including source of funding and amount):

No ancillary studies

#### **5. List of Publications and Presentations (full citations, also note manuscripts in progress)**

Leon JB, Majerle AD, Soinski JA, Kushner I, Ohri-Vachaspati P, Sehgal AR. Can a nutrition intervention improve albumin levels among hemodialysis patients? A pilot study. Journal of Renal Nutrition. 2001;11:9-15.

Kushner I, Sehgal AR. Is high sensitivity C-reactive protein an effective screening test for cardiovascular disease? Archives of Internal Medicine. 2002;162:867-869.

Kidney Disease Clinical Studies Initiative, Major Kidney Clinical Research Studies and Projects Inventory,\* Overcoming Barriers to Adequate Delivery of Hemodialysis

Covinsky KE, Covinsky MH, Palmer RM, Sehgal AR. Serum albumin concentration and clinical assessments of nutritional status in hospitalized older people: Different sides of different coins? Journal of the American Geriatrics Society. 2002;50:631-637.

Zimmerer JL, Leon JB, Covinsky KE, Desai U, Sehgal AR. Diet monotony as a correlate of poor nutritional intake among hemodialysis patients. Journal of Renal Nutrition. In press.

Sehgal AR. Do quality improvement efforts reduce race and gender disparities in health outcomes? In preparation.