Appendix A. CMS-2728 Medicare Eligibility Form

Form Approved
OMB No. 0938-0046

END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION

A. COMPLETE FOR ALL ESRD PATIENTS *Check one:* ☐ Initial ☐ Re-entitlement ☐ Supplemental

1. Name *(Last, First, Middle Initial)*

2. Medicare Claim Number	3. Social Security Number	4. Date of Birth *(mm/dd/yyyy)*

5. Patient Mailing Address *(Include City, State and Zip)*	6. Phone Number *(including area code)*

7. Sex	8. Ethnicity	9. Country/Area of Origin or Ancestry
☐ Male ☐ Female	☐ Not Hispanic or Latino ☐ Hispanic or Latino (Complete Item 9)	

10. Race *(Check all that apply)*
☐ White
☐ Black or African American
☐ American Indian/Alaska Native
Print Name of Enrolled/Principal Tribe _____
☐ Asian
☐ Native Hawaiian or Other Pacific Islander*
*complete Item 9

11. Is patient applying for ESRD Medicare coverage?
☐ Yes ☐ No

12. Current Medical Coverage *(Check all that apply)*	13. Height	14. Dry Weight	15. Primary Cause of Renal Failure *(Use code from back of form)*
☐ Medicaid ☐ Medicare ☐ Employer Group Health Insurance ☐ DVA ☐ Medicare Advantage ☐ Other ☐ None	INCHES _____ OR CENTIMETERS _____	POUNDS _____ OR KILOGRAMS _____	

16. Employment Status *(6 mos prior and current status)*

Prior	Current	
☐	☐	Unemployed
☐	☐	Employed Full Time
☐	☐	Employed Part Time
☐	☐	Homemaker
☐	☐	Retired due to Age/Preference
☐	☐	Retired (Disability)
☐	☐	Medical Leave of Absence
☐	☐	Student

17. Co-Morbid Conditions *(Check all that apply currently and/or during last 10 years)* *See instructions

a. ☐ Congestive heart failure
b. ☐ Atherosclerotic heart disease ASHD
c. ☐ Other cardiac disease
d. ☐ Cerebrovascular disease, CVA, TIA*
e. ☐ Peripheral vascular disease*
f. ☐ History of hypertension
g. ☐ Amputation
h. ☐ Diabetes, currently on insulin
i. ☐ Diabetes, on oral medications
j. ☐ Diabetes, without medications
k. ☐ Diabetic retinopathy
l. ☐ Chronic obstructive pulmonary disease
m. ☐ Tobacco use (current smoker)
n. ☐ Malignant neoplasm, Cancer
o. ☐ Toxic nephropathy
p. ☐ Alcohol dependence
q. ☐ Drug dependence*
r. ☐ Inability to ambulate
s. ☐ Inability to transfer
t. ☐ Needs assistance with daily activities
u. ☐ Institutionalized
☐ 1. Assisted Living
☐ 2. Nursing Home
☐ 3. Other Institution
v. ☐ Non-renal congenital abnormality
w. ☐ None

18. Prior to ESRD therapy:

a. Did patient receive exogenous erythropoetin or equivalent?	☐ Yes	☐ No	☐ Unknown	If Yes, answer:	☐ 6-12 months	☐ >12 months
b. Was patient under care of a nephrologist?	☐ Yes	☐ No	☐ Unknown	If Yes, answer:	☐ 6-12 months	☐ >12 months
c. Was patient under care of kidney dietitian?	☐ Yes	☐ No	☐ Unknown	If Yes, answer:	☐ 6-12 months	☐ >12 months
d. What access was used on first outpatient dialysis:	☐ AVF	☐ Graft	☐ Catheter	☐ Other		
If not AVF, then: Is maturing AVF present?	☐ Yes	☐ No				
Is maturing graft present?	☐ Yes	☐ No				

19. Laboratory Values Within **45** Days Prior to the Most Recent ESRD Episode. (Lipid Profile within 1 Year of Most Recent ESRD Episode).

LABORATORY TEST	VALUE	DATE	LABORATORY TEST	VALUE	DATE
a.1. Serum Albumin (g/dl)	___ . ___		d. HbA1c	___ ___ . ___%	
a.2. Serum Albumin Lower Limit	___ . ___		e. Lipid Profile TC	___ ___ ___	
a.3. Lab Method Used (BCG or BCP)			LDL	___ ___ ___	
b. Serum Creatinine (mg/dl)	___ ___ . ___		HDL	___ ___	
c. Hemoglobin (g/dl)	___ ___ . ___		TG	___ ___ ___ ___	

B. COMPLETE FOR ALL ESRD PATIENTS IN DIALYSIS TREATMENT

20. Name of Dialysis Facility	21. Medicare Provider Number *(for item 20)*

22. Primary Dialysis Setting	23. Primary Type of Dialysis
☐ Home ☐ Dialysis Facility/Center ☐ SNF/Long Term Care Facility	☐ Hemodialysis (Sessions per week____/hours per session____) ☐ CAPD ☐ CCPD ☐ Other

24. Date Regular Chronic Dialysis Began *(mm/dd/yyyy)*	25. Date Patient Started Chronic Dialysis at Current Facility *(mm/dd/yyyy)*

26. Has patient been informed of kidney transplant options?	27. If patient NOT informed of transplant options, please check all that apply:		
☐ Yes ☐ No	☐ Medically unfit	☐ Patient declines information	☐ Unsuitable due to age
	☐ Patient has not been assessed	☐ Psychologically unfit	☐ Other

C. COMPLETE FOR ALL KIDNEY TRANSPLANT PATIENTS

28. Date of Transplant *(mm/dd/yyyy)*	29. Name of Transplant Hospital	30. Medicare Provider Number for Item 29

Date patient was admitted as an inpatient to a hospital in preparation for, or anticipation of, a kidney transplant prior to the date of actual transplantation.

31. Enter Date *(mm/dd/yyyy)*	32. Name of Preparation Hospital	33. Medicare Provider number for Item 32

34. Current Status of Transplant *(if functioning, skip items 36 and 37)*	35. Type of Donor:
☐ Functioning ☐ Non-Functioning	☐ Deceased ☐ Living Related ☐ Living Unrelated
36. If Non-Functioning, Date of Return to Regular Dialysis *(mm/dd/yyyy)*	37. Current Dialysis Treatment Site
	☐ Home ☐ Dialysis Facility/Center ☐ SNF/Long Term Care Facility

D. COMPLETE FOR ALL ESRD SELF-DIALYSIS TRAINING PATIENTS (MEDICARE APPLICANTS ONLY)

38. Name of Training Provider	39. Medicare Provider Number of Training Provider (for Item 38)
40. Date Training Began *(mm/dd/yyyy)*	41. Type of Training ☐ Hemodialysis a. ☐ Home b. ☐ In Center ☐ CAPD ☐ CCPD ☐ Other
42. This Patient is Expected to Complete *(or has completed)* Training and will Self-dialyze on a Regular Basis. ☐ Yes ☐ No	43. Date When Patient Completed, or is Expected to Complete, Training *(mm/dd/yyyy)*

I certify that the above self-dialysis training information is correct and is based on consideration of all pertinent medical, psychological, and sociological factors as reflected in records kept by this training facility.

44. Printed Name and Signature of Physician personally familiar with the patient's training			45. UPIN of Physician in Item 44
a.) Printed Name	b.) Signature	c.) Date *(mm/dd/yyyy)*	

E. PHYSICIAN IDENTIFICATION

46. Attending Physician *(Print)*	47. Physician's Phone No. *(include Area Code)*	48. UPIN of Physician in Item 46

PHYSICIAN ATTESTATION

I certify, under penalty of perjury, that the information on this form is correct to the best of my knowledge and belief. Based on diagnostic tests and laboratory findings, I further certify that this patient has reached the stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplant to maintain life. I understand that this information is intended for use in establishing the patient's entitlement to Medicare benefits and that any falsification, misrepresentation, or concealment of essential information may subject me to fine, imprisonment, civil penalty, or other civil sanctions under applicable Federal laws.

49. Attending Physician's Signature of Attestation *(Same as Item 46)*	50. Date *(mm/dd/yyyy)*
51. Physician Recertification Signature	52. Date *(mm/dd/yyyy)*

53. Remarks

F. OBTAIN SIGNATURE FROM PATIENT

I hereby authorize any physician, hospital, agency, or other organization to disclose any medical records or other information about my medical condition to the Department of Health and Human Services for purposes of reviewing my application for Medicare entitlement under the Social Security Act and/or for scientific research.

54. Signature of Patient *(Signature by mark must be witnessed.)*	55. Date *(mm/dd/yyyy)*

G. PRIVACY STATEMENT

The collection of this information is authorized by Section 226A of the Social Security Act. The information provided will be used to determine if an individual is entitled to Medicare under the End Stage Renal Disease provisions of the law. The information will be maintained in system No. 09-70-0520, "End Stage Renal Disease Program Management and Medical Information System (ESRD PMMIS)", published in the Federal Register, Vol. 67, No. 116, June 17, 2002, pages 41244-41250 or as updated and republished. Collection of your Social Security number is authorized by Executive Order 9397. Furnishing the information on this form is voluntary, but failure to do so may result in denial of Medicare benefits. Information from the ESRD PMMIS may be given to a congressional office in response to an inquiry from the congressional office made at the request of the individual; an individual or organization for research, demonstration, evaluation, or epidemiologic project related to the prevention of disease or disability, or the restoration or maintenance of health. Additional disclosures may be found in the *Federal Register* notice cited above. You should be aware that P.L.100-503, the Computer Matching and Privacy Protection Act of 1988, permits the government to verify information by way of computer matches.

LIST OF PRIMARY CAUSES OF END STAGE RENAL DISEASE

Item 15. Primary Cause of Renal Failure should be completed by the attending physician from the list below. Enter the ICD-9-CM code to indicate the primary cause of end stage renal disease. If there are several probable causes of renal failure, choose one as primary. **Code effective as of September 2003**.

ICD-9	NARRATIVE
	DIABETES
25040	Diabetes with renal manifestations Type 2
25041	Diabetes with renal manifestations Type 1
	GLOMERULONEPHRITIS
5829	Glomerulonephritis (GN) (histologically not examined)
5821	Focal glomerulosclerosis, focal sclerosing GN
5831	Membranous nephropathy
58321	Membranoproliferative GN type 1, diffuse MPGN
58322	Dense deposit disease, MPGN type 2
58381	IgA nephropathy, Berger's disease (proven by immunofluorescence)
58382	IgM nephropathy (proven by immunofluorescence)
5834	With lesion of rapidly progressive GN
5800	Post infectious GN, SBE
5820	Other proliferative GN
	SECONDARY GN/VASCULITIS
7100	Lupus erythematosus, (SLE nephritis)
2870	Henoch-Schonlein syndrome
7101	Scleroderma
28311	Hemolytic uremic syndrome
4460	Polyarteritis
4464	Wegener's granulomatosis
58392	Nephropathy due to heroin abuse and related drugs
44620	Other Vasculitis and its derivatives
44621	Goodpasture's syndrome
58391	Secondary GN, other
	INTERSTITIAL NEPHRITIS/PYELONEPHRITIS
9659	Analgesic abuse
5830	Radiation nephritis
9849	Lead nephropathy
5909	Nephropathy caused by other agents
27410	Gouty nephropathy
5920	Nephrolithiasis
5996	Acquired obstructive uropathy
5900	Chronic pyelonephritis, reflux nephropathy
58389	Chronic interstitial nephritis
58089	Acute interstitial nephritis
5929	Urolithiasis
27549	Other disorders of calcium metabolism
	HYPERTENSION/LARGE VESSEL DISEASE
40391	Unspecified with renal failure
4401	Renal artery stenosis
59381	Renal artery occlusion
59383	Cholesterol emboli, renal emboli

ICD-9	NARRATIVE
	CYSTIC/HEREDITARY/CONGENITAL DISEASES
75313	Polycystic kidneys, adult type (dominant)
75314	Polycystic, infantile (recessive)
75316	Medullary cystic disease, including nephronophthisis
7595	Tuberous sclerosis
7598	Hereditary nephritis, Alport's syndrome
2700	Cystinosis
2718	Primary oxalosis
2727	Fabry's disease
7533	Congenital nephrotic syndrome
5839	Drash syndrome, mesangial sclerosis
75321	Congenital obstruction of ureterpelvic junction
75322	Congenital obstruction of uretrovesical junction
75329	Other Congenital obstructive uropathy
7530	Renal hypoplasia, dysplasia, oligonephronia
75671	Prune belly syndrome
75989	Other (congenital malformation syndromes)
	NEOPLASMS/TUMORS
1890	Renal tumor (malignant)
1899	Urinary tract tumor (malignant)
2230	Renal tumor (benign)
2239	Urinary tract tumor (benign)
23951	Renal tumor (unspecified)
23952	Urinary tract tumor (unspecified)
20280	Lymphoma of kidneys
20300	Multiple myeloma
20308	Other immuno proliferative neoplasms (including light chain nephropathy)
2773	Amyloidosis
99680	Complications of transplanted organ unspecified
99681	Complications of transplanted kidney
99682	Complications of transplanted liver
99683	Complications of transplanted heart
99684	Complications of transplanted lung
99685	Complications of transplanted bone marrow
99686	Complications of transplanted pancreas
99687	Complications of transplanted intestine
99689	Complications of other specified transplanted organ
	MISCELLANEOUS CONDITIONS
28260	Sickle cell disease/anemia
28269	Sickle cell trait and other sickle cell (HbS/Hb other)
64620	Post partum renal failure
042	AIDS nephropathy
8660	Traumatic or surgical loss of kidney(s)
5724	Hepatorenal syndrome
5836	Tubular necrosis (no recovery)
59389	Other renal disorders
7999	Etiology uncertain

INSTRUCTIONS FOR COMPLETION OF END STAGE RENAL DISEASE MEDICAL EVIDENCE REPORT MEDICARE ENTITLEMENT AND/OR PATIENT REGISTRATION

For whom should this form be completed:

This form **SHOULD NOT** be completed for those patients who are in acute renal failure. Acute renal failure is a condition in which kidney function can be expected to recover after a short period of dialysis, i.e., several weeks or months.

This form **MUST BE** completed within 45 days for **ALL** patients beginning any of the following:

Check the appropriate block that identifies the reason for submission of this form.

Initial

For all patients who initially receive a kidney transplant instead of a course of dialysis.

For patients for whom a regular course of dialysis has been prescribed by a physician because they have reached that stage of renal impairment that a kidney transplant or regular course of dialysis is necessary to maintain life. The first date of a regular course of dialysis is the date this prescription is implemented whether as an inpatient of a hospital, an outpatient in a dialysis center or facility, or a home patient. The form should be completed for all patients in this category even if the patient dies within this time period.

Re-entitlement

For beneficiaries who have already been entitled to ESRD Medicare benefits and those benefits were terminated because their coverage stopped 3 years post transplant but now are again applying for Medicare ESRD benefits because they returned to dialysis or received another kidney transplant.

For beneficiaries who stopped dialysis for more than 12 months, have had their Medicare ESRD benefits terminated and now returned to dialysis or received a kidney transplant. These patients will be reapplying for Medicare ESRD benefits.

Supplemental

Patient has received a transplant or trained for self-care dialysis within the first 3 months of the first date of dialysis and initial form was submitted.

All items except as follows: To be completed by the attending physician, head nurse, or social worker involved in this patient's treatment of renal disease.

Items 15, 17-18, 26-27, 49-50: To be completed by the attending physician.
Item 44: To be signed by the attending physician or the physician familiar with the patient's self-care dialysis training.
Items 54 and 55: To be signed and dated by the patient.

1. Enter the patient's legal name (Last, first, middle initial). Name should appear exactly the same as it appears on patient's social security or Medicare card.
2. If the patient is covered by Medicare, enter his/her Medicare claim number as it appears on his/her Medicare card.
3. Enter the patient's own social security number. This number can be verified from his/her social security card.
4. Enter patient's date of birth (2-digit Month, Day, and 4-digit Year). Example 07/25/1950.
5. Enter the patient's mailing address (number and street or post office box number, city, state, and ZIP code.)
6. Enter the patient's home area code and telephone number.
7. Check the appropriate block to identify sex.
8. Check the appropriate block to identify ethnicity. Definitions of the ethnicity categories for Federal statistics are as follows:

   Not Hispanic or Latino—A person of culture or origin not described below, regardless of race.

   Hispanic or Latino—A person of Cuban, Puerto Rican, or Mexican culture or origin regardless of race. Please complete Item 9 and provide the country, area of origin, or ancestry to which the patient claims to belong.
9. Country/Area of origin or ancestry—Complete if information is available or if directed to do so in question 8.
10. Check the appropriate block(s) to identify race. Definitions of the racial categories for Federal statistics are as follows:

    White—A person having origins in any of the original white peoples of Europe, the Middle East or North Africa.

    Black or African American—A person having origins in any of the black racial groups of Africa. This includes native-born Black Americans, Africans, Haitians and residents of non-Spanish speaking Caribbean Islands of African descent.

    American Indian/Alaska Native—A person having origins in any of the original peoples of North America and South America (including Central America) and who maintains tribal affiliation or community attachment. Print the name of the enrolled or principal tribe to which the patient claims to be a member.

    Asian—A person having origins in any of the original peoples of the Far East, Southeast Asia or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand and Vietnam.

    Native Hawaiian or Other Pacific Islander—A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands. Please complete Item 9 and provide the country, area of origin, or ancestry to which the patient claims to belong.

DISTRIBUTION OF COPIES:

- Forward the first part (blue) of this form to the Social Security office servicing the claim.
- Forward the second part (green) of this form to the ESRD Network Organizations.
- Retain the last part (white) in the patient's medical records file.

11. Check the appropriate yes or no block to indicate if patient is applying for ESRD Medicare. **Note: Even though a person may already be entitled to general Medicare coverage, he/she should reapply for ESRD Medicare coverage.**

12. Check **all** the blocks that apply to this patient's current medical insurance status.

    Medicaid—Patient is currently receiving State Medicaid benefits.

    Medicare—Patient is currently entitled to Federal Medicare benefits.

    Employer Group Health Insurance—Patient receives medical benefits through an employee health plan that covers employees, former employees, or the families of employees or former employees.

    DVA—Patient is receiving medical care from a Department of Veterans Affairs facility.

    Medicare Advantage—Patient is receiving medical benefits under a Medicare Advantage organization.

    Other Medical Insurance—Patient is receiving medical benefits under a health insurance plan that is not Medicare, Medicaid, Department of Veterans Affairs, HMO/M+C organization, nor an employer group health insurance plan. Examples of other medical insurance are Railroad Retirement and CHAMPUS beneficiaries.

    None—Patient has no medical insurance plan.

13. Enter the patient's most recent recorded height in inches **OR** centimeters at time form is being completed. If entering height in centimeters, round to the nearest centimeter. Estimate or use last known height for those unable to be measured. (Example of inches - 62. DO NOT PUT 5'2") NOTE: For amputee patients, enter height prior to amputation.

14. Enter the patient's most recent recorded dry weight in pounds **OR** kilograms at time form is being completed. If entering weight in kilograms, round to the nearest kilogram.

NOTE: For amputee patients, enter actual dry weight.

15. **To be completed by the attending physician**. Enter the ICD-9-CM from back of form to indicate the primary cause of end stage renal disease. These are the only acceptable causes of end stage renal disease.

16. Check the first box to indicate employment status 6 months prior to renal failure and the second box to indicate current employment status. **Check only one box for each time period**. If patient is under 6 years of age, leave blank.

17. **To be completed by the attending physician**. Check all co-morbid conditions that apply.

    ***Cerebrovascular Disease** includes history of stroke/ cerebrovascular accident (CVA) and transient ischemic attack (TIA).

    ***Peripheral Vascular Disease** includes absent foot pulses, prior typical claudication, amputations for vascular disease, gangrene and aortic aneurysm.

    ***Drug dependence** means dependent on illicit drugs.

18. Prior to ESRD therapy, check the appropriate box to indicate whether the patient received Exogenous erythropoetin (EPO) or equivalent, was under the care of a nephrologist and/or was under the care of a kidney dietitian. Provide vascular access information as to the type of access used (Arterio-Venous Fistula (AVF), graft, catheter (including port device) or other type of access) when the patient first received outpatient dialysis. If an AVF access was not used, was a maturing AVF or graft present?

NOTE: For those patients re-entering the Medicare program after benefits were terminated, Items 19a thru 19c should contain initial laboratory values within 45 days prior to the most recent ESRD episode. Lipid profiles and HbA1c should be within 1 year of the most recent ESRD episode. Some tests may not be required for patients under 21 years of age.

19a1. Enter the serum albumin value (g/dl) and date test was taken. This value and date must be within 45 days prior to first dialysis treatment or kidney transplant.

19a2. Enter the lower limit of the normal range for serum albumin from the laboratory which performed the serum albumin test entered in 19a1.

19a3. Enter the serum albumin lab method used (BCG or BCP).

19b. Enter the serum creatinine value (mg/dl) and date test was taken. **THIS FIELD MUST BE COMPLETED.** Value must be within 45 days prior to first dialysis treatment or kidney transplant.

19c. Enter the hemoglobin value (g/dl) and date test was taken. This value and date must be within 45 days prior to the first dialysis treatment or kidney transplant.

19d. Enter the HbA1c value and the date the test was taken. The date must be within 1 year prior to the first dialysis treatment or kidney transplant.

19e. Enter the Lipid Profile values and date test was taken. These values: TC–Total Cholesterol; LDL–LDL Cholesterol; HDL–HDL Cholesterol; TG–Triglycerides, and date must be within 1 year prior to the first dialysis treatment or kidney transplant.

20. Enter the name of the dialysis facility where patient is currently receiving care and who is completing this form for patient.

21. Enter the 6-digit Medicare identification code of the dialysis facility in item 20.

22. If the person is receiving a regular course of dialysis treatment, check the appropriate **anticipated long-term treatment setting** at the time this form is being completed.

23. If the patient is, or was, on regular dialysis, **check the anticipated long-term primary type of dialysis**: Hemodialysis, (enter the number of sessions prescribed per week and the hours that were prescribed for each session), CAPD (Continuous Ambulatory Peritoneal Dialysis) and CCPD (Continuous Cycling Peritoneal Dialysis), or Other. **Check only one block**. NOTE: Other has been placed on this form to be used only to report IPD (Intermittent Peritoneal Dialysis) and any new method of dialysis that may be developed prior to the renewal of this form by Office of Management and Budget.

24. Enter the date (month, day, year) that a "regular course of chronic dialysis" began. The beginning of the course of dialysis is counted from the beginning of regularly scheduled dialysis necessary for the treatment of end stage renal disease (ESRD) regardless of the dialysis setting. The date of the first dialysis treatment after the physician has determined that this patient has ESRD and has written a prescription for a "regular course of dialysis" is the "Date Regular Chronic Dialysis Began" regardless of whether this prescription was implemented in a hospital/ inpatient, outpatient, or home setting and regardless of any acute treatments received prior to the implementation of the prescription.

NOTE: For these purposes, end stage renal disease means irreversible damage to a person's kidneys so severely affecting his/her ability to remove or adjust blood wastes that in order to maintain life he or she must have either a course of dialysis or a kidney transplant to maintain life.

If re-entering the Medicare program, enter beginning date of the current ESRD episode. Note in Remarks, Item 53, that patient is restarting dialysis.

25. Enter date patient started chronic dialysis at current facility of dialysis services. In cases where patient transferred to current dialysis facility, this date will be after the date in Item 24.

26. Enter whether the patient has been informed of their options for receiving a kidney transplant.

27. If the patient has not been informed of their options (answered "no" to Item 26), then enter all reasons why a kidney transplant was not an option for this patient at this time.

28. Enter the date(s) of the patient's kidney transplant(s). If reentering the Medicare program, enter current transplant date.

29. Enter the name of the hospital where the patient received a kidney transplant on the date in Item 28.

30. Enter the 6-digit Medicare identification code of the hospital in Item 29 where the patient received a kidney transplant on the date entered in Item 28.

31. Enter date patient was admitted as an inpatient to a hospital in preparation for, or anticipation of, a kidney transplant prior to the date of the actual transplantation. This includes hospitalization for transplant workup in order to place the patient on a transplant waiting list.

32. Enter the name of the hospital where patient was admitted as an inpatient in preparation for, or anticipation of, a kidney transplant prior to the date of the actual transplantation.

33. Enter the 6-digit Medicare identification number for hospital in Item 32.

34. Check the appropriate functioning or non-functioning block.

35. Enter the type of kidney transplant organ donor, Deceased, Living Related or Living Unrelated, that was provided to the patient.

36. If transplant is nonfunctioning, enter date patient returned to a regular course of dialysis. If patient did not stop dialysis post transplant, enter transplant date.

37. If applicable, check where patient is receiving dialysis treatment following transplant rejection. A nursing home or skilled nursing facility is considered as home setting.

Self-dialysis Training Patients (Medicare Applicants Only)

Normally, Medicare entitlement begins with the third month after the month a patient begins a regular course of dialysis treatment. This 3-month qualifying period may be waived if a patient begins a self-dialysis training program in a **Medicare approved training facility** and is expected to self-dialyze after the completion of the training program. Please complete items 38-43 if the patient has entered into a self-dialysis training program. Items 38-43 must be completed if the patient is applying for a Medicare waiver of the 3-month qualifying period for dialysis benefits based on participation in a self-care dialysis training program.

38. Enter the name of the provider furnishing self-care dialysis training.

39. Enter the 6-digit Medicare identification number for the training provider in Item 38.

40. Enter the date self-dialysis training began.

41. Check the appropriate block which describes the type of self-care dialysis training the patient began. If the patient trained for hemodialysis, enter whether the training was to perform dialysis in the home setting or in the facility (in center). If the patient trained for IPD (Intermittent Peritoneal Dialysis), report as Other.

42. Check the appropriate block as to whether or not the physician certifies that the patient is expected to complete the training successfully and self-dialyze on a regular basis.

43. Enter date patient completed or is expected to complete self-dialysis training.

44. Enter printed name and signature of the attending physician or the physician familiar with the patient's self-care dialysis training.

45. Enter the Unique Physician Identification Number (UPIN) of physician in Item 44. (See Item 48 for explanation of UPIN.)

46. Enter the name of the physician who is supervising the patient's renal treatment at the time this form is completed.

47. Enter the area code and telephone number of the physician who is supervising the patient's renal treatment at the time this form is completed.

48. Enter the physician's UPIN assigned by CMS.

    A system of physician identifiers is mandated by Section 9202 of the Consolidated Omnibus Budget Reconciliation Act of 1985. It requires a unique identifier for each physician who provides services for which Medicare payment is made. An identifier is assigned to each physician regardless of his or her practice configuration. The UPIN is established in a national Registry of Medicare Physician Identification and Eligibility Records (MPIER). Transamerica Occidental Life Insurance Company is the Registry Carrier that establishes and maintains the national registry of physicians receiving Part B Medicare payment. Its address is: UPIN Registry, Transamerica Occidental Life, P.O. Box 2575, Los Angeles, CA 90051-0575.

49. To be signed by the physician supervising the patient's kidney treatment. Signature of physician identified in Item 46. A stamped signature is unacceptable.

50. Enter date physician signed this form.

51. To be signed by the physician who is currently following the patient. If the patient had decided initially not to file an application for Medicare, the physician will be re-certifying that the patient is end stage renal, based on the same medical evidence, by signing the copy of the CMS-2728 that was originally submitted and returned to the provider. If you do not have a copy of the original CMS-2728 on file, complete a new form.

52. The date physician re-certified and signed the form.

53. This remarks section may be used for any necessary comments by either the physician, patient, ESRD Network or social security field office.

54. The patient's signature authorizing the release of information to the Department of Health and Human Services must be secured here. **If the patient is unable to sign the form, it should be signed by a relative, a person assuming responsibility for the patient or by a survivor**.

55. The date patient signed form.

Appendix B. CMS-2746 Death Notification Form

Form Approved
OMB No. 0938-0048

ESRD DEATH NOTIFICATION
END STAGE RENAL DISEASE MEDICAL INFORMATION SYSTEM

1. Patient's Last Name	First	MI	2. Medicare Claim Number

3. Patient's Sex	4. Date of Birth	5. Social Security Number
a. ☐ Male b. ☐ Female	___ ___ / ___ ___ / ___ ___ ___ ___ Month Day Year	

6. Patient's State of Residence	7. Place of Death	8. Date of Death
	a. ☐ Hospital c. ☐ Home e. ☐ Other b. ☐ Dialysis Unit d. ☐ Nursing Home	___ ___ / ___ ___ / ___ ___ ___ ___ Month Day Year

9. Modality at Time of Death

a. ☐ Incenter Hemodialysis b. ☐ Home Hemodialysis c. ☐ CAPD d. ☐ CCPD e. ☐ Transplant f. ☐ Other

10. Provider Name and Address *(Street)*	11. Provider Number

Provider Address *(City/State)*

12. Causes of Death (enter codes from list on back of form)

a. Primary Cause: ___ ___ ___

b. Were there secondary causes?
☐ No
☐ Yes, specify: ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

c. If cause is other (98) please specify: _____

13. Renal replacement therapy discontinued prior to death: ☐ Yes ☐ No

If yes, check one of the following:

a. ☐ Following HD and/or PD access failure
b. ☐ Following transplant failure
c. ☐ Following chronic failure to thrive
d. ☐ Following acute medical complication
e. ☐ Other
f. Date of last dialysis treatment ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

14. Was discontinuation of renal replacement therapy after patient/family request to stop dialysis?

☐ Yes ☐ No
☐ Unknown ☐ Not Applicable

15. If deceased ever received a transplant:

a. Date of most recent transplant ___ ___ / ___ ___ / ___ ___ ___ ___ ☐ Unknown
Month Day Year

b. Type of transplant received
☐ Living Related ☐ Living Unrelated ☐ Deceased ☐ Unknown

c. Was graft functioning (patient not on dialysis) at time of death?
☐ Yes ☐ No ☐ Unknown

d. Did transplant patient resume chronic maintenance dialysis prior to death?
☐ Yes ☐ No ☐ Unknown

16. Was patient receiving Hospice care prior to death?

☐ Yes ☐ No
☐ Unknown

17. Name of Physician *(Please print complete name)*	18. Signature of Person Completing this Form	Date

This report is required by law (42, U.S.C. 426; 20 CFR 405, Section 2133). Individually identifiable patient information will not be disclosed except as provided for in the Privacy Act of 1974 (5 U.S.C. 5520; 45 CFR Part 5a).

ESRD DEATH NOTIFICATION FORM
LIST OF CAUSES

CARDIAC
23 Myocardial infarction, acute
25 Pericarditis, incl. Cardiac tamponade
26 Atherosclerotic heart disease
27 Cardiomyopathy
28 Cardiac arrhythmia
29 Cardiac arrest, cause unknown
30 Valvular heart disease
31 Pulmonary edema due to exogenous fluid
32 Congestive Heart Failure

VASCULAR
35 Pulmonary embolus
36 Cerebrovascular accident including intracranial hemorrhage
37 Ischemic brain damage/Anoxic encephalopathy
38 Hemorrhage from transplant site
39 Hemorrhage from vascular access
40 Hemorrhage from dialysis circuit
41 Hemorrhage from ruptured vascular aneurysm
42 Hemorrhage from surgery (not 38, 39, or 41)
43 Other hemorrhage (not 38-42, 72)
44 Mesenteric infarction/ischemic bowel

INFECTION
33 Septicemia due to internal vascular access
34 Septicemia due to vascular access catheter
45 Peritoneal access infectious complication, bacterial
46 Peritoneal access infectious complication, fungal
47 Peritonitis (complication of peritoneal dialysis)
48 Central nervous system infection (brain abscess, meningitis, encephalitis, etc.)
51 Septicemia due to peripheral vascular disease, gangrene
52 Septicemia, other
61 Cardiac infection (endocarditis)
62 Pulmonary infection (pneumonia, influenza)
63 Abdominal infection (peritonitis (not comp of PD), perforated bowel, diverticular disease, gallbladder)
70 Genito-urinary infection (urinary tract infection, pyelonephritis, renal abscess)

LIVER DISEASE
64 Hepatitis B
71 Hepatitis C
65 Other viral hepatitis
66 Liver-drug toxicity
67 Cirrhosis
68 Polycystic liver disease
69 Liver failure, cause unknown or other

GASTRO-INTESTINAL
72 Gastro-intestinal hemorrhage
73 Pancreatitis
75 Perforation of peptic ulcer
76 Perforation of bowel (not 75)

METABOLIC
24 Hyperkalemia
77 Hypokalemia
78 Hypernatremia
79 Hyponatremia
100 Hypoglycemia
101 Hyperglycemia
102 Diabetic coma
95 Acidosis

ENDOCRINE
96 Adrenal insufficiency
97 Hypothyroidism
103 Hyperthyroidism

OTHER
80 Bone marrow depression
81 Cachexia/failure to thrive
82 Malignant disease, patient ever on Immunosuppressive therapy
83 Malignant disease (not 82)
84 Dementia, incl. dialysis dementia, Alzheimer's
85 Seizures
87 Chronic obstructive lung disease (COPD)
88 Complications of surgery
89 Air embolism
104 Withdrawal from dialysis/uremia
90 Accident related to treatment
91 Accident unrelated to treatment
92 Suicide
93 Drug overdose (street drugs)
94 Drug overdose (not 92 or 93)
98 Other cause of death
99 Unknown

INSTRUCTIONS FOR COMPLETING OF ESRD DEATH NOTIFICATION: CMS-2746-U2

ITEM **PROCEDURE**

1. **Patient's Last Name, First, and Middle Initial**
Enter the patient's last name, first name, and middle initial as it appears on the Medicare Card or other official SSA notification.

2. **Medicare Claim Number**
Enter the patient's Medicare number as it appears on the Medicare Card or other official SSA notification.

3. **Patient's Sex**
Check the box that indicates the patient's sex.

4. **Date of Birth**
Enter the date in month, day, and year order, using an 8-digit number; e.g., 07/24/2000 for July 24, 2000.

5. **Social Security Number**
Enter the patient's own social security number.

6. **Patient's State of Residence**
Enter the two-letter United States Postal Service abbreviation for State in the space provided; e.g., MD for Maryland, NY for New York.

7. **Place of Death**
Check the one block which indicates the location of the patient at time of death. In-transit deaths or dead on arrival (DOA) cases are to be identified by checking "Other."

8. **Date of Death**
Enter the date in month, day, and year order, using an 8-digit number.

9. **Modality at Time of Death**
Check the one block, which indicates the patient's modality at time of death. "Other" has been placed on the form to be used only to report IPD (Intermittent Peritoneal Dialysis) and any new method of dialysis that may be developed prior to the renewal of this form by the Office of Management and Budget.

10. **Provider Name and Address (City and State)**
Enter the complete name of the provider submitting the form and the city and State in which the provider is located.

11. **Provider Number**
Enter the provider number (6-digit Medicare identification code) assigned by the Centers for Medicare & Medicaid Services.

12. **Causes of Death**

a. Primary Cause: Enter the numeric code from the list on the form, which represents the patient's primary cause of death. Do not report the same cause of death for primary and secondary causes.

b. Were there secondary causes?
Check the one block, which indicates whether or not there were secondary cause(s) of death.
If yes, enter the code from the list on the form, which represents the secondary cause(s) of death.

c. If cause is "Other" (98) please specify.

NOTES:

1. Code 82, "Malignant disease, patient ever on immunosuppressive therapy" means immunosuppressive therapy prior to the diagnosis of malignant disease.

2. Code 104, "Withdrew from dialysis" may not be reported as a cause of death (e.g., Code 98; "Other") and specify.

13. Renal Replacement Therapy Discontinued Prior to Death Indicate Yes / No
Check the one block, which indicates whether or not the patient voluntarily discontinued renal replacement therapy prior to death.

If **YES**, check one of the following:
Check the one box, which best describes the condition under which the patient discontinued renal replacement therapy.

a. Following HD and/or PD access failure
b. Following transplant failure
c. Following chronic failure to thrive
d. Following acute medical complication
e. Other
f. Enter date of last dialysis treatment using an 8-digit number

14. Was Discontinuation of Renal Replacement Therapy after Patient/Family Request to Stop Dialysis
Check the appropriate box that applies. Yes / No / Unknown / or Not Applicable

15. If Deceased Ever Received a Transplant
If the patient had ever received a transplant, complete items a through d.

a. Date of most recent transplant. Enter the date of the most recent transplant in month, day, and year order using an 8-digit number. If unknown, check box for unknown.
b. Type of transplant received. Check the block that indicates type of transplant received.
c. Was graft functioning at time of death?
Check appropriate block Yes / No or Unknown.
d. Did transplant patient resume chronic maintenance dialysis prior to death?
Check appropriate block Yes / No or Unknown.

16. Was Patient Receiving Hospice Care Prior to Death?
Check appropriate block Yes / No / or Unknown.

17. Name of Physician
Enter the name of the physician supplying the information for this form.

18. Signature of Person Completing this Form
The person completing the form should sign this space. The date should be entered.

Distribution of Copies:

Complete the ESRD Death Notification, CMS-2746, within 2 weeks of the date of death. If the patient was a dialysis patient, the dialysis facility last responsible for the patient's maintenance dialysis (or home dialysis) must complete this form. If the patient was a transplant patient, the transplant center is responsible for completing this form.

Mail the original (GREEN) copy to the ESRD network.

Retain the facility (WHITE) copy at your facility.

The form CMS-2746 can be obtained from your ESRD Network office.

Appendix C. Comparison of Quality-of-Care Indicators in Patients with End-Stage Renal Disease Secondary to Lupus Nephritis vs. Other Causes

Title: Comparison of Quality-of-Care Indicators in Patients with End-Stage Renal Disease Secondary to Lupus Nephritis vs. Other Causes

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Word Count: 3985
Abstract Word Count: 216

Tables: 3
Figures: 2

Financial Support: L.C.P. was supported by Laney Graduate School, Emory University. R.E.P. was supported in part by grants from the National Center for Advancing Translational Sciences of the National Institutes of Health (NIH; ULl TR000454 and KL2TR000455). R.E.P. and S.O.P are both supported in part by R24MD008077-01 through the National Institute on Minority Health and Health Disparities. C.D. and S.S.L. are supported in part by NIH R01AR065493 and CDC U01DP005119. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

Objective. To determine whether patients with end-stage renal disease (ESRD) due to lupus nephritis (LN-ESRD) have better quality of care than other ESRD patients.

Methods. Among incident patients (7/05-9/11) with ESRD due to LN (*n*=6,594) vs. other causes (*n*=617,758), identified using a national surveillance cohort (United States Renal Data System), we determined the association between attributed cause of ESRD and quality-of-care indicators (pre-ESRD nephrology care, placement on the deceased donor kidney transplant waitlist, and placement of permanent vascular access). Multivariable logistic and Cox proportional hazards models were used to estimate adjusted odds ratios (ORs) and hazard ratios (HRs).

Results. LN-ESRD patients were more likely than other ESRD patients to receive pre-ESRD care (71% vs. 66%; OR=1.68, 95% CI 1.57-1.78) and be waitlisted in the first year (206 vs. 86 per 1000 patient-years; HR=1.42, 95% CI 1.34-1.52). However, only 24% had a permanent vascular access (fistula or graft) in place at dialysis start (vs. 36%; OR=0.63, 95% CI 0.59-0.67).

Conclusion. LN-ESRD patients are more likely to receive pre-ESRD care and have better access to transplant—but are less likely to have a permanent vascular access for dialysis—than other ESRD patients. Further studies are warranted to examine barriers to permanent vascular access placement, as well as morbidity and mortality associated with temporary access, in patients with LN-ESRD.

Among end-stage renal disease (ESRD) patients, receipt of pre-ESRD care (1-9), access to kidney transplantation (10-15), and permanent vascular accesses for dialysis, which include arteriovenous fistulae (AVFs) and grafts (16-23), are all associated with better patient outcomes and lower healthcare costs. Benchmarks for each of these aspects of ESRD healthcare quality are provided in Healthy People 2020 (www.healthypeople.gov) (24), which sets nationwide goals to improve the overall health of the U.S. population. Further, Centers for Medicare & Medicaid Services (CMS) covers end-stage renal disease (ESRD) care for all eligible U.S. patients and, thus, is incentivized to promote quality of care. Accordingly, CMS mandates ESRD pay-for-performance (25) and quality improvement projects addressing various aspects of quality of ESRD care that are regionally implemented through its 18 ESRD Networks. Since 2005, CMS has also collected information on quality-of-ESRD-care indicators on all incident ESRD patients via the CMS Medical Evidence Report (CMS Form 2728), which is completed for all patients at the start of ESRD treatment.

Recently, we reported on the sociodemographic and geographic predictors of quality of ESRD care in this population (Plantinga *et al*., submitted manuscript), and others have reported specifically on patterns of placement on the deceased donor kidney transplant waitlist among LN-ESRD patients (26, 27). However, the translation of these indicators among LN-ESRD patients has not been compared to that among other ESRD patients. Translation of quality-of-care indicators should theoretically be as good—or better—in patient populations treated by multiple specialty providers, such as those with LN-ESRD, relative to the overall population. However, a similar U.S. population of ESRD patients in terms of age and race as well as receipt

of multi-provider treatment—those with ESRD secondary to sickle cell disease—was shown to have substantially decreased likelihood of pre-ESRD care or a functioning AVF at the start of dialysis, compared to patients with ESRD due to other causes (28). A similar comparison among patients with ESRD due to LN vs. other causes is important because rheumatologists, who currently have few guidelines to address the preparation for ESRD among their SLE patients (29), could partner with nephrologists and other providers to address identified gaps in the quality of ESRD care among these patients. Thus, we sought to compare the translation of ESRD quality-of-care indicators among U.S. patients with LN-ESRD vs. ESRD due to other causes.

Methods

Study Population and Data Sources

Data from the most recent (2005) version of the CMS-2728, completed on all treated U.S. incident ESRD patients, were obtained from the United States Renal Data System (USRDS) (15). A total of 675,889 incident ESRD patients were identified who initiated treatment from 7/1/05 to 9/30/11 and had data from the CMS-2728 regarding primary attributed cause of ESRD. Of these, 81,333 (12.0%) had unknown pre-ESRD nephrology care status and were excluded from these analyses (Figure 1). For analyses of indicators of access to kidney transplantation [informed of transplant options and placement on the deceased donor kidney waitlist (=kidney transplant waitlisting], those who were pre-emptively transplanted (n=17,054) or pre-emptively waitlisted (*n*=19,431) or who were aged ≥70 years (*n*=246,891) were excluded from the 675,889 ESRD patients, leaving 392,513 for analyses (Figure 1). For analyses of permanent vascular access, those with pre-emptive transplants (*n*=17,054) and those treated with peritoneal dialysis (*n*=42,810) were excluded, leaving 616,025 (Figure 1).

Primary attributed cause of ESRD, quality-of-care indicators (nephrology care prior to ESRD, being informed of transplant options, and vascular access at first dialysis), race/ethnicity, insurance, and clinical factors were all obtained from the CMS-2728 through the USRDS. Waitlisting information was obtained from United Network for Organ Sharing (UNOS) data, also available through USRDS.

Study Variables

Attributed Cause of ESRD. The exposure of interest was the primary attributed cause of ESRD, which was defined by ICD-9 codes as listed on the CMS-2728. LN-ESRD was defined as ESRD attributed to secondary glomerulonephritis due to SLE (CMS-2728 ICD-9 code = 710.0). ESRD due to other GN was included as a separate category for comparison with LN-ESRD due to potential similarities in patient population, disease course, and treatment. GN-ESRD was defined by CMS-2728 ICD-9 codes for glomerulonephritis (582.9, 582.1, 583.1, 583.21, 583.22, 583.81, 583.82, 583.4, 580.0, and 582.0) or secondary glomerulonephritis/vasculitis (excluding LN-ESRD; 287.0, 710.1, 283.11, 446.0, 446.4, 583.92, 446.20, 446.21, and 583.91). All other causes of ESRD, which served as the referent group in main analyses, included all other ICD-9 codes as listed on the CMS-2728. Since the majority of incident ESRD in the United States is attributed to diabetes or hypertension (72%) or GN (6%) (15) and the remaining attributed causes represent a fairly diverse group of ESRD etiologies such as cystic kidney disease, we conducted sensitivity analyses including only patients with ESRD attributed to diabetes (250.4x) or hypertension or large vessel disease (CMS-2728 ICD-9 code = 403.91, 440.1, 583.81, 593.83)—representing typical U.S. ESRD patients—in the referent group.

Quality-of-Care Indicators. The outcomes of interest were quality-of-care indicators related to pre-ESRD care, access to transplant, and permanent vascular access placement. Pre-ESRD nephrology care was defined by an answer of "Yes" to item 18b on the CMS-2728: "Prior to ESRD therapy: was the patient under the care of a nephrologist?" Whether patients were informed of transplant option was defined by CMS -2728 item 26: "Has patient been informed of kidney transplant options?" with possible responses of "Yes" and "No." Date of placement on the deceased donor transplant waitlist was determined from UNOS data and used to calculate

time to transplant waitlisting (date of waitlisting – first ESRD service date). Censoring occurred at death or at the end of follow-up (9/30/11; median follow-up, 1.9 years). Finally, vascular access was determined from CMS-2728 item 18d: "What access was used on first outpatient dialysis?" with possible responses of "AVF," "Graft," "Catheter," and "Other" and two additional prompts for maturing permanent accesses in place ("Is maturing AVF present?" and "Is maturing graft present?"). Permanent vascular access was defined as AVF or graft used or in place on first dialysis.

Other Variables. Incident age and sex were obtained from the USRDS patient demographics file. Race/ethnicity (defined as white, black, Hispanic, and other), insurance prior to ESRD (defined as private, Medicaid, none, or other), smoking status, BMI, presence of comorbid conditions, and serum albumin and hemoglobin at the start of ESRD were obtained from the CMS-2728.

Statistical Analysis

Patient characteristics including sociodemographics and clinical factors were summarized overall and by attributed cause (LN-ESRD, GN-ESRD, and other ESRD). Quality-of-care indicators were summarized overall and by incident year within appropriate study populations, and tests for linear trend over time were performed. Odds ratios (ORs) and confidence intervals (CIs) for the associations between dichotomous outcomes (pre-ESRD nephrology care, informed of transplant options, and permanent vascular access placement) were estimated with multivariable logistic regression models. For transplant waitlisting, time-to-event analyses were used. Tests of Schoenfeld residuals suggested Cox proportional hazards assumptions may be violated ($P<0.001$ for unadjusted and adjusted models) and log-log curves indicated some potential non-

proportionality after 1 year. Thus, hazard ratios (HRs) and CIs were obtained from multivariable Cox proportional hazards models with a Heaviside function, allowing calculation of hazard before and after 1 year of ESRD treatment, to account for this potential violation. Factors that were associated with both attributed cause and quality-of-care indicators and were not thought *a priori* to be mediators of the association were considered potential confounders. Sensitivity analyses (*i*) with diabetes and hypertension as the referent group (see above) and (*ii*) with further adjustment for albumin (missing on 23% of patients), as well as indicator-specific sensitivity analyses, were also conducted. Stata v. 13 (StataCorp, College Station, TX) was used for all analyses.

Results

Characteristics of the Study Population by Attributed ESRD Cause

Patients with ESRD due to LN had a mean age of 40 years and were, on average, 14 years younger than patients with ESRD due to other glomerulonephritis (GN), who were, in turn, 10 years younger than those with ESRD due to other causes (Table 1). The majority of LN-ESRD patients were female, compared to fewer than half of GN-ESRD and other ESRD patients (Table 1). Similarly, half of LN-ESRD patients were black, compared to approximately one-quarter of GN-ESRD and other ESRD patients (Table 1). Those with LN and GN were more likely to have private insurance than other ESRD patients (Table 1). While cardiovascular disease was far more common in other ESRD patients than among LN- or GN-ESRD patients, the prevalence of hypertension did not vary considerably by attributed cause of ESRD (Table 1). Those with LN-ESRD were less likely to report smoking and also had lower BMI and lower levels of albumin and hemoglobin than those with GN-ESRD or other ESRD (Table 1).

Association of Attributed Cause of ESRD with Quality-of-Care Indicators

Pre-ESRD Care. Overall, about two-thirds of U.S. ESRD patients received pre-ESRD nephrology care, with LN-ESRD (71%) and GN-ESRD (69%) patients more likely to receive pre-ESRD care than other ESRD (65%) patients (Table 2). Receipt of pre-ESRD care among incident patients increased slightly from 2005 to 2011 for each attributed cause, although the trend was not statistically significant for LN-ESRD (Table 2). After adjustment for potential sociodemographic and clinical confounders, those with LN-ESRD were nearly 70% more likely than other ESRD patients to receive pre-ESRD care, whereas GN-ESRD patients were only about 20% more likely to receive this care (Table 3). The magnitude of the association of LN vs.

other ESRD was increased when models were further adjusted for albumin (OR=2.02, 95% CI 1.88-2.17) but reduced when those with ESRD due to diabetes or hypertension only were used as a referent group (OR=1.56, 95% CI 1.46-1.56).

Access to Transplant. Overall, 79% of U.S. ESRD patients were informed of transplant options at the start of ESRD, with 85%, 84%, and 78% of patients with ESRD due to LN, GN, and other causes being informed. Absolute increases of about 5% in being informed of transplant options were seen over study follow-up for all incident ESRD patients (Table 2), although the trend was only marginally statistically significant for LN-ESRD patients. With adjustment, ESRD patients with LN and GN were 10% and 19% more likely than those with other causes to be informed of the transplant options. Results were nearly identical when models were further adjusted for albumin (data not shown). When diabetes and hypertension were used as the referent group, being informed of transplant options did not differ for those with LN-ESRD vs. the comparison group (OR=0.98, 95% CI 0.91-1.06).

Incidence of transplant waitlisting was 97 per 1000 patient-years overall but was more than twice as high among LN-ESRD and GN-ESRD patients as compared to other ESRD patients (Table 2). Waitlisting incidence increased over time among patients with all causes of ESRD, although the trend was only marginally statistically significant for LN-ESRD patients (Table 2). Time to waitlisting was similar among ESRD patients with LN and GN but was much shorter among both groups of patients compared to other ESRD patients (Figure 2). Adjusted analyses showed that the rate of waitlisting among LN-ESRD patients was 42% higher than that among other ESRD patients in the first year of ESRD; this relatively increased rate was even higher (56%)

after the first year (Table 3). In comparison, GN-ESRD patients had nearly twice the rate of waitlisting as other ESRD patients in the first year but only a ~40% higher rate after the first year (Table 3). When models were further adjusted for albumin and diabetes or hypertension only was used as the comparison group, results were slightly higher in magnitude for the first year for LN-ESRD (HR=1.53, 95% CI 1.43-1.63) but not substantially different after the first year (HR=1.56, 95% CI, 1.45-1.67). When being transplanted without waitlisting (which occurred in 1.6%, 1.2%, and 1.0% of patients with ESRD due to LN, GN, and all other causes, respectively) was combined with waitlisting as an outcome, results were similar but attenuated (LN-ESRD: first year, HR=1.31, 95% CI, 1.24-1.40; after first year, HR=1.41, 95% CI, 1.31-1.51; GN-ESRD: first year, HR=1.81, 95% CI, 1.76-1.85; after first year, HR=1.32, 95% CI, 1.28-1.37).

Permanent Vascular Access. More than one-third of all dialysis patients had a permanent vascular access in place at the start of treatment, but fewer than one-quarter of LN-ESRD patients had a fistula or graft in place (Table 2). There were no differences over time in permanent vascular access placement overall or by cause of ESRD (Table 2). With adjustment, LN-ESRD patients remained nearly 40% less likely than other ESRD patients to have a permanent vascular access used or in place at first dialysis, whereas GN-ESRD patients were 10% more likely than other ESRD patients to have a permanent vascular access (Table 3). Results were nearly identical when models were further adjusted for albumin (data not shown). When the referent group was limited to diabetes and hypertension only, results showed that LN-ESRD patients remained less likely to have a permanent vascular access (OR=0.63, 95% CI 0.59-0.67). Patients with other causes of ESRD who had early transplants (within 1 year of ESRD start) were more likely than similar patients who either did not receive a transplant or

received a transplant after 1 year of ESRD start to have a permanent vascular access (46.4% vs. 35.8%, $P<0.001$), but this was not true among LN-ESRD (27.2% vs. 24.3%, $P=0.32$) or GN-ESRD (36.5% vs. 37.8%, $P=0.26$) patients. Among those with early transplants and with full adjustment, both LN-ESRD (OR=0.66, 95% CI, 0.48-0.92) and GN-ESRD (OR=0.83, 95% CI, 0.74-0.93) patients were less likely than other ESRD patients to have a permanent vascular access in place at start of ESRD. For all attributed cause groups, males were more likely than females to have a permanent vascular access used or in place at the start of ESRD [LN-ESRD, 27.8% vs. 23.9% ($P=0.038$); GN-ESRD, 41.0% vs. 32.8% ($P<0.001$); and other ESRD, 37.2% vs. 34.2% ($P<0.001$)].

Discussion

Compared to other ESRD patients, LN-ESRD patients represent a group that may receive greater clinical attention due not only to their underlying SLE but also their young age. Our results showed that, indeed, receipt of pre-ESRD nephrology care and access to transplant waitlisting were higher among LN-ESRD vs. other ESRD patients. After adjustment for striking differences across the patient populations—including age, sex, race, and insurance, as well as clinical characteristics—LN-ESRD patients remained more likely than other ESRD patients to have had pre-ESRD care, to be informed of transplant options at the start of ESRD, and to be waitlisted for kidney transplantation while on dialysis. These patterns were similar to those seen in the comparison of GN-ESRD to other ESRD patients. However, only about one-quarter of LN-ESRD patients had a permanent vascular access in place at the start of dialysis, and LN-ESRD patients remained strikingly less likely than either GN-ESRD or other ESRD patients to have a permanent vascular access in place at the start of dialysis, accounting for patient characteristics and early transplant status.

While LN-ESRD patients were nearly 70% more likely than other ESRD patients to have pre-ESRD nephrology care after adjustment for differences in the populations, nearly one-third of patients with SLE and LN progressed to ESRD without ever having seen a nephrologist. Further, the percentage of patients receiving pre-ESRD care generally increased slightly over time among most ESRD patients, but not among those with LN-ESRD. Progression of LN is much faster among black patients (30, 31), who are overrepresented in LN and SLE and may also be less likely to access care early, which may make nephrology referral prior to development of ESRD more difficult. It is also possible that presentation with ESRD among some SLE patients, as well

as the relapsing-remitting nature of SLE and LN, potentially involving sudden renal flares (32), may make it difficult in some cases to refer to nephrology prior to the urgent need for dialysis treatment. However, it is likely that such presentations are rare and that, with greater attention to signs of renal damage and dysfunction (biopsy-proven GN, hematuria, proteinuria, and reduced glomerular filtration rate) among patients with adequate access to SLE care, lack of pre-ESRD nephrology care among LN-ESRD patients could be, if not eliminated, at least greatly reduced.

Being informed of transplant options and especially waitlisting increased over study follow-up for patients with all attributed causes of ESRD; secular trends of increased waitlisting have been noted in the U.S. LN-ESRD population previously (26, 27). Changes in waitlisting criteria that have reduced racial disparities in waitlisting (33, 34) may have resulted in greater access to waitlisting among the minority LN-ESRD population. Additionally, increasing evidence that transplant outcomes among LN-ESRD and other ESRD patients appear to be equivalent (35-37) may have contributed to this increase, if more providers are taking this evidence into account when deciding whether to refer patients for transplant evaluation. While both LN-ESRD and GN-ESRD patients were more likely to be waitlisted for kidney transplantation than patients with other ESRD, the association was even stronger after the first year of ESRD among LN-ESRD patients (the opposite pattern of that seen in GN-ESRD), which may reflect clinical recommendations to wait to transplant LN-ESRD patients to allow SLE activity to decrease (38, 39). However, whether such delays are necessary or potentially even detrimental to kidney transplant outcomes in this population remains in question (40).

Despite a national quality initiative program initially implemented in 2003-2004 to increase the use of AVFs (41), most U.S. ESRD patients started dialysis without a permanent vascular access in place, and the percentage with a permanent vascular access at the start of dialysis did not increase appreciably over study follow-up for any ESRD group we examined—mirroring recent reports that show that, while placements of fistulae have increased, the use of temporary catheters rates has not decreased substantially (42). LN-ESRD patients were far less likely than either GN-ESRD or other ESRD patients to have a permanent access in place, a gap that has been noted previously in pediatric SLE patients (43, 44). While female sex may be associated with more difficulty placing AVFs (but not necessarily grafts) (45) and with greater likelihood of body image issues associated with permanent vascular access (46), accounting for the female predominance in the LN-ESRD population did not change the results. Further, we found that males with LN-ESRD were only slightly more likely than females with LN-ESRD—and far less likely than males or females with GN-ESRD or other ESRD—to have a permanent vascular access. The possibility that providers may skip permanent vascular access among patients that may be slated for early transplants was also not supported by our findings that having a permanent vascular access in place at the start of dialysis was as (or even more) likely among those patients who received a transplant within a year of ESRD start than other ESRD patients. History of multiple, prolonged intravenous treatments in SLE patients could play a role in decisions not to refer for vascular access surgery, as could hypercoagulable states in SLE patients, particularly in the setting of anti-phospholipid syndrome (39); however, neither of these possibilities could be examined with available data. Greater anticipated recovery from ESRD among SLE patients could play a role (47) but seems unlikely to explain our results, given that transplant access was much higher among LN-ESRD patients than other ESRD patients.

Similar to the population with ESRD secondary to sickle cell disease (28), another young, primarily minority patient population with multiple providers, the LN-ESRD population showed substantial gaps in placement of permanent vascular access for hemodialysis. However, unlike the sickle cell population, LN-ESRD patients were more likely than the general ESRD population receive pre-ESRD care. Such disparate patterns of adequacy of care in LN-ESRD could be the result of so-called "silos" of care, in which there is lack of communication and coordination among specialty providers and a loss of patient-centeredness (48). Lack of direct communication between nephrologists and rheumatologists and the general lack of guidelines in rheumatology to address preparation for ESRD (29) may discourage the rheumatologist from actively participating in certain treatment decisions for their LN-ESRD patients. While rheumatologists may refer appropriately to nephrologists, they may leave discussions of specific preparation for transplantation and dialysis to nephrologists; in turn, nephrologists may assume that rheumatologists are coordinating the overall care of the patient approaching LN-ESRD and spend less time discussing ESRD preparation with these patients. Such gaps in communication in this critical period could lead to less preparedness for the initiation of ESRD (*e.g.*, placement of permanent vascular access) but greater access to treatment options (*e.g.*, waitlisting for kidney transplantation) after the start of ESRD, when SLE activity may "burn out" (38), leading to patients being primarily treated by nephrologists at dialysis facilities.

This study has several limitations. The USRDS does not capture non-Medicare-eligible individuals who have untreated ESRD, including some undocumented residents. Also, attribution of ESRD cause on the CMS-2728 has unknown validity; only one small validation study has

been published (49), suggesting a low sensitivity. There is the potential for selection bias due to missing data (12.0%) in analyses of pre-ESRD care. Misclassification of quality of care indicators on the CMS-2728 is also possible, due to variability in provider knowledge about patients. Many potential confounders, such as hemoglobin and albumin, may be the result of the adequacy of care, rather than a factor that leads to adequate care. Such factors may serve as mediating factors rather than confounders, leading to potential overadjustment, although we found that crude and adjusted results generally did not differ substantially. As with any observational study, residual confounding is possible. However, this study also has several powerful strengths, including the capture of all U.S. patients treated for ESRD, limited loss to follow-up due to universal coverage of ESRD services by CMS, and the completion of the CMS-2728 for all treated patients.

There is room for improvement in all quality-of-care indicators among SLE patients approaching ESRD. While patients with LN-ESRD are more likely to receive pre-ESRD care and have better access to transplant than patients with ESRD due to other causes, they are far less likely than their counterparts to have a permanent vascular access in place for dialysis. Further studies are warranted to specifically examine patient-, provider-, and system-level barriers to permanent vascular access placement and to estimate the morbidity and mortality associated with temporary access in the LN-ESRD population, as well as to examine, more generally, potential barriers to adequate ESRD care in patients with complex diseases and multiple providers, such as those with SLE.

Acknowledgements

The data reported here have been supplied by the United States Renal Data System (USRDS). The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official policy or interpretation of the U.S. government.

Tables & Figures

Table 1. Characteristics of U.S. ESRD patients with attributed causes of lupus nephritis, other types of glomerulonephritis, and all other causes, 7/05-9/11

Characteristic	Overall	Attributed Cause of ESRD*		
		LN	Other GN	All Other
N	*675,889*	*6,594*	*51,537*	*617,758*
Sociodemographic				
Age, years, mean (SD)	62.5 (16.0)	39.6 (15.4)	53.9 (18.9)	63.4 (15.3)
Sex, %				
Female	43.7%	81.1%	40.7%	43.5%
Male	56.3%	18.9%	59.3%	56.5%
Race/ethnicity, %				
White	52.9%	24.7%	57.8%	52.7%
Black	28.1%	49.7%	22.5%	28.3%
Hispanic	13.4%	17.7%	12.3%	13.4%
Other	5.7%	7.9%	7.4%	5.6%
Insurance at ESRD start, %				
Private	31.3%	37.4%	41.8%	30.3%
Medicaid	24.5%	32.8%	18.6%	24.9%
Medicare/other	36.8%	18.4%	30.0%	37.5%
None	7.5%	11.5%	9.6%	7.3%
Clinical				

Characteristic	Overall	Attributed Cause of ESRD*		
		LN	Other GN	All Other
Smoking, %				
No	93.8%	95.7%	92.7%	93.9%
Yes	6.2%	4.3%	7.3%	6.1%
BMI, kg/m^2, mean (SD)	28.9 (7.8)	26.9 (7.4)	28.1 (7.5)	29.0 (7.8)
Hypertension, %				
No	15.4%	16.4%	17.0%	15.3%
Yes	84.6%	83.6%	83.0%	84.7%
CVD, %				
No	57.8%	81.4%	75.8%	56.0%
Yes	42.2%	18.6%	24.2%	44.0%
Albumin, g/dl, mean (SD)	3.1 (0.7)	2.9 (0.8)	3.2 (0.8)	3.1 (0.7)
Hemoglobin, g/dl, mean (SD)	10.0 (1.7)	9.5 (1.7)	10.0 (1.8)	10.0 (1.6)

LN, lupus nephritis; GN, glomerulonephritis; BMI, body mass index; CVD, cardiovascular disease, including pericarditis; p-y, person-years.

*$P<0.001$ for all comparisons across attributed cause, by ANOVA, chi-square, or log-rank test.

Table 2. Attainment of quality-of-care indicators by cause of ESRD (lupus nephritis, other glomerulonephritis, and all other causes) and by incident year, among U.S. ESRD patients initiating treatment 7/05-9/11

Quality-of-care indicator*	Entire follow-up (7/05-9/11)	Incident year							P_{trend}
		2005	2006	2007	2008	2009	2010	2011	
Pre-ESRD nephrology care, %									
All ESRD	65.7%	65.9%	65.6%	65.0%	65.0%	65.5%	65.9%	67.7%	*<0.001*
ESRD attributed to:									
Lupus nephritis	71.1%	72.2%	70.2%	71.7%	70.3%	73.1%	68.9%	72.3%	*0.96*
Other glomerulonephritis	69.3%	69.3%	69.1%	67.7%	69.2%	69.0%	70.4%	71.2%	*0.002*
All other causes	65.3%	65.5%	65.2%	64.6%	64.6%	65.1%	65.5%	67.4%	*<0.001*
Informed of transplant options, %									
All ESRD	78.9%	76.9%	76.2%	76.6%	78.0%	80.5%	81.4%	82.4%	*<0.001*
ESRD attributed to:									
Lupus nephritis	84.8%	87.0%	82.6%	82.6%	84.8%	85.9%	86.5%	85.8%	*0.07*
Other glomerulonephritis	83.6%	82.3%	82.1%	81.6%	83.6%	84.5%	85.1%	87.0%	*<0.001*
All other causes	78.3%	76.1%	75.5%	76.0%	77.4%	80.1%	81.1%	82.0%	*<0.001*
Waitlisting, events/1000 p-y									
All ESRD	97	83	88	91	99	114	122	95	*<0.001*
ESRD attributed to:									
Lupus nephritis	206	194	177	208	210	230	263	180	*0.07*
Other glomerulonephritis	203	162	181	190	211	240	277	232	*<0.001*
All other causes	86	74	78	80	88	102	108	82	*<0.001*
Permanent vascular access used or in place at ESRD start, %									

Quality-of-care indicator*	Entire follow-up (7/05-9/11)	Incident year							P_{trend}
		2005	2006	2007	2008	2009	2010	2011	
All ESRD	35.9%	37.4%	36.7%	35.4%	34.3%	35.1%	36.4%	37.4%	*0.89*
ESRD attributed to:									
Lupus nephritis	24.4%	22.3%	25.7%	23.9%	23.5%	24.3%	25.5%	25.3%	*0.45*
Other glomerulonephritis	37.7%	40.3%	38.6%	37.4%	36.1%	36.7%	37.1%	39.6%	*0.83*
All other causes	35.9%	37.3%	36.7%	35.4%	34.2%	35.0%	36.5%	37.4%	*0.11*

ESRD, end-stage renal disease; p-y, patient year. *P<0.001 for all overall and within-year comparisons of indicators across attributed cause of ESRD.

Table 3. Risk ratios for attributed causes of lupus nephritis and other glomerulonephritis vs. other causes of ESRD, among U.S. ESRD patients initiating treatment 7/05-9/11

Quality of care indicator	Risk ratio for attributed cause of ESRD (95% CI)		
		Adjusted	
	Unadjusted	+ Sociodemographic	+ Sociodemographic and Clinical
Pre-ESRD care, yes vs. no (odds ratio)			
All other causes	1.00 (ref)	1.00 (ref)	1.00 (ref)
Lupus nephritis	1.64 (1.54-1.74)	1.51 (1.42-1.61)	1.68 (1.57-1.78)
Other glomerulonephritis	1.26 (1.23-1.28)	1.19 (1.17-1.22)	1.22 (1.19-1.24)
Informed of transplant options, yes vs. no (odds ratio)			
All other causes	1.00 (ref)	1.00 (ref)	1.00 (ref)
Lupus nephritis	1.10 (1.02-1.19)	1.09 (1.01-1.18)	1.10 (1.02-1.19)
Other glomerulonephritis	1.19 (1.15-1.23)	1.21 (1.17-1.25)	1.19 (1.15-1.23)
Time to kidney transplant waitlisting (hazard ratio)			
In 1st year of ESRD			
All other causes	1.00 (ref)	1.00 (ref)	1.00 (ref)
Lupus nephritis	2.29 (2.15-2.43)	1.47 (1.39-1.57)	1.42 (1.34-1.52)
Other glomerulonephritis	2.73 (2.66-2.80)	2.00 (1.95-2.05)	1.91 (1.86-1.96)
After 1st year of ESRD			
All other causes	1.00 (ref)	1.00 (ref)	1.00 (ref)
Lupus nephritis	2.45 (2.29-2.63)	1.60 (1.49-1.72)	1.56 (1.45-1.67)
Other glomerulonephritis	1.90 (1.84-1.97)	1.45 (1.40-1.50)	1.39 (1.35-1.44)
Permanent vascular access used/in place, yes vs. no (odds ratio)			
All other causes	1.00 (ref)	1.00 (ref)	1.00 (ref)

Lupus nephritis	0.57 (0.53-0.61)	0.58 (0.55-0.62)	0.63 (0.59-0.67)
Other glomerulonephritis	1.07 (1.05-1.10)	1.07 (1.05-1.10)	1.10 (1.07-1.12)

Sociodemographic: age, race, sex, and insurance; clinical: body mass index, cardiovascular disease (including pericarditis), and hemoglobin.

Figure 1. Selection of analytic populations for examination of the association of attributed cause of ESRD with pre-ESRD nephrology care, access to transplant, and vascular access, among U.S. ESRD patients initiating treatment 7/05-9/11. **boldface**, patients with ESRD attributed to lupus nephritis**,** *italic*, patients with other glomerulonephritis; ***boldface italic***, patients with all other causes of ESRD.

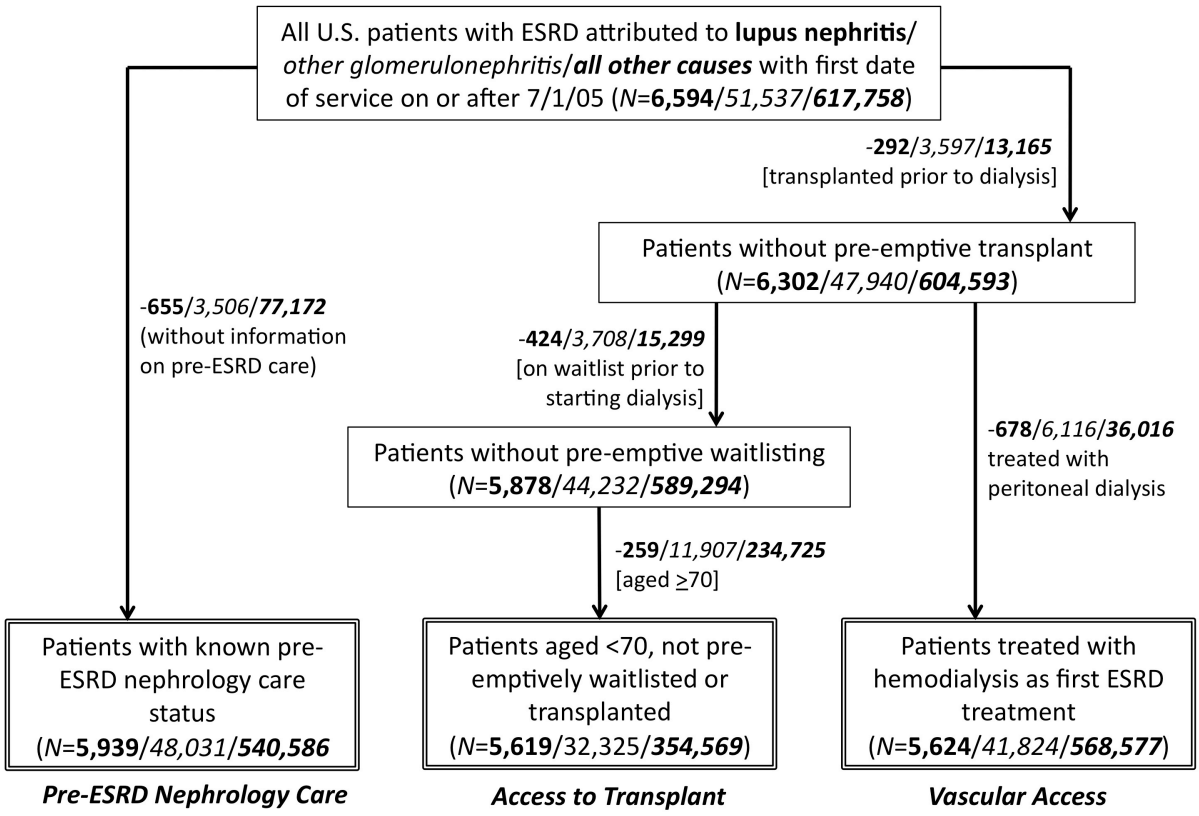
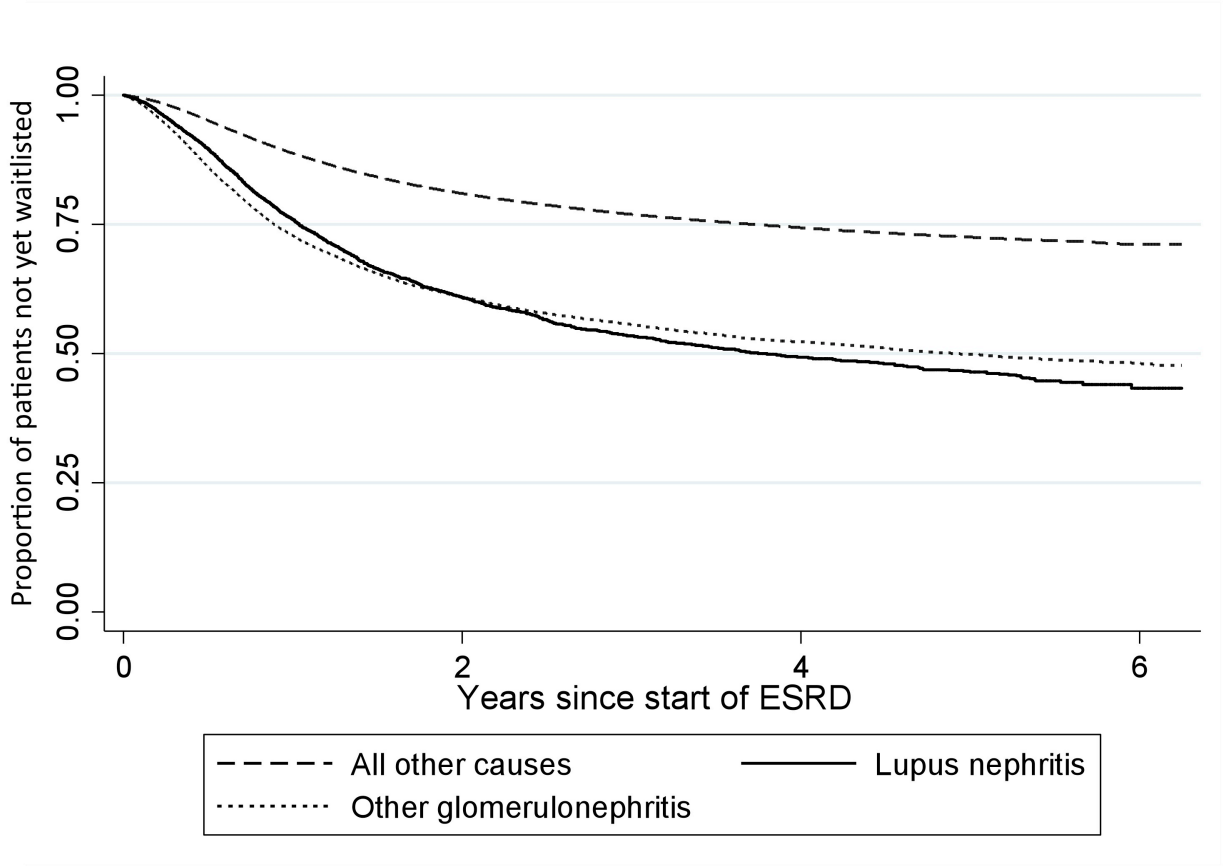


Figure 2. Kaplan-Meier curve for time to waitlisting among U.S. ESRD patients initiating treatment 7/05-9/11, by attributed cause of ESRD. *P*<0.001 by log-rank.



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