

Chronic Kidney Disease Registry



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Abstract

- ▶ Successful development of and sustainable research-oriented clinical disease registries based on Electronic Health Record (EHR) data are dependent on a multidisciplinary team
- ▶ CKD registry is a model for the initial planning, implementation and plans for sustaining a large disease-specific registry with data from the EHR
- ▶ The importance of multidisciplinary collaboration, ongoing governance and a focus on future planning are demonstrated success factors in this type of disease registries.

Chronic Kidney Disease

» National Trends

CKD National Burden

Table 3. Prevalence of Chronic Kidney Disease (CKD) Stages in US Adults Aged 20 Years or Older Based on NHANES 1988-1994 and NHANES 1999-2004

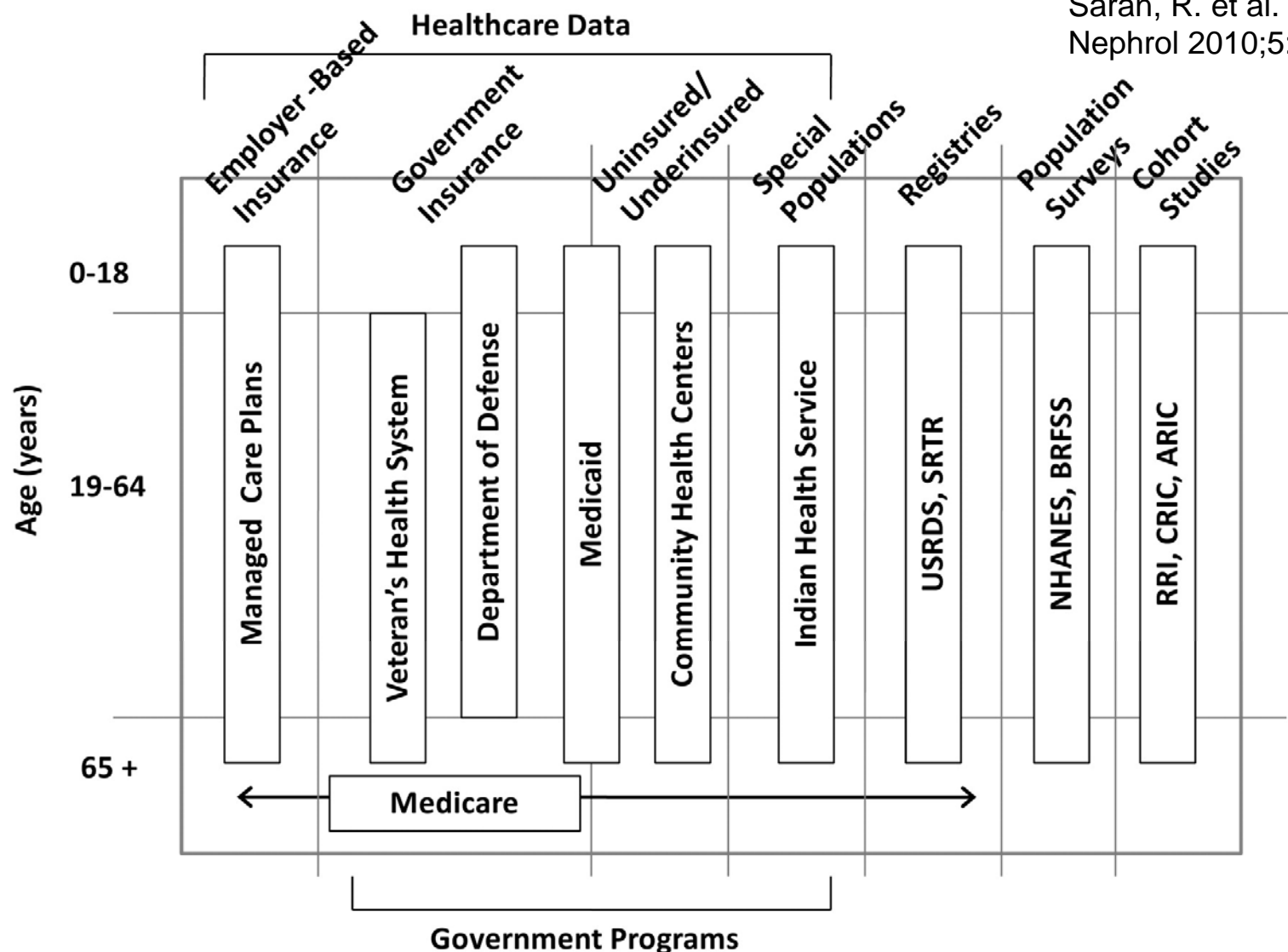
CKD Stage ^a	Prevalence, % (95% CI)		Prevalence Ratio for NHANES 1999-2004 to 1988-1994 (95% CI)	Estimated No. of US Adults in 2000, No. in Millions (95% CI)
	NHANES 1988-1994	NHANES 1999-2004		
1	1.71 (1.28-2.18)	1.78 (1.35-2.25)	1.05 (0.85-1.30)	3.6 (2.7-4.5)
2	2.70 (2.17-3.24)	3.24 (2.61-3.88)	1.21 (1.03-1.41)	6.5 (5.2-7.8)
3	5.42 (4.89-5.95)	7.69 (7.02-8.36)	1.42 (1.25-1.62)	15.5 (14.1-16.8)
4	0.21 (0.15-0.27)	0.35 (0.25-0.45)	1.70 (1.11-2.51)	0.7 (0.5-0.9)
5	NA	NA	NA	NA
Total	10.03 (9.16-10.91)	13.07 (12.04-14.10)	1.30 (1.19-1.43)	26.3 (24.2-28.3)

Abbreviations: CI, confidence interval; NA, data not included because patients with CKD stage 5 were excluded; NHANES, National Health and Nutrition Examination Surveys.

^aDefined based on standard criteria¹: stage 1, persistent albuminuria with glomerular filtration rate (GFR) higher than 90 mL/min/1.73 m²; stage 2, persistent albuminuria with GFR of 60 to 89 mL/min/1.73 m²; stage 3, GFR of 30 to 59 mL/min/1.73 m²; stage 4, GFR of 15 to 29 mL/min/1.73 m². The age-adjusted prevalence rates for CKD stages 1, 2, 3, and 4 in 1988-1994 adjusted to the 1999-2004 age distribution in Table 1 are 1.7%, 2.8%, 5.6%, and 0.2%, respectively, for a total of 10.3%.

Data sources for into the CDC CKD Surveillance System

Saran, R. et al. Clin J Am Soc Nephrol 2010;5:152-161



Major Renal Registries

Relation Between Kidney Function, Proteinuria, and Adverse Outcomes

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Anita Lloyd, MSc

Matthew T. James, MD

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for the Alberta Kidney Disease Network

Context The current staging system for chronic kidney disease is based primarily on estimated glomerular filtration rate (eGFR) with lower eGFR associated with higher risk of adverse outcomes. Although proteinuria is also associated with adverse outcomes, it is not used to refine risk estimates of adverse events in this current system.

Objective To determine the association between reduced GFR, proteinuria, and adverse clinical outcomes.

Design, Setting, and Participants Community-based cohort study with participants identified from a province-wide laboratory registry that includes eGFR and proteinuria measurements from Alberta, Canada, between 2002 and 2007. There were 920 985 adults who had at least 1 outpatient serum creatinine measurement and who did not require renal replacement treatment at baseline. Proteinuria was assessed by urine dipstick or albumin-creatinine ratio (ACR).

EMRs and Registries



1999 2000 2002 2004 2006 2008 2010

Aligning Research goals with Implementation

Billing & Reimbursement

ADT

???

Optime

Inpt Notes

Inpt CPOE

Doc Scanning

Tethered Patient Portal

Enterprise Master Patient Index

Electronic Prescriptions

Clinical Decision Support and Quality Reporting

Ambulatory EMR CPOE + Documentation

Integrated Lab/Radiology Results Reporting

Scheduling & Registration

Advantages over Administrative and Claims Data

- ▶ Rich clinical data gathered at the point of care
- ▶ Not limited to reimbursable services
- ▶ Not filtered by coders
- ▶ More longitudinal data

CKD Registry

»» At Cleveland Clinic

Chronic Kidney Disease Registry

- ▶ Established in 2009
- ▶ using data from the electronic health record (EHR) as a mechanism to improve quality
- ▶ Interdisciplinary team established
- ▶ Define cohort
- ▶ Identify data elements
- ▶ EMR – Epic Systems, Inc.

Purpose of the CKD Registry

- ▶ Identify CKD patients in CCHS so that processes of care for CKD could be examined and quality of care programs developed and implemented
- ▶ Describe the course of CKD and its complications in the outpatient setting through outcomes related research
- ▶ Serve as a comprehensive data source for evaluation of intervention programs related to CKD

Interdisciplinary Team

- ▶ Nephrologists
- ▶ Internal Medicine
- ▶ Nursing
- ▶ Biostatisticians
- ▶ Informaticists
- ▶ Health Services Researchers

IRB Approval

- ▶ Expedited review as registry
- ▶ Did not require informed consent
- ▶ Data transferred from the EMR and stored securely
- ▶ Limit access to biostatisticians doing analysis

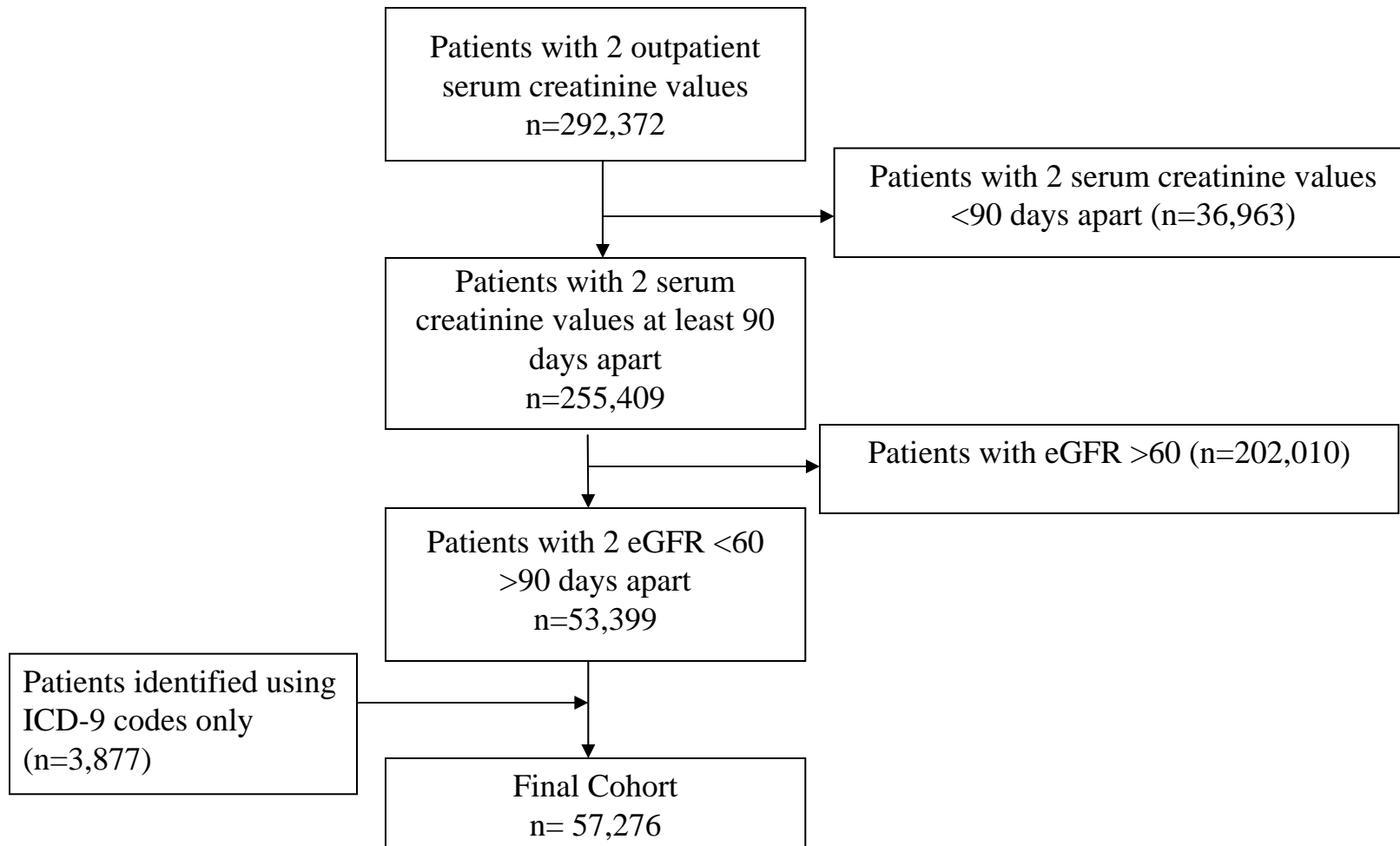
Inclusion Criteria

- ▶ Patients who had at least one face-to-face outpatient encounter with a Cleveland Clinic health care provider and
- ▶ a) had two eGFR (4-variable MDRD equation) values <60 ml/min/1.73m² more than 90 days apart as of January 1, 2005 and/or
- ▶ b) patients with International Classification of Diseases (ICD-9) codes (used twice in an outpatient encounter) for CKD, polycystic kidney disease, glomerulonephritis, diabetic nephropathy, hypertensive nephrosclerosis, renovascular disease as of January 1, 2005

Exclusion Criteria

- ▶ Age <18 years
- ▶ End Stage Renal Disease (those on dialysis, and those who had a kidney transplant)
- ▶ GFR values based on inpatient labs

Defining the Cohort



Data Elements in the Registry

- ▶ Demographics including SS# to compare with the SSDI
- ▶ Lab results
- ▶ Encounters
- ▶ Vital signs
- ▶ Medications prescribed
- ▶ Co morbidities
(from the problem list and encounter diagnosis)

Data Curation and Governance

1. Data management (are additional data elements needed, do existing ones require refinement)
2. Data validation
3. Publications and abstracts
4. Sustainability including grant applications and both internal/external collaborations, and
5. Knowledge transfer to clinical decision support

Presentations

- ▶ Development and Validation of an Electronic Health Record–Based Chronic Kidney Disease Registry – ASN
- ▶ Obesity Is Associated with Higher Rates of Vitamin D Deficiency among CKD Patients – ASN
- ▶ Traditional Risk Factors Predict Renal Function Decline among Younger but Not Older CKD Patients – ASN
- ▶ Implications of the CKD–EPI GFR Estimation Equation in a Health Care System
- ▶ Use of a large Electronic Health Record Based Registry: Characteristics of Chronic Kidney Disease (CKD) Patients with Diabetes who have CKD noted in their Problem List—A Call to Action – SGIM

Publications

- ▶ Development and Validation of an Electronic Health Record based Chronic Kidney Disease Registry. Clin J Am Soc Nephrol January 2011, 6: (1) 40–49
- ▶ Related Editorial – W Hersh. Electronic Health Records Facilitate Development of Disease Registries and More. Clin J Am Soc Nephrol 6: 2011

Validation of CKD Comorbidities



Characteristics of chronic kidney disease patients	Combined N=57,276
Age [Mean(SD)]	69.5 (13.4)
Years in Registry* [Mean(SD)]	2.8 (1.5)
Gender [n (%)]	
Female	31,614 (55.2)
Male	25,662 (44.8)
Ethnic Group [n (%)]	
Missing	613 (1.1)
Caucasian	48,371 (84.5)
African American	6,910 (12.1)
Hispanic/Latino	554 (1.0)
Asian/Pacific	255 (0.4)
Other	573 (1.0)
Insurance Group [n (%)]	
Missing	1,439 (2.5)
Medicare	30,594 (53.4)
Medicaid	1,210 (2.1)
Others	24,033 (42.0)

Co morbidities at Inclusion	n (%)
Diabetes	12,370 (21.6)
Hypertension	46,217 (80.7)
Coronary artery disease	10,306 (18.0)
Congestive heart failure	4,113 (7.2)
Hyperlipidemia	42,334 (73.9)
Cerebrovascular disease	4,318 (7.5)

Validation of a Chronic Kidney Disease Registry

Stage	Number	Mean Age
3 (GFR 30–59)	48,195	70.4
4 (GFR 15–29)	3804	70.8
5 (GFR <15)	1400	62.2
ICD9 Code only	3877	59.9
Combined	57,276	69.5

Comorbidities

Diagnosis	Number	Percent
Diabetes	12,370	21.6
Hypertension	46,217	80.7
Coronary artery disease	10,306	18.0
Congestive heart failure	4,113	7.2
Hyperlipidemia	42,334	73.9

Comorbidity Validation Process

- ▶ 20 randomly selected charts were reviewed to assess whether the ICD–9 was confirmed
- ▶ Reviewed problem list, physician notes, laboratory reports, and imaging results based on prespecified validation criteria
- ▶ To reduce the chance of misclassification because of “rule out” diagnoses, we required two occurrences of the ICD–9 code for each comorbid disease condition from the “encounter diagnosis”

Validation Results

Table 4. Agreement rates between EHR and chart review for ICD-9 codes related to nephrology diagnosis and selected comorbid conditions

Condition	κ Statistic (95% CI)	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value
Diabetic nephropathy	0.75 (0.55 to 0.95)	85%	90%	90%	85%
Glomerulonephritis	0.85 (0.69 to 1.00)	95%	90%	90%	85%
Polycystic kidney disease	0.90 (0.77 to 1.00)	100%	90%	90%	100%
Diabetes	0.90 (0.77 to 1.00)	91%	100%	100%	90%
Hypertension	0.45 (0.20 to 0.70)	65%	90%	95%	50%
Hyperlipidemia	0.85 (0.69 to 1.00)	95%	90%	90%	95%
Coronary artery disease	0.60 (0.35 to 0.85)	80%	80%	80%	80%
Congestive heart failure	0.85 (0.69 to 1.00)	87%	100%	100%	85%
Cerebrovascular disease	0.90 (0.76 to 1.00)	95%	95%	95%	95%

Validation Conclusions

- ▶ Our dataset's agreement with EHR-extracted data for documentation of the presence and absence of comorbid conditions, ranged from substantial to near perfect agreement.
- ▶ Hypertension and coronary artery disease were exceptions –
 - 65% sensitivity
 - 50% negative predictive value

Value of the Registry



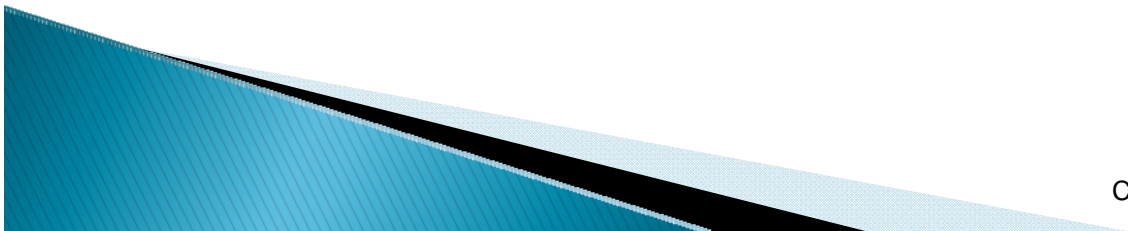
Value of the Registry

- ▶ Our CKD registry is a unique data source rich with clinical data, representing:
- ▶ A large population of patients with **Medicare** as primary payer
- ▶ a large **minority** population
- ▶ a large **geriatric** population,
- ▶ which lends itself to answering important questions about CKD *progression, treatment, and management*

Clinical Decision Support

- ▶ Future development of clinical decision support tailored to CKD screening and/or management
- ▶ *e.g., pop-up messages to convey patient-specific guidance or process of care reminders*
- ▶ Based on stages of CKD – 3, 4, 5

How can we impact the progression of CKD?



NIDDK R34 Grant

Navigating the Challenges of CKD

- ▶ Create a CKD Patient Navigator program
- ▶ Personal health record (PHR) that will use electronic communication to disseminate CKD stage-specific goals of care and CKD education modeling
- ▶ Investigate the clinical outcomes of two interventions
- ▶ Joseph Nally, MD – PI

Grant Outcome Criteria

- ▶ *More prepared, proactive patient–caregiver team than usual care.*
- ▶ *More informed, engaged patient than usual care*
- ▶ *Slower rate of decline in eGFR than usual care.*

Limitations of EMR data

- ▶ One of the major challenges for the re-use of EHR data is that data from clinician documentation are not always of optimal quality for such re-use.
- ▶ “I’m a doctor, not a clerk,” – resistance to CPOE
- ▶ Data in patient documentation are usually not as meticulous or reliable as that collected by, say, a clinical researcher

Critique – Editorial

- ▶ This particular registry may have been simpler than, say, a registry of patients with back pain, in which the diagnostic criteria are some what more nebulous or complex.
- ▶ We should not shirk from the challenges of developing registries for other diseases but rather just know that their construction may be more challenging
- ▶ *William Hersh, CJSAN editorial, 1/2011*

Sustainability – Registry Success Factors

- ▶ Strong interdisciplinary team including informaticists, meeting regularly
- ▶ Well defined cohort of patients
- ▶ Well defined data elements with cognizance of the limits of EMR data
- ▶ Pursue funding from industry sponsors, private foundations and federal grants
- ▶ Catalyze needed improvements in CKD care – Clinical Decision Support

Learning Healthcare System

- ▶ “As our nation enters a new era of medical science that offers the real prospect of personalized health care, we will be confronted by an increasingly complex array of healthcare options and decisions.”
- ▶ There are “opportunities for the creation of a sustainable, learning healthcare system that gets the right care to people when they need it and then captures the results for improvement.”
- ▶ *IOM, 2007*

Support

- ▶ CKD registry created with help of an unrestricted grant to the Department of Nephrology and Hypertension Research and Education fund from Amgen.

The Team

- ▶ Joseph Nally – Nephrology
- ▶ Sankar D. Navaneethan – Nephrology
- ▶ Stacey E. Jolly – Internal Medicine
- ▶ Jesse D. Schold – Epidemiology
- ▶ Susana Arrigain – Biostatistics
- ▶ Welf Saupe – Informatics
- ▶ Jennifer Lyons – Nursing
- ▶ James F. Simon – Nephrology
- ▶ Martin J. Schreiber, Jr. – Nephrology
- ▶ Anil Jain – Informatics