

Lab-Initiated Care Model for Chronic Kidney Disease

Improving Detection and Management of Kidney Disease Through Health System Integration – A Guide for Clinical Laboratories

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This Lab-Initiated Care Model for Chronic Kidney Disease was developed in Collaboration with the National Kidney Foundation and Project Santa Fe Foundation

Version 1 October 29, 2022

a. CL2.0 Ingredients

i. Disease Prevalence

Chronic kidney disease (CKD) affects an estimated one in seven American adults, with about 37 million individuals having some level of CKD and is the ninth leading cause of death.¹ Over 40% of patients with severe renal impairment are unaware that their kidneys are impaired.²

According to the CDC, \$81.6 billion was spent on treating Medicare beneficiaries with CKD, with an additional \$49.2 billion spent treating those with end stage renal disease (ESRD).³ In the United States, the two leading causes of CKD are diabetes and hypertension, which account for 67% of ESRD cases.³

Current guidelines for monitoring CKD patients are often not followed by providers with as many as 90% of people living with CKD undiagnosed in primary care settings, which includes as many as 40% of people whose CKD is advanced.⁴ The literature highlights that provider discussions with hypertensive patients only included CKD in about 25% of the time but included laboratory testing 89% of the time.⁵

CKD is asymptomatic in its early stages. Two widely available, inexpensive laboratory tests, serum creatinine with estimated glomerular filtration rate (eGFR) and urine albumin-creatinine ratio (uACR) detect CKD and are recommended for routine annual screening for people living with diabetes and/or hypertension.⁶ Recent data illustrates that almost 80% of the population at risk for CKD do not receive guideline-recommended testing on an annual basis.⁷ Plantinga, et al,⁸ published a framework that describes the interaction of provider, patient, risk factors, and consequences for CKD testing to describe why patients are not being screened for CKD. In a group of 236 patients, the authors describe that CKD discussions occurred in only 26% of patients with hypertension while 89% of discussions involving CKD involved laboratory monitoring. Laboratory involvement in clinical decision support systems (CDS) for CKD identification and management may provide promise.⁹

CKD is a disease multiplier that often occurs with other chronic co-morbidities and also increases the risk for emergency department (ED) visits, hospitalizations, cardiovascular events, kidney failure, and death.^{10,11} People living with CKD are hospitalized at least twice as often as individuals without CKD^{11,12,13} and hospital utilization increases with declining kidney function.^{14,15} Early diagnosis, implementation of lifestyle modification, and medical management can prevent CKD progression, reduce cardiovascular complications, reduce ED visits, hospitalizations, readmissions, and avert end-stage kidney disease.¹⁶⁻¹⁸

Communities of color are also disproportionately affected by CKD. People who identify as Black/African American comprise 13% of the US population¹⁹ yet account for over 30% of people with end-stage kidney disease (ESKD)³ and those with Hispanic ancestry are 1.3 times more likely to develop kidney failure when compared with non-Hispanic groups.³ There are disparities in care present at all stages of kidney disease.

As serum creatinine with eGFR is included in the basic/comprehensive metabolic panels and one of the most frequently ordered laboratory tests, this data may be utilized to identify people in the earliest stages of CKD when intervention can improve care and slow progression. An analysis of longitudinal laboratory data can reveal when CKD patients are not captured in claims data, risk adjustment scores, and have gaps in care due to missing follow-up. Additionally, the clinical laboratory can identify diabetes patients not screened for CKD using the Kidney Health Evaluation Measure developed by the National Kidney Foundation (NKF).²⁰

ii. Laboratory Leadership and Domain Knowledge

Chronic kidney disease is defined as abnormalities of kidney structure and or function for greater than 3 months. Kidney function is assessed using laboratory values such as estimated glomerular filtration (eGFR) rate, albumin to creatinine ratio, or protein to creatinine ratio. The laboratory with its longitudinal data is uniquely positioned to aid in the identification of patients with this often-asymptomatic disease.

iii. Key Stakeholders and Partnerships

The literature has recognized the importance of the provider, patient, community, communication and education in supporting CKD testing.⁸ While the laboratory clearly plays a central role, key partnerships are needed to implement a laboratory driven care model for chronic kidney disease should. These would include:

1. Population Health teams tasked with improving overall performance in reducing ED visits, hospitalizations, and readmissions.
2. Chief Medical Information Officers and the Information Technology teams to assist with longitudinal data extraction (see CKD definition below).
3. Primary care teams to assist with early identification and gaps in care with follow-up for CKD patients. Plantinga, et al⁵ has described a framework describing the interaction of the provider and patient awareness of CKD, risk factors, and outcomes. This framework identifies the rold of public and health policy to drive awareness, treatment guidelines, and awareness.
4. Nephrologists to assist in defining referral pathways and developing co-management strategies to support improved primary care management of CKD.
5. Hospital administrators and Chief Medical Officers of integrated health systems to provide information on the value of the laboratory in this high-cost disease and articulate the clinical and economic opportunities as a result of missed billing and risk stratification.
6. Teams tasked with improving health equity as low socioeconomic status, low educational attainment, and food insecurity are associated with increased risk of CKD and poorer outcomes including the identification of barriers to screening.
7. Quality Department personnel who are responsible for the collection and reporting of quality metrics for the Joint Commission and Healthcare Effectiveness Data and Information Set (HEDIS) to understand and document the barriers to evidence based treatment guidelines .
8. Information technology teams responsible for the development and implementation of decision support systems.
9. Interdisciplinary groups within integrated health systems that can develop and implement specific interventions to improve the detection and management of CKD using new and existing tools available. These interventions should include provider education, patient education, and policy development.

b. CL2.0 Insights and Actions

i. Clinical Protocols

Since laboratory results seen with acute kidney injury in the inpatient setting can mimic those of chronic kidney disease, this care model uses only outpatient laboratory results.

Longitudinal laboratory results can be used to identify patients with the following health conditions: CKD, CKD plus diabetes, CKD plus heart failure, CKD with diabetes AND heart disease, diabetes without laboratory screening for CKD. (Appendix A)

Longitudinal data for CKD is defined as two or more values separated by 3 months. This data extraction can be challenging for Laboratory Information Systems (LISs) but might be available through the electronic medical record (EMR), support from a third-party vendor or other data extraction mechanism available at the institution.

One or more of the following laboratory results or CPT codes can be used to identify patients with CKD who remain undiagnosed. Two or more of the following values separated by 3 months:

- eGFR: $<60\text{ml/min/1.72m}^2$ OR (CPT 82565)
- ACR: $\geq 30\text{mg/g}$ OR (CPT 82043, 82570)
- PCR: $\geq 150\text{mg/g}$ OR (CPT 84156, 82570)
- 24 hour urine $\geq 150\text{mg protein/24 hour urine}$

Stages of CKD should be defined using the following information from KDIGO national treatment guidelines.²¹

CKD is classified based on: -Cause (C) -GFR (G) -Albuminuria (A)				Albuminuria categories Description and range		
				A1	A2	A3
				Normal to mildly increased <30 mg/g <3 mg/mmol	Moderately increased 30-299 mg/g 3-29 mg/mmol	Severely increased $\geq 300\text{ mg/g}$ $\geq 30\text{ mg/mmol}$
GFR categories (ml/min/1.73m ²) Description and range	G1	Normal or high	≥ 90	1 if CKD	Treat 1	Refer* 2
	G2	Mildly decreased	60-89	1 if CKD	Treat 1	Refer* 2
	G3a	Mildly to moderately decreased	45-59	Treat 1	Treat 2	Refer 3
	G3b	Moderately to severely decreased	30-44	Treat 2	Treat 3	Refer 3
	G4	Severely decreased	15-29	Refer* 3	Refer* 3	Refer 4+
	G5	Kidney failure	<15	Refer 4+	Refer 4+	Refer 4+

CKD Stage	ICD-10 Codes
Stage 1	N18.1
Stage 2	N18.2
Stage 3	N18.3
Stage 4	N18.4
Stage 5	N18.5
CKD unspecified	N18.9

The eGFR and albuminuria grid depicts the risk of progression, morbidity, and mortality by color, from lowest to highest (green, yellow, orange, red, deep red). The numbers in the boxes are a guide to the frequency of assessment annually. Green: annual assessment for those at risk. (Green can reflect CKD with normal eGFR and albumin-to-creatinine ratio (uACR) only in the presence of other markers of kidney damage, such as imaging showing polycystic kidney disease or kidney biopsy abnormalities); Yellow suggests assessment at least once per year; Orange suggests assessment twice per year; Red suggests assessment three times annually; Deep red suggests assessment four times annually. These are general parameters only, based on expert opinion and must consider underlying comorbid conditions and disease state, as well as the likelihood of impacting a change in management for any individual patient!

An A1C of $\geq 6.5\%$ can be used to identify patients with diabetes.

Heart failure is often diagnosed through a combination of laboratory results and physical signs/symptoms. As a result, the identification of heart failure using laboratory values alone will not capture all patients with heart failure. Additional data to identify heart failure patients can come from ICD10 billing data or other mechanisms available from the institution.

The following laboratory results can be used to identify patients with heart failure:

One or more of the following laboratory results in 2021:

- a. BNP (CPT 83880) > 100 pg/mL
- b. NTpro (CPT 83880) > 210 pg/mL

The following laboratory results can be used to identify patients with diabetes without CKD screening:

One or more of the following laboratory results:

- a. A1C: $\geq 6.5\%$ AND
- b. No eGFR result (any value) AND
- c. No uACR result (any value)

While the identification of CKD patients using laboratory data can lead to significant opportunities for detection and management, the comparison of laboratory findings to ICD billing information, provides an opportunity to identify missed billing opportunities and highlight the financial risk of this patient population. For this reason, it is recommended that you work with others in the health system to compare the patients identified through ICD10 codes to the patients identified using longitudinal laboratory data.

The following is a list of ICD10 codes that can be utilized:

- a. N18.9: Chronic kidney disease unspecified
- b. N18.1 Stage 1 CKD
- c. N18.2 Stage 2 CKD
- d. N18.3: Stage 3 CKD
- e. N18.4: Stage 4 CKD
- f. E11.9: Diabetes w/o complications
- g. E11.8: Diabetes with complications
- h. E11.65: Diabetes Mellitus, II with hyperglycemia
- i. I50.: Heart failure (with all categories)
- j. I11.0 Hypertensive heart disease with heart failure
- k. I130: Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease

Using ICD codes alone, without laboratory result data, may result in patients with the disease not being identified due to missing billing documentation or documentation errors. It is recommended that if ICD codes are utilized, this data be compared to laboratory result data.

As clinicians may not routinely risk stratify people with CKD to the most appropriate staging of CKD, there is value in comparing the reported laboratory values with assigned ICD codes. Progression in CKD may impact therapeutic options as well as Hierarchical Condition Category (HCC) coding.

ii. Risk stratification

- a. Laboratories can provide risk stratification through the early identification of chronic kidney disease. This allows primary care providers to monitor patients and manage early disease to slow progression.
- b. Laboratories can identify the number of patients in each stage of chronic kidney disease which supports appropriate referrals to nephrologists.

iii. Care gaps

- a. Using data elements described in the clinical protocol section of this care model, the laboratory can identify patients without on-going monitoring for chronic kidney disease as recommended the KIDGO national guidelines.
- b. The laboratory can identify patients not screened for chronic kidney disease using the Kidney Health Evaluation Measure developed by the National Kidney Foundation (NKF).
- c. Laboratories can contribute real time data and monitoring for other quality measures for chronic kidney disease, such as MIPS or HEDIS measures, that rely on longitudinal laboratory values.

iv. High risk

- a. Laboratories can identify rapidly progressing chronic kidney disease for referral to nephrologists.
- b. Patients with concomitant health conditions often seen in the chronic kidney disease population such as diabetes and heart failure can be identified in real time using laboratory values.

v. Workflow and Facilitated Interventions

The laboratory can provide actionable data and facilitate interventions involving CKD patients in real time. Examples of actionable data and facilitated interventions that promote the lab's role in Clinical Lab 2.0 with improved patient outcomes and reduced health care costs may include:

1. Reports to primary care providers/specialists including:
 - a. New patients with CKD Stage 3 in the last 3 months
 - b. Patients whose CKD stage has changed in the last 3 months

- c. Patients with CKD to develop routine monitoring strategies
 - d. Patients with CKD and diabetes to develop routine monitoring strategies
 - e. Patients with CKD and heart disease to develop routine monitoring strategies
 - f. Patients with CKD, diabetes, and heart disease to develop routine monitoring strategies
2. Guidance/policy documents for when to refer CKD patients to specialty nephrology clinics or medical nutrition therapy
 3. Home phlebotomy services for CKD patients needing follow-up laboratory draws.
 4. Referral to CKD-specific education programs
 5. Work with clinical pharmacists to provide laboratory results.

Recommended interventions that can slow CKD progression and improve patient outcomes are included in the NKF CKD Change Package (<https://www.kidney.org/contents/chronic-kidney-disease-change-package>).

c. CL2.0 Value Proposition and Outcomes

1. Clinical Outcomes

1. Early identification of CKD patients (Stage 3A or 3B) in the primary care setting.
2. Identification of CKD patients who are rapidly progressing for referral to specialists.
3. Number of patients with gaps in care as a result of missing laboratory monitoring as defined by KIDGO national guidelines.
4. Number of patients within each stage of CKD.
5. Number of patients with concomitant health risks that can be identified using longitudinal laboratory data such as diabetes or heart disease.
6. Identify the proportion of patients with diabetes not screened for CKD using the Kidney Health Evaluation Measure developed by the National Kidney Foundation (NKF).

2. Financial Outcomes

1. Number of patients with missing ICD10 codes for CKD identified through longitudinal laboratory data.
2. Number of patients without Hierarchical Condition Category (HCCs) documentation, or other risk stratification identifier, who have chronic kidney disease identified through longitudinal laboratory data.
3. Number of CKD-related ED visits, hospitalizations, and readmissions.
4. Total cost of care for individuals with eGFR <60ml/min or uACR \geq 30mg/g.

3. Policy Development

Several policy considerations will influence the success of this model. Specifically, we seek to address the following policy issues to enhance CKD detection and management in the primary care setting:

1. **Reimbursement for Laboratory Screening:** Reimbursement mechanisms need to allow for the ordering and payment of laboratory testing needed for routine screening of chronic diseases as outlined by national and international treatment guidelines.
2. **Ordering and Reimbursement of Laboratory Test Profiles or Order Sets:** Remove ordering and payment barriers for the use of testing profiles or order sets on the laboratory requisition or electronic health record. Testing profiles or order sets incorporate several tests into a single order to support evidence-based clinical practice guidelines recommending multiple laboratory tests, standardize the tests used to detect and monitor a disease, and improve comparison of test results between laboratories. An example of a test profile is the “Kidney Profile” recommended by the National Kidney Foundation for CKD assessment and diagnosis. This CKD specific test profile simplifies ordering of the two tests needed to detect and diagnose.
3. **US Preventive Services Task Force (USPSTF) Screening Recommendation:** Primary care providers often look to the USPSTF to determine which screenings to offer patients. Further, health insurers are required to cover USPSTF recommended screenings with no cost sharing. The absence of a USPSTF screening recommendation for CKD is a barrier to care and interferes with the ability of patients to receive guideline concordant care.
4. **Quality Measurement:** Development of the kidney evaluation for diabetes measure and its adoption by HEDIS and MIPS is a significant step forward in assuring that clinicians are incentivized to test for CKD. Additional measures are needed, however, to incentivize screening in patients with hypertension, and to assess and incentivize whether providers are delivering care (e.g., Medical Nutrition therapy, drug therapy, etc.) that has demonstrated efficacy in delaying CKD progression.
5. **Kidney Disease Education:** KDE is highly effective in promoting informed dialysis selection, optimal dialysis starts, and home-dialysis use. Unfortunately, less than one percent of patients with kidney failure receive Medicare KDE prior to dialysis initiation, and African American race, Hispanic ethnicity, and the presence of congestive heart failure and hypoalbuminemia are associated with significantly lower odds of receiving KDE services. Further, KDE is currently restricted to patients with CKD Stage 4. Expansion

of this benefit could empower patients to slow their kidney disease progression, manage their kidney health, and more appropriately transition to dialysis care.

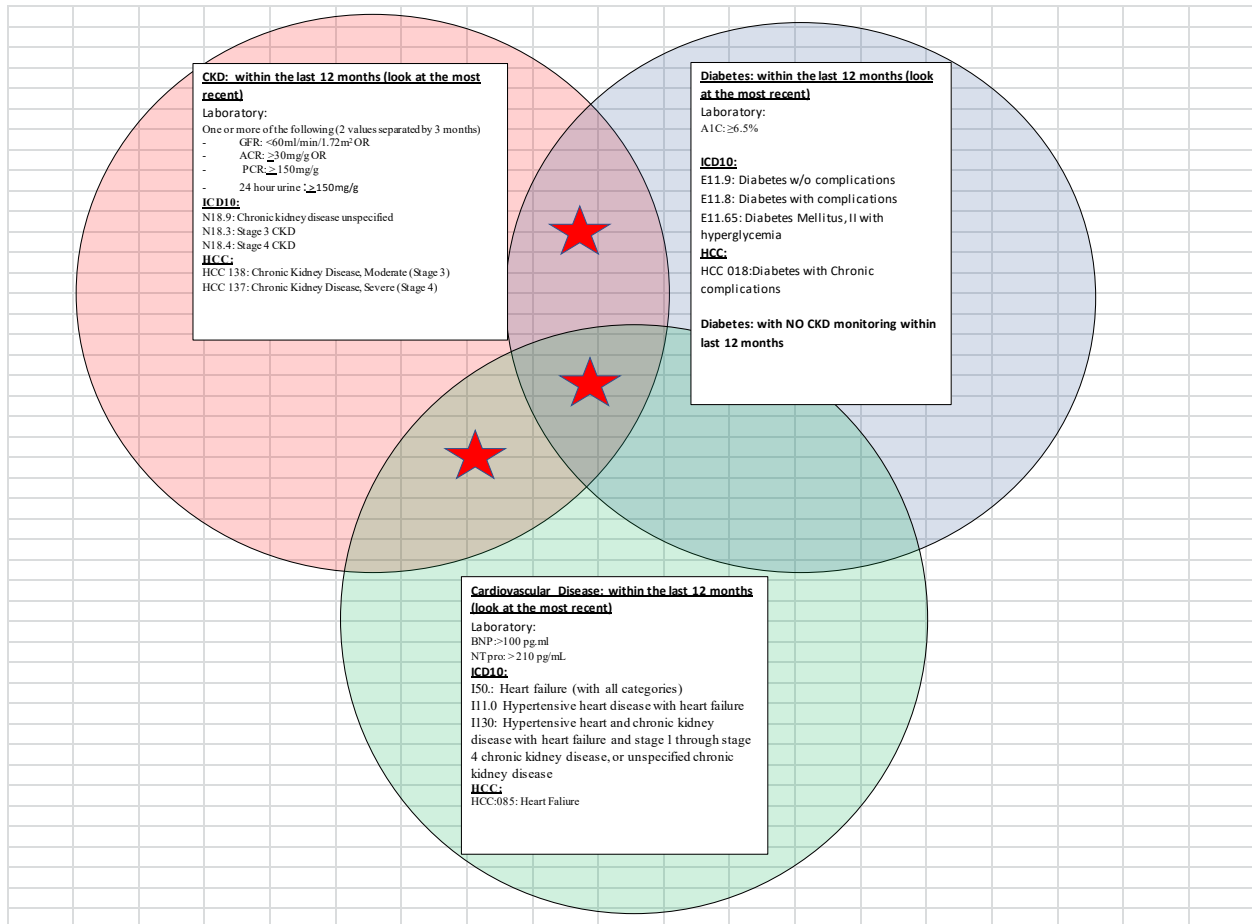
6. **Medical Nutrition Therapy (MNT):** MNT is a significantly under-utilized benefit that could more broadly and deeply benefit patients and their families if simple policy changes – such as expanding coverage to patients with earlier stages of CKD and allowing greater flexibility for who can provide MNT services and access where these services are offered.

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Appendix A – Four types of CKD patients identified with longitudinal laboratory data



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About Project Santa Fe Foundation:

Project Santa Fe Foundation, a 501c3 not-for-profit, is a coalition of laboratory leaders, coming together to create a disruptive value paradigm and explore alternative business models that expand the role of diagnostic services in the future healthcare ecosystem.

We will leverage laboratory medicine and pathology domain knowledge to establish the standards and evidence for Clinical Lab 2.0. We will facilitate diverse partner collaborations in order to guide policies,

