National Kidney Foundation Joins Project Santa Fe Foundation and the Diagnostic Medicine Consortium as Patient Advocacy Partner

Locking arms to move kidney care from reaction to prediction — building on published evidence that tens of thousands of patients had chronic kidney disease their medical records never recorded

SALT LAKE CITY, OCTOBER 2026, FOR IMMEDIATE RELEASE — Project Santa Fe Foundation (PSFF), the non-profit organization behind the Clinical Lab 2.0 movement, and the Diagnostic Medicine Consortium (DMC), the non-profit joint venture between PSFF and the Association for Pathology Informatics (API), today announced that the National Kidney Foundation (NKF) has joined both organizations as a patient advocacy partner.

The partnership joins the movement and the infrastructure to the patient's advocate: PSFF builds the evidence and the model, DMC builds the data layer that makes the model run at scale, and NKF brings the voice of the 37 million Americans living with kidney disease into the design of both.

The partnership formalizes a collaboration that has already produced peer-reviewed evidence. Working together, PSFF member institutions and NKF examined a full year of laboratory data across three U.S. health systems and found **32,398 adults whose laboratory results met the diagnostic criteria for stage 3 or stage 4 chronic kidney disease, but whose medical records carried no corresponding diagnosis.** At one institution, 78 percent of patients with laboratory evidence of CKD had never been coded as having it.

The same study found that among patients with laboratory-confirmed diabetes, which is the leading cause of kidney failure in the United States, between 59 and 83 percent had not received guideline-recommended kidney screening during the same twelve months.

The findings were published in *BMC Nephrology* in December 2024.

The mission: engineering the shift from reaction to prediction

Project Santa Fe Foundation exists for a single purpose — to re-engineer laboratory medicine from the reactive confirmation of diagnosis to the proactive prediction and management of disease.

The verb matters. A movement that only argues produces conferences. Engineering the shift means building every component required to make it real: the published evidence, the business model, the care pathway, the workforce and credentialing, the payment argument, and the data infrastructure underneath all of it.

Over nine years PSFF has produced each of these in turn, through multi-institutional demonstration projects and peer-reviewed publication rather than position statements.

The urgency is economic as well as clinical. American healthcare is moving from the business of volume to the business of value — and value, in practice, means risk. Someone is now financially accountable for what happens to a population rather than for what was ordered on a given afternoon. Risk is priced on probability. An organization that intends to carry risk must get better at prediction, because a higher probability of knowing what comes next is the only thing that simultaneously improves the outcome and changes the financial result.

Longitudinal laboratory data is where that probability lives. Chronic kidney disease is where PSFF has now demonstrated it.

The disease was visible. The system did not look.

An estimated 37 million American adults have chronic kidney disease. Among those not under the care of a nephrologist, roughly nine in ten do not know they have it. The disease is silent in its early stages and progresses continuously, while care is delivered in episodes. Nearly half of patients with CKD die of cardiovascular disease before their kidneys ever fail.

What the published work demonstrates is that for tens of thousands of these patients, the information was not missing. It was sitting in the laboratory record — an estimated glomerular filtration rate, measured and reported in the ordinary course of care, meeting the international diagnostic threshold, and going unaddressed.

This is the problem the Clinical Lab 2.0 model was built to solve. Rather than waiting for a clinician to order a test that confirms a diagnosis, the laboratory examines longitudinal data across an entire population to identify who already meets criteria, who has fallen outside guideline-concordant care, and who should be seen now rather than later. The care pathway is initiated by the laboratory, not merely reported by it.

Kidney disease does not travel alone

CKD is not a single-organ condition, and treating it as one is part of why it goes unaddressed. Diabetes and heart disease cause three of every four new cases. Nearly half of patients with CKD die of cardiovascular disease before their kidneys ever fail. The American Heart Association now describes this cluster as cardiovascular-kidney-metabolic (CKM) syndrome — a single interconnected disease process rather than three separate specialties' problems.

The scale is difficult to overstate. Nearly 90 percent of American adults have CKM syndrome at stage 1 or higher, and more than half of adults over 65 are at advanced stages. CKM-related conditions drive an estimated **$900 billion in annual direct health care costs in the United States**, and the American Heart Association's presidential advisory notes that indirect costs from lost economic productivity add more than a trillion dollars on top of that.

This is what makes the finding in the published study consequential beyond nephrology. The same laboratory data that identifies a patient's kidney disease also identifies their diabetes and their heart failure — and identifies the patients carrying two or three of these conditions at once, who represent the highest clinical

and financial risk in any population. The study measured exactly that overlap. It also found that between 59 and 83 percent of patients with laboratory-confirmed diabetes had not been screened for kidney disease at all.

A laboratory looking at one result sees a number. A laboratory looking at the longitudinal record across a population sees the syndrome — and sees it years before anyone reaches dialysis, an emergency department, or a cardiac event.

From evidence to infrastructure

Identifying 32,398 patients retrospectively, in a research study, is not the same as identifying them prospectively, in the course of care, at every institution that serves them. That requires infrastructure.

That infrastructure is DMC. Established as a 501(c)(3) joint venture between Project Santa Fe Foundation and the Association for Pathology Informatics — the professional society for the discipline that builds and governs diagnostic data systems — DMC exists to carry the model beyond the study. Where PSFF supplies the movement — the evidence, the committees, the published model, and the policy advocacy — DMC supplies the operational layer that makes the model run: the longitudinal biomarker repository, the patient consent framework, and the analytics required to detect a trajectory across time rather than a value at a moment.

The division of labor is deliberate. A care pathway that must be assembled by hand at each new site is a research project. A care pathway that runs on shared infrastructure is a standard of practice. NKF's partnership spans both: the patient advocacy voice belongs in the design of the evidence and in the design of the systems that carry it.

What the partnership will pursue

Together, PSFF and NKF will work to:

- **Replicate the laboratory-initiated CKD care pathway** across additional health systems and academic medical centers
- **Identify undiagnosed and under-managed kidney disease** at population scale using longitudinal laboratory data, including patients with diabetes who have never been screened
- **Empower patients and consumers** with access to their own kidney function over time, and the interpretive support to understand what it means
- **Build the health economics evidence** documenting the clinical and financial consequences of earlier intervention
- **Advocate for policy** that recognizes and funds laboratory-initiated care within value-based payment models
- **Extend the model globally**, beyond the United States, to health systems facing the same silent epidemic

Quotes

James M. Crawford, MD, PhD — Chair of the Board, Project Santa Fe Foundation

"Our moral responsibility does not end when we release a result. Rather, that is where it begins. Our multi-site study asked a simple question: if we look carefully at laboratory data already generated in the course of routine care, will we find patients with kidney disease that no one has identified? The answer was more than thirty-two thousand of them, across just three health systems. That is not a data problem. It is a care gap, and it is one the laboratory is uniquely positioned to close. For decades the clinical laboratory has answered the question *what is wrong with this patient?* The evidence in kidney disease shows we can answer a more consequential one — *what is coming, and how do we intervene now?* Partnering formally with the National Kidney Foundation brings the patient's advocate into the room where we design those pathways. It makes our science accountable to the people it is meant to serve."

Khosrow R. Shotorbani, MBA, MLS(ASCP) — President and CEO, Project Santa Fe Foundation

"Thirty-two thousand patients had their kidney disease measured, reported, and filed — and nothing happened. Unaddressed data is not neutral. When the abnormal result is measured, reported, and filed, that is diagnostic harm — and we have normalized it. The laboratory was first to know and last to act. That is the failure we exist to correct. Locking arms with the National Kidney Foundation changes the equation, because it puts an advocate for the patient at the center of how we build these pathways. We are moving diagnostics from reaction to prediction — not for one cohort at one institution, but across populations and across borders. That is why we built the Diagnostic Medicine Consortium with the Association for Pathology Informatics: the movement without the infrastructure is a conference, and the infrastructure without the patient's advocate is a database. And we intend to put a patient's own trajectory in their hands, in language they can use. A person who understands what their numbers are doing over time is the most underused asset in healthcare."

Elizabeth Montgomery — National Vice President, Clinical Practice Innovation and Population Health, National Kidney Foundation

“Too often, kidney disease is hiding in plain sight—visible in laboratory data but not translated into timely diagnosis and care. This partnership brings together the National Kidney Foundation’s commitment to patients with the laboratory community’s ability to identify risk across entire populations. By turning longitudinal data into action, we can find kidney disease earlier, empower people to understand their kidney health, and connect more patients to proven interventions before preventable complications occur.”

About Project Santa Fe Foundation

Project Santa Fe Foundation is a 501(c)(3) non-profit organization and the originator of the Clinical Lab 2.0 movement. Its mission is to re-engineer laboratory medicine from the reactive confirmation of diagnosis to the proactive prediction and management of disease — moving the clinical laboratory from the business of volume to the business of value, measured by risk. Through multi-institutional demonstration projects, peer-reviewed publication, committee workstreams, and policy advocacy, PSFF builds the evidence and the operating model for laboratories to serve as strategic partners in population health and value-based care. Learn more at cl2lab.org.

About the Diagnostic Medicine Consortium

The Diagnostic Medicine Consortium is a 501(c)(3) non-profit organization established as a joint venture between Project Santa Fe Foundation and the Association for Pathology Informatics (API). DMC builds and operates the data infrastructure that makes laboratory-initiated care operationally possible at scale, including a longitudinal biomarker repository, a patient consent framework, and analytic services that translate diagnostic data into actionable risk identification for health systems, payers, and patients.

About the National Kidney Foundation

The National Kidney Foundation is revolutionizing the fight to save lives by eliminating preventable kidney disease, accelerating innovation for the dignity of the patient experience, and dismantling structural inequities in kidney care, dialysis, and transplantation. For more information about NKF, visit www.kidney.org.

Reference

Ndumele CE, Rangaswami J, Chow SL, et al. Cardiovascular-Kidney-Metabolic Health: A Presidential Advisory From the American Heart Association. *Circulation*. 2023;148:1606-1635.

Fung M, Haghamad A, Montgomery E, Swanson K, Wilkerson ML, et al. A retrospective multi-site examination of chronic kidney disease using longitudinal laboratory results and metadata to identify clinical and financial risk. *BMC Nephrology*. 2024;25:447. https://doi.org/10.1186/s12882-024-03869-4

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