CRITICAL PATH INSTITUTE

Biomarkers 101: A Patient's Perspective on the Importance of Identifying New Biomarkers

Biomarkers are emerging as powerful tools in the field of kidney health, playing a crucial role in the diagnosis, monitoring, and treatment of kidney diseases. From the perspective of patients, understanding and monitoring these biomarkers enables us to take control of our health and participate as an equal partner in shared decision making?with our healthcare teams.?

Biomarkers are biological indicators that provide essential insights into our kidney function, thereby enabling early intervention and personalized care. The timely use of kidney biomarkers, such as serum creatinine, cystatin C, blood urea nitrogen, and urinary albumin, which are a regular part of our lab work, can significantly improve patient outcomes, reducing the likelihood of serious complications like kidney failure, and providing people living with kidney diseases with a better quality of life.

A lot of patients don't know what biomarkers are, but they are talked about all the time. There are a lot of biomarkers that come into play when looking at individual health, but patients don't know what they are because clinicians don't describe them as biomarkers. It would be good for nephrologists to understand that there is a value to explaining to people what biomarkers are and which of the items they talk about are and are not biomarkers.

Kidney diseases are silent killers. For many patients, the detection of kidney problems through biomarkers marks the difference between a condition that can be managed and a life-threatening disease. For instance, Chronic Kidney Disease (CKD) often progresses silently without noticeable symptoms until it has advanced. Traditional biomarkers such as albumin in the urine or elevated serum creatinine levels allow for the early identification of CKD, giving patients and healthcare professionals the opportunity to implement lifestyle changes and treatment changes before the disease becomes more severe. For me, a routine employee physical found albumin in my urine when I was 20 years old. This early detection permitted my physician and I to make shared decisions, such as dietary and lifestyle changes that slowed the progression of my kidney disease. This biomarker data helped prevent the need for invasive treatments like dialysis or kidney transplantation for over 40 years.

One of the most valuable aspects of biomarkers from a patient perspective is the ability to monitor kidney function over time. Regular monitoring provides a sense of control over one's health, helping patients actively participate in their care. By tracking biomarker changes, patients can work with their healthcare providers to adjust treatment plans and make necessary modifications in their daily lives. Shared decision-making is an essential goal for this process. For example, one of the outcomes of my evolving health profile has been the development of Cardiovascular-Kidney-Metabolic (CKM) syndrome. CKM syndrome is a multifaceted disorder that involves an interconnected relationship between cardiovascular disease, chronic kidney disease (CKD), and metabolic conditions, such as diabetes and obesity. The complexity of CKM syndrome makes diagnosis and management challenging, but biomarkers offer valuable insights into the underlying processes that drive the syndrome. The biomarkers discussed below help healthcare providers detect early signs of disease, assess risk, and develop personalized treatment plans that can improve patient outcomes.

One of the central biomarkers in CKM syndrome is the estimated Glomerular Filtration Rate (eGFR). eGFR measures how well the kidneys filter blood and is crucial for determining the severity of CKD. In patients

with CKM syndrome, a low eGFR is often indicative of reduced kidney function, which can accelerate cardiovascular complications and worsen metabolic conditions. By monitoring eGFR levels, healthcare professionals and patients can identify declining kidney function early and pursue interventions before more severe damage occurs.

Another key biomarker is the Urine Albumin-to-Creatinine Ratio (UACR), which detects the presence of albumin in the urine. Elevated UACR levels signal early kidney damage and are often associated with increased cardiovascular risk. This is especially significant in CKM syndrome, where kidney dysfunction and cardiovascular disease are closely intertwined. By identifying albumin in the urine early, UACR can help to pinpoint individuals at higher risk of both kidney and heart issues, thereby enabling more aggressive management of the condition.

For patients with diabetes, the Hemoglobin A1c (HbA1c)?is an essential biomarker, reflecting average blood glucose levels over the past three months. High HbA1c levels are not only an indicator of poor blood sugar control but also increase the risk of both CKD and cardiovascular disease. In CKM syndrome, managing blood glucose through regular monitoring of HbA1c is critical to preventing further complications. Keeping blood sugar levels in check can slow the progression of CKD and reduce the burden on the cardiovascular system.?

These are a few biomarkers that are indispensable in understanding and managing Cardio-Kidney-Metabolic syndrome. They provide early detection of disease, help in risk assessment, and guide personalized treatment strategies, ultimately improving patient outcomes. By monitoring markers such as eGFR, UACR, HbA1c, healthcare professionals and patients, working together, can better manage the complex interplay of cardiovascular, kidney, and metabolic issues in CKM syndrome, improving both quality of life and long-term health outcomes for affected patients. Through these biomarkers, working with their healthcare team, patients are empowered to make informed decisions regarding treatment, improving their health and outcomes.

The discovery of new biomarkers is especially significant for patients, because it opens the door to more precise and earlier detection of kidney issues. For instance, novel biomarkers I learned about through participating in C-Path’s Biomarker Data Repository (BmDR) project, such as neutrophil gelatinase-associated lipocalin (NGAL), kidney injury molecule-1 (KIM-1), and liver fatty acid-binding protein (L-FABP), can detect kidney injury in clinical trials at a much earlier stage than traditional markers. These newer biomarkers are more sensitive to subtle changes in kidney function, which means patients can receive a diagnosis and begin treatment before the damage becomes too severe.?

Importantly, the identification of these and other more advanced biomarkers may lead to more personalized treatments. ?By understanding the specific type and extent of kidney damage through such biomarkers, healthcare professionals can customize treatment plans to suit the individual needs of each patient. Precision therapies not only increase the chances of treatment success but also reduce the side effects associated with broad, one-size-fits-all approaches. In addition, the discovery and understanding of new biomarkers may lead to safer and more specific drugs and therapies, offering hope for more effective management and potential cures for kidney diseases in the future.

In conclusion, kidney biomarkers are indispensable tools for patients managing kidney health. They enable early diagnosis, effective monitoring, and personalized treatment, all of which improve patient outcomes. For individuals living with kidney disease, these biomarkers provide the ability to take control of their health, offering hope for better, more tailored care, and a brighter future.

About the Author?

Glenda V. Roberts, Mount Sinai Center for Kidney Innovation Patient Representative

Glenda V. Roberts is a dedicated activist with a passion for kidney research and the well-being of individuals living with kidney disease. Her extensive involvement in numerous national and international transformative research and healthcare initiatives aims to enhance patient outcomes. Drawing from her personal experience with kidney disease, she has become a powerful advocate for the patient's perspective, consistently elevating the patient's voice in research endeavors.

In addition to serving on over 15 patient advisory committees, Glenda has authored, co-authored, or been featured in more than 50 kidney-related publications. She co-chairs the APOLLO Community Advisory Council, directs communications for the Kidney Precision Medicine Project, chairs an industry patient advisory committee, and serves on the Kidney Health Initiatives Board of Directors. She is also the inaugural co-chair of the Critical Path Institute's Biomarker Data Repository Governing Committee. Glenda has contributed her expertise to several organizations and initiatives focused on improving outcomes and increasing patient centricity, including Kidney Disease Improving Global Outcomes (KDIGO), the International Society of Nephrology (ISN) Global Kidney Trials, the American Society of Nephrology (ASN), the National Kidney Foundation (NKF), and the NKF-ASN Taskforce for Reassessing the Use of Race in Diagnosing Kidney Disease. Her work underscores her commitment to improving kidney health globally.

Glenda's contributions have been recognized with several prestigious awards, including the President's Volunteer Service Award from Presidents Trump and Biden in 2020 and 2022, respectively. She is the first patient to receive both the President's Award from the American Society of Nephrology and the Celeste Castillo Lee Patient Engagement Award from the National Kidney Foundation. These acknowledgments reflect her significant contributions to the field and her unwavering commitment to patient engagement advocacy.

Before joining Mount Sinai as the inaugural Director of Communications and Patient Engagement for the Mount Sinai Center for Kidney Innovation, Glenda amassed over 35 years of experience as an Information Technology executive at global companies like Microsoft and General Electric. She also served as the Executive Director of the Seattle Transplant House and dedicated 6.5 years to the University of Washington (UW), where she was the Director of External Relations, Communications, and Patient Engagement for both the Kidney Research Institute (KRI) and the Center for Dialysis Innovation (CDI). In these roles, her commitment to treating patients as equal research partners fostered a deep sense of trust within the community.