

A collaboration between Northwest Kidney Centers and UW Medicine



LEFT: Jonathan Himmelfarb, Kidney Research Institute Director and Mary McHugh, Northwest Kidney Centers Vice President of Administrative Operations and External Relationships, signing-in for a KRI Learn @ Lunch event. RIGHT: Event attendees learning more about the connection between kidney and heart health.

Growth, changes and additions

A message from the director

DR. JONATHAN HIMMELFARB

Through innovation and discovery, the Kidney Research Institute is focused on early detection, prevention and treatment of kidney disease and its complications. Over the past three years, we have assembled an interdisciplinary team of physician-investigators who use new tools and technology to approach problems. We are excited to update you on recent developments and how we are advancing the field of kidney disease research.

A few highlights:

- Last fall we hosted our first international scholar, Hanne van Ballegooijen. (Read more about her on page 4.)
- With Northwest Kidney Centers, we continue to host the ever popular Learn @ Lunch series around the Puget Sound area.
- In April, we opened a 1,500-square-foot clinical research suite at Northwest Kidney Centers' 700 Broadway building. The space is fully furnished with a reception area, flexible office space, treatment rooms to see and dialyze patients, and a nursing station. The facility allows us to build on our established infrastructure for pilot clinical projects. Using an "incubator" concept, the KRI is creating a mechanism that will bridge clinical laboratory and large-scale clinical trials.
- Late summer 2012 marks the arrival of the new Harborview section head and KRI investigator, Dr. Rajnish Mehrotra from Harbor-UCLA Medical Center. (Details on page 2.)
- And this September, we will host our fourth annual Scientific Advisory Committee meeting.

The increase in chronic kidney disease is cause for alarm, but we live in an exciting time for biotechnology advances. In this newsletter, you will learn more about KRI trials of the wearable artificial kidney, which holds great promise for the treatment of kidney failure. At the Kidney Research Institute, we strive to make a difference, and we appreciate your continued support.

ON THE HORIZON

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**TRANSFORMING LIVES THROUGH
INNOVATION AND DISCOVERY**

KIDNEY RESEARCH INSTITUTE

Mailing Address:
Box 359606
325th 9th Ave
Seattle, WA 98104

206-616-8574
info@kri.washington.edu

www.kri.washington.edu

The promise of a wearable artificial kidney is exciting...

A patient's perspective

BILL PECKHAM

In the time I've been using hemodialysis I have seen new machines come into use and while each offered clinical or logistical advantages, they all required the same dull process. Whether in clinic or at home, hemodialysis has always meant passively passing the treatment moored to a machine. I welcome a new hemodialysis option.

This research is working to improve my choices; it is research to develop a better dialysis option, to develop my best choice. That's exciting.



The wearable artificial kidney offers a new vision: a device that can be worn on a belt; hemodialysis that goes with you as you go about your day! It is hard for me to imagine all the implications. Could I drive and work normally? What sort of accommodations will the wearable artificial kidney require?

To take one obvious question: How will a wearable artificial kidney access the blood? A fistula has long been held out as the best way to routinely access the blood, but a wearable artificial kidney will likely use a catheter or something catheter-like. I've used my fistula for over 20 years,

without an infection. Could catheter technology improve to rival that outcome? It would be an advance in itself if catheters could be made as safe and reliable as fistulas.

Picking a dialysis option is a very individualistic decision. Each person must weigh the pros and cons of the options available. For me, in a word, I want the dialysis option that impacts my life least: the least this day, this year, this life. This research is working to improve my choices; it is research to develop a better dialysis option, to develop my best choice. That's exciting.

About the Author: Bill Peckham of Seattle is a writer and editor, and author of the blog, *Dialysis from the Sharp End of the Needle*. He is an active volunteer for Northwest Kidney Centers and the Kidney Research Institute. He treats his Stage 5 chronic kidney disease with self-dialysis at home.



Dr. Rajnish Mehrotra

New Harborview Nephrology Section Head and Kidney Research Institute Investigator

We welcome Dr. Rajnish Mehrotra to Seattle as a KRI Investigator, UW Professor of Medicine, and the new Nephrology section head at Harborview Medical Center. He is recognized internationally for his scholarship and expertise in many aspects of the care of patients with kidney disease, with a particular focus on the home dialysis population. He comes from Harbor-UCLA as professor of medicine at the David Geffen School of Medicine, as well as the associate chief of the Division of Nephrology and Hypertension at Harbor-UCLA Medical Center.

New technology to help people with kidney failure

The Kidney Research Institute will play a major role in the first U.S. trials of a wearable artificial kidney. The initial clinical trials will be conducted in Seattle in collaboration with the Food and Drug Administration (FDA) under their new Innovations Pathway program. The wearable artificial kidney is a compact dialysis machine that allows greater mobility and autonomy. The battery-powered device weighs about 10 pounds and is worn in a belt around the waist. It delivers dialysis therapy on an ongoing basis, making it an ideal alternative to in-center dialysis.

Dr. Victor Gura, associate clinical professor at the David Geffen School of Medicine, University of California Los Angeles, invented the device. The goal is to free end-stage kidney disease patients from being tethered to a large dialysis machine for three or more days a week, and to improve their overall quality of life.

The FDA conceived Innovations Pathway as a joining of forces between the federal regulatory agency, universities, small businesses, and other researchers. The Innovations Pathway will try to expedite the pre-market evaluation of promising medical devices without sacrificing rigorous safety and effectiveness standards. The wearable artificial kidney is one of three kidney treatment devices the FDA selected among 32 applications from start-up businesses or academic institutions to pilot the new approach to product review.

Dr. Jonathan Himmelfarb, director of the Kidney Research Institute, and Dr. Larry Kessler, professor and chair of the Department of Health Services in the UW School of Public Health are working with Dr. Gura to design these important clinical trials. Dr. Himmelfarb and Dr. Kessler also will work with a team of UW biostatisticians, health care researchers and health care economists.

The research team will work closely with the FDA at each step, from research protocol design through final analysis of results and then application submittal for putting the product on the market. The collaboration is expected to align the trial with all the requirements for FDA approval.

The details of the trial and when it will start will be determined in conjunction with the FDA.

We expect that initial studies of the wearable artificial kidney will take place under close medical and nursing supervision in the hospital. If the device passes a number of safety checks, patients likely will then try wearing it on supervised visits away from the hospital.

“Ultimately the goal of new technologies for dialysis such as the wearable artificial kidney is to improve the lives of patients, foster better outcomes, and lower the costs of treatment,” said Dr. Himmelfarb.

The testing of the wearable artificial kidney builds on Seattle’s history in saving the lives of people with end-stage kidney failure as well as exploring the boundaries of new technology. In the 1960s, University of Washington Prof. Belding Scribner and his team built a shunt that allowed such patients, who otherwise would have succumbed to their illness, to receive long-term kidney dialysis. His work paved the way for the formation of Northwest Kidney Centers in 1962, the world’s first kidney dialysis organization. A wearable dialysis device was envisioned for the future by early pioneers in the development of dialysis therapy.



NIH

Researchers will be testing a wearable device that takes over the blood-cleaning functions of the kidneys, shown in blue.

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A woman models a prototype of a wearable artificial kidney. On the right is the inventor of the device, Dr. Victor Gura of UCLA. To the left is his collaborator, Dr. Andrew Davenport of University College London Center for Nephrology, Royal Free Hospital, London

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Northwest Kidney Centers
700 Broadway
Seattle, WA 98122

RETURN SERVICE REQUESTED



Our first international scholar looks at mineral metabolism markers



About Hanne:

Hanne graduated from HAN University in Nijmegen with a Bachelor's degree in Nutrition, and received her Masters in Nutrition and Health with a major in public health and epidemiology at Wageningen University, the Netherlands. Her main research interests are to identify dietary-related factors in the etiology of chronic diseases. She has a particular interest in how mineral metabolism disturbances affect cardiovascular disease risk.

In 2011, the Kidney Research Institute welcomed its first international scholar: Hanne van Ballegooijen, a doctoral student in the Nutrition and Health Department at Vrije University in Amsterdam. Hanne's research focuses on nutritional determinants of heart function. For most of the autumn, Hanne worked with data from the Cardiovascular Health Study, a large population-based cohort study. She investigated the role between mineral metabolism markers and biochemical, electrocardiographic, and structural measures of the heart.

"My time at the Kidney Research Institute gave me the opportunity to work closely with brilliant epidemiologists and clinicians to conduct research and collaborate with international researchers," said Hanne.

Hanne's findings suggest that excess parathyroid hormone; a hormone frequently elevated in kidney disease, is associated with a higher left ventricular mass in the heart, putting people at a higher risk for heart disease. Her results were written in a scientific paper, which will be used for her dissertation.

"Working with Hanne helped foster international connections between Seattle and Amsterdam in terms of cardiovascular health. It also gave Hanne the opportunity to bolster her education outside of her home country," said Hanne's mentor at the KRI, Dr. Bryan Kestenbaum. "Seattle was breathtaking and I met many friends I still keep in touch with," Hanne said of her experience. We wish her luck as she pursues her doctorate.