said that he and his colleagues are searching for a commercial partner for the joint preclinical and clinical development of the Dutch group's new technique for generating in vivo tissue–engineered blood vessels for hemodialysis vascular access. He noted the technique was developed at LUMC labs as part of the DialysisXS consortium, a research collaboration with the University of Twente in the Netherlands, the Dutch Kidney Foundation, and the Swiss biotech firm Xeltis.

Also searching for partners is the French nephrologist Mokhtar Chawki, MD, founder of the Nephrokit compressive device named IRIS, which is designed to reduce the postdialysis time to clot by securing dialysis needle vascular access puncture sites. The device speeds up coagulation time from 10.5 minutes, the average duration for conventional techniques, to 2 to 3 minutes, said Chawki. Nephrokit already has a nonexclusive agreement for IRIS distribution with Bellco in France and Belgium and Gambro in France, and the device is also sold in dialysis kits by Mölnylcke Health Care in Europe, he said.

At an adjacent Innovators Place booth, several nephrologists from the Henry Ford Health System in Detroit presented their universal regional citrate anticoagulation (RCA). Balazs Szamosfalvi, MD, said that he and his fellow nephrologists designed the sustained low-efficiency dialysis (SLED)-RCA technology to provide 100 percent–effective RCA with automated delivery using integrated intravenous pumps and optical blood and dialyzer effluent sensing. It can be adapted to most commercial renal replacement therapy devices with a customized RCA protocol and dialysis machine data interface program, Szamosfalvi said. In over 50,000 hours of clinical use, the technology prevented systematic citrate accumulation in patients with severe liver failure, and predictive-calcium infusion dosing maintains normal systematic ionized calcium levels, according to the display material.

Another Innovators Place participant was FAST BioMedical, whose cofounders include ASN President Bruce A. Molitoris, MD, FASN, of Indiana University. The Indianapolis medical device company has developed a small, durable bedside device to accurately measure GFR in approximately 40 minutes, based on technology licensed from Indiana University, said co-founder and president James Strickland. Over 30 clinical trials of FAST (Filtration Assessment and Surveillance Technology) have been conducted in Europe, Strickland said.

Argutus Medical of Dublin, Ireland, likely demonstrated the most professional marketing display at Innovators Place, where visitors learned about RenaStat, a new point of care test benchtop device for early detection of AKI in critical care requiring 100 µL of patient urine. Argutus Medical also provided scientific information about the development and use of biomarkers for AKI detection.

Journal View

Age Interacts with Kidney Measures on Mortality Risk

Although effects on relative versus absolute risk differ, low estimated glomerular filtration rate (eGFR) and high albuminuria are linked to increased mortality in all age groups, reports a study in *The Journal of the American Medical Association*.

The meta-analysis examined whether age modified the associations of eGFR and albuminuria with clinical outcomes. The investigators pooled individual-level data on more than 2 million members of Chronic Kidney Disease Prognosis Consortium (CKD-PC) cohorts. The data included 33 non-kidney disease cohorts (general population or people at high vascular disease risk) and 13 CKD cohorts. Clinical associations with eGFR and albuminuria were examined across age groups, with adjustment for other risks.

In non-CKD cohorts, individuals with lower eGFR and higher albuminuria were at higher risk of death and end stage renal disease (ESRD). At an eGFR of 45 mL/min/1.73 m^2 (versus 80 mL/min/1.73 m^2), the adjusted hazard ratio for death decreased with age: from 3.50 for people aged 18 to 54 years, to 2.21 at 55 to 64 years, 1.59 for 65 to 74 years, and 1.35 at 75 years or older. In contrast, absolute risk increased with age: excess deaths per 1000 person-years were 9.0, 12.2, 13.3, and 27.2, respectively.

The absolute risk of death associated with higher levels of albuminuria also increased with age. At an albumin-creatinine ratio of 300 mg/g (versus 10 mg/g), excess mortality per 1000 person years was 7.5 at 18 to 54 years, 12.2 per 1000 at 55 to 64 years, 22.7 per 1000 at 65 to 74 years, and 34.3 per 1000 at age 75 or older.

The CKD cohorts showed no age-related decrease in the adjusted relative hazards of mortality. For all cohorts, the relative risks of ESRD and the absolute risk differences associated with both kidney markers were similar across age groups.

It has been suggested that the CKD classification system should be revised to include a combination of eGFR and albuminuria levels. Before this is done, it is important to understand how age affects the clinical risks associated with these measures.

This meta-analysis finds that low eGFR and high albuminuria affect mortality risk in all age groups, across a wide range of populations. At older ages, the relative risk is lower but the absolute risk differences are higher. The researchers call for "a common definition and staging of CKD based on eGFR and albuminuria for all age groups" [Hallan SI, et al: Age and association of kidney measures with mortality and end-stage renal disease. *JAMA*. 2012; doi:10.1001/jama.2012.16817].

Industry Spotlight

Trials for Best Ways to Treat Non-Dialysis–Dependent CKD

The search for effective treatments for non-dialysis–dependent chronic kidney disease (NDD-CKD) is gaining renewed interest. In the United States, more than one and a half million people suffering from stages 3 to 5 non-dialysis dependent NDD-CKD have iron deficiency anemia, but no oral iron supplements have yet been approved by the FDA for use for the condition. Likewise, no FDA-approved phosphate binders exist for use in NDD-CKD.

The federal government issued a request for application (RFA) for CKD clinical trials that closed on Nov. 21. That RFA sought pilot studies that optimize critical elements of a full-scale, randomized controlled trial design in return for U01 grant funding. The National Institute of Diabetes and Digestive and Kidney Diseases noted in its RFA that studies to date have looked at treatments and effects in small groups of patients, and that many questions remain regarding optimal dosing and drugs' ability to reach appropriate patient outcomes.

One new NDD-CKD study that builds on earlier work was announced in early November. Keryx Biopharmaceuticals said that it had started a phase 2 study of its drug Zerenex (ferric citrate) for the treatment of patients with stage 3 to stage 5 non-dialysis dependent chronic kidney disease.

Zerenex is a ferric iron–based phosphate binder drug candidate for managing serum phosphorus and iron deficiency in anemic patients with NDD-CKD.

Several studies have shown that higher serum phosphorus concentrations may be associated with increased mortality and morbidity in CKD.

The phase 2 study will be a multicenter, randomized, safety and efficacy clinical trial designed to compare the ability of Zerenex to manage serum phosphorus and iron deficiency versus placebo in anemic patients. Eligible patients will be randomized in similar groups to receive either Zerenex or placebo for a 12-week treatment period.

The primary endpoints of the study are designed to demonstrate changes in ferritin, transferrin saturation (the ratio of serum iron and total iron-binding capacity), and serum phosphorus levels over the 12-week treatment period.

The study plans to randomize about 150 patients from about 15 sites in the United States. Patient enrollment should take about six months, and Keryx expects the study to wrap up in mid-2013.