In the article, “Results of customer-based, post-market surveillance survey of HeRO access device (Vascular Access, NN&I August 2010), I would be interested in hearing more about the rate of occlusion among these patients with HeRO devices, since this is the major cause of device loss. Since there is no outflow anastomosis, intimal hyperplasia is not the problem as it is with the arteriovenous graft-vein junction—and the continuous flow through the outflow component segment avoids the stasis that often causes catheter thrombosis. I am looking for an analysis/review of the cases of occlusion by the investigators. Have the occlusion cases been evaluated following occlusion and failure to recanalize to ascertain the cause for permanent occlusion? Why were some occluded devices removed? Why couldn’t the majority be salvaged? Does a sheath form around the outflow component tip, as with standard central venous catheters? Does thrombus form at the PTFE graft-outflow component junction? If the causes of occlusion could be identified and managed, the patency might be significantly improved, even spectacular.

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The author responds
Since this was an informal survey and not a controlled study, information on device salvage or removal is not available. In regard to occlusions, the majority of patients (72.3%) did not experience this with the HeRO device. For the patients who did occlude, hypotension or thrombophilia was the source of occlusion when the source was identified. Once these problems were addressed by maintaining blood pressure above 100 mmHg or treating the thrombophilia with low dose aspirin or coumadin, the device did not occlude any further (12 of 18 patients experienced only one occlusive episode). One patient had a history of labile blood pressure before the HeRO implant; however, the physician chose to implant the device despite knowing this patient was not a good candidate due to no other options.

For optimal outcomes, patients should be selected for a HeRO if they:
- have become catheter-dependent or are approaching catheter-dependency (i.e., have exhausted all other access options for AV grafts).
- are not candidates for upper extremity fistulas or grafts due to poor venous outflow as determined by a history of previous access failures or vessel mapping.
- are failing fistulas or grafts due to poor venous outflow as determined by access failure of vessel mapping.
- have a compromised central venous system or central venous stenosis (CVS) as determined by history of previous access failures.

There were only three patients who were explanted for occlusion.

It is a physician’s discretion of when to deem a device not salvageable. Once that determination is made it is recommended the HeRO venous outflow component and connection portion be removed. If thrombus is present, special consideration is required to ensure that thrombus is not dislodged during the explant procedure. Instructions for thrombectomy and explant may be found on www.heroaccess.com in the Technical Bulletins provided in the document library section of the website.

We have not received any reports, images, or explanted devices with a fibrin sheath around the tip of the outflow component. We have examined the explanted devices that were returned to us. For the few explanted devices sent back with clot, we were able to identify damage to the device...
that was possibly the source of occlusion. The damage most likely occurred during implant.

Our goal is to educate physicians so that with proper patient selection, careful handling of the device at implant, and appropriate patient management, patients will have an alternative to tunneled dialysis catheters for long-term hemodialysis access.

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Product Evaluation Specialist
Hemosphere, Inc.

Correction
In the article, “Dissecting the bundle: The final rules for the prospective payment system for dialysis (Renal Economics, September 2010), there was an error in Table 1 in calculating the reductions imposed by CMS on providers to keep the new payment system budget neutral.

The chart section should be:

**Reductions**
- Congressionally mandated: -2%
- Outlier payments: -1%
- Case mix adjusters: -5.9%
- **Total base payment: $229.62**

[ NEWS, continued from page 11 ]
Renal Administrators Association and other public entities such as the Quality Improvement Organizations (QIOs), the Fistula First Breakthrough Initiative (FFBI) and the ESRD Networks to establish the VAL. The initiative includes a number of support documents, which are accessible on the RPA website.

AAKP appoints new executive director
The American Association of Kidney Patients announced the appointment of its new executive director, Karen Ryals. Prior to joining AAKP, Ryals worked for the United Cerebral Palsy of Tampa Bay Inc. as chief executive office, executive director and director of program services and consulting. “The American Association of Kidney Patients has a history of meeting the needs of our nation’s kidney patients and their families, enriching their lives through education and advocacy,” Ryals said. “I am honored to have been chosen to lead this organization which has contributed so much to the nation’s chronically ill people, and to have the opportunity to take it to new levels in patient services and community outreach.” Ryals hold a bachelor’s degree in Speech Pathology and Audiology from the University of Florida and a Master’s degree in Speech Language Pathology from Florida State University.

[ NATIONAL, continued on page 28 ]

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