

House Committee on Ways and Means

Statement of American Society of Pediatric Nephrology, Indianapolis, Indiana

The American Society of Pediatric Nephrology (ASPN) appreciates this opportunity to submit testimony for the record of the Committee on Ways and Means hearing on “Patient Safety and Quality Issues in End-Stage Renal Disease Treatment.” The ASPN is a professional society composed of pediatric kidney specialists whose goal is to promote optimal care for children with kidney disease and to disseminate advances in the clinical practice and basic science of pediatric nephrology. The ASPN currently has over 600 members, making it the primary representative of the pediatric nephrology community in North America.

Background

Anemia is a complication of kidney disease, known as Chronic Kidney Disease (CKD) or kidney failure, and End Stage Renal Disease (ESRD) or Stage V CKD. Patients with kidney failure suffer from anemia because their kidneys do not produce a hormone (erythropoietin) that regulates red blood cell production. Anemia directly affects a pediatric patient’s quality of life, including neurocognitive development, school attendance, exercise capacity and family support,^[1] making proper anemia management critical to a patient’s well-being. One of the key medications used to treat anemia in this population of patients is recombinant human erythropoietin (rHuEPO), commonly referred to as EPO.

Doctors determine a patient’s degree of anemia with simple blood tests, measuring the hemoglobin level. The hemoglobin levels that define anemia in children with kidney disease differ from those in adults, as they depend on the age and gender of the patient. In the case of those patients who are then treated with EPO, the existing National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF KDOQI™) or KDOQI™ opinion-based guidelines recommend a target hemoglobin level of 11.0 to 13.0 g/dl, for children up to 19 years of age. Treatment thresholds in anemia management should always be individualized to the needs of the patient, allowing a trained professional, in consultation with the patient, to determine the optimal dosing of EPO.

In light of the recent studies published in the *New England Journal of Medicine*, ASPN agrees that it is essential for the kidney care community to continue examining all available data to ensure that public policies reflect appropriate anemia management for all patients, both children and adults, with kidney disease and kidney failure. However, it is important to point out that no reliable scientific studies have been published that examine optimal hemoglobin levels for children with CKD. For this reason, the ASPN requests that Congress commission a study through the National Institutes of Health to test and evaluate optimal hemoglobin levels specific to children with kidney disease. Armed with this scientific literature, the kidney community and government can work to promote the safest practices with the highest quality of care for children with this chronic disease. ASPN is committed to working with clinical researchers to carry out such scientific studies.

Children Are More Vulnerable Than Adults

It has been said that children are not little adults, and this is especially pertinent in the treatment

of children with both CKD and ESRD. Proper EPO dosing must take the age of the patient into consideration. Furthermore, and in contrast to the adult patient, the developing minds and bodies of children with kidney disease places them at a disproportionate risk in the event of inappropriate anemia management. Poor statural growth, impaired nutrition and abnormal cognitive development are all potential adverse outcomes of poor anemia management that mandate prospective study.

Children Have Unique Treatment Needs

Once children are diagnosed with CKD or ESRD, it is critical that the pediatric nephrologist be able to adequately target the proper hemoglobin level for the patient. Due to their size and age, a child's body will respond differently than adults in similar stages of CKD or ESRD.

Consequently, pediatric treatment needs are unique in several ways:

Children need different dosages of erythropoietin than adults – not only because they are smaller, but also because the way their bodies metabolize the drug may be different than what occurs in adults.

Children sustain unique developmental and psychological responses to kidney disease and kidney failure. The identification and optimal management of these disorders in children and their relationship to anemia management requires professionals with expertise in pediatric nephrology.

Most importantly, there are distinct differences in the frequency and type of co-existing illnesses that characterize the adult and pediatric CKD populations which may result in the optimal hemoglobin targets for children and adults receiving EPO to be different.

Conclusion

ASPEN appreciates the opportunity to provide these comments to the Committee. The kidney community is largely unified in communicating a concern that actions taken by Congress and the Centers for Medicare and Medicaid Services (CMS) to revise anemia management guidelines must be based on all available scientific literature. The recent studies published in the *New England Journal of Medicine* only address the adult chronic kidney disease population. For this reason, it is imperative that further anemia management studies be conducted in all CKD and ESRD populations, including children, to ensure that revised government policies reflect sound scientific evidence.

The Society remains dedicated to providing the highest standard of care and ensuring patient safety for our nation's pediatric kidney disease patients.

[1] *American Journal of Kidney Diseases*, S90-S92 (May 2006).