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Because health matters

April 20, 2011

Helen Burstin, MD, MPH
Senior Vice President, Performance Measures
National Quality Forum
601 13th Street NW, Suite 500 North
Washington, DC 20005

RE: Comment on National Voluntary Consensus Standards for End-Stage Renal Disease

Dear Dr. Burstin,

On behalf of sanofi-aventis, we are pleased to respond to National Quality Forum's (NQF) call for comments on the project: National Voluntary Consensus Standards for End-Stage Renal Disease (ESRD). We acknowledge the impact of ESRD on patients and families as well as the overall burden on society. We therefore support efforts by NQF in the use of consensus standards to drive significant improvements in the care received by pediatric and adult patients with ESRD. In particular, sanofi-aventis recognizes the need to increase the number of standards focusing on the pediatric population, a theme which is reflected in the choice of seven of the eleven proposed quality measures recommended by the steering committee. Overall, sanofi-aventis applauds continuing efforts by NQF to influence the quality of care for patients with ESRD and we look forward to being fully engaged with the upcoming endorsement maintenance cycle project for renal disease.

Although NQF has already endorsed 25 measures through its 2008 National Voluntary Consensus Standards for ESRD project, we believe significant gaps remain, specifically with respect to iron deficiency anemia and the use of iron therapy. Therefore we, take this opportunity to highlight the need for further research into the treatment of iron deficiency anemia in ESRD patients undergoing hemodialysis. For example, with regards to a measure that was not recommended for endorsement namely, 'Avoidance of Iron Therapy in Iron Overload' (1429), a reason given by the committee for not recommending the measure was that definitions of iron overload are not evidence-based. While the measure developer selected 1200 ng/ml as the threshold above which iron should not be administered, there is little published evidence to support this threshold. This calls for broader research into appropriate markers for determining the adequacy of iron therapy in the context of overall clinical benefit and safety.

In addition, from the DRIVE study there is evidence to support clinical benefits and safety of intravenous (IV) iron therapy in anemic hemodialysis patients with serum ferritin between 500 ng/ml and 1200 ng/ml and transferring saturation (TSAT) below <25%[1]. As an extension of DRIVE, the DRIVE-II study found that epoetin requirements were reduced in patients who received iron during DRIVE while they remained the same for the control (no iron therapy) group[2]. The outcome of DRIVE-II has significant implications because lower utilization of epoetin is associated with a lower risk of

[1] Coyne DW, Kapoian T, Suki W, et al. Ferric gluconate is highly efficacious in anemic hemodialysis patients with high serum ferritin and low transferrin saturation: results of the Dialysis Patients' Response to IV Iron with Elevated Ferritin (DRIVE) Study. J Am Soc Nephrol 2007; 18:975

[2] Kapoian T, O'Mara NB, Singh AK, et al. Ferric gluconate reduces epoetin requirements in hemodialysis patients with elevated ferritin. J Am Soc Nephrol. 2008;19:372-379

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adverse events such as strokes and cardiovascular events[3,4]. However, current National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines specify a serum ferritin of 500 ng/ml as the threshold above which iron therapy decisions should be made after evaluating the patient's clinical status and the results of additional tests such as TSAT and hemoglobin[5]. Given that clinical guidelines have significant influence on clinical practice and when tied to incentives have the potential to change patient outcomes, this highlights the need for further research into the clinical benefits of wider adoption of this alternative treatment strategy, i.e., treating up to 1200 ng/ml.

In conclusion, sanofi-aventis fully supports this project and looks forward to seeing the development, endorsement, and use of additional performance measures in the ESRD space as tools to promote improvements in patient-centered care.

Sincerely,

Dr. H/A Akbary

Akbar Akbary, MD
Senior Director
US Medical Affairs

[3] Phrommintikul A, Haas SJ, Elsik M, Klum H: Mortality and target haemoglobin concentrations in anemia patients with chronic kidney disease treated with erythropoietin: A meta-analysis. Lancet 369: 381–388, 2007.

[4] Singh AK, Szczech L, Tang KL, Barnhart H, Sapp S, Wolfson M, Reddan, CHOIR Investigators: Correction of anemia with epoetin alfa in chronic kidney disease. N Engl J Med 355: 2085–2098,2006.

[5] K/DOQI Clinical practice guidelines and clinical practice recommendations for anemia in chronic kidney disease. Am J Kidney Dis 2006; 47(Suppl 3):S1.