

THE IMPACT OF ESA USE ON RENAL TRANSPLANT GRAFT SURVIVAL

A Patient Perspective

PRESENTATION TO MEDCAC

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Thank you for allowing me the opportunity to present before you today. I am a kidney transplant recipient and have managed kidney disease and failure for thirty years. Over the course of my professional career, I have our country and my state under four presidents, four Federal cabinet secretaries and three governors – including service as one of the youngest Deputy Secretaries of Health and Human Resources for the Commonwealth of Virginia. I presently serve as the Vice President of the American Association of Kidney Patients and Chair of the AAKP Public Policy Committee. My appearance before you today is due in part to my strong faith and discipline – and to multiple teams of highly skilled doctors, nurses, researchers and pharmaceutical companies whose noble efforts to extend life and to develop life sustaining treatments have saved my life and the lives of tens of thousands of other patients. As an American, I am proud of those who choose these professions, I respect their avocations and professional pursuits and will be forever grateful that we live in a nation whose free market philosophy values both the protection and extension of life and advancements in medicine as the traditional hallmarks of a high quality medical system.

I am fortunate in that I have received the gift of life through a kidney transplant. Many patients never have that opportunity. There are disparities based upon blood groups and race. However, one disparity, totally preventable, is the presence of panel reactive antibodies secondary to a blood transfusion. Kidney patients lose blood from their gastrointestinal tracts. This was shown in predialysis and in dialysis patients in 1982 by a team of doctors, including Dr. Fadem.¹ Back in those days, there was not a drug to stimulate red blood cell production, and patients often required blood transfusions. These were given routinely, right in dialysis units. In the 1990s we started using erythropoiesis-stimulating agents, and the requirement for blood transfusions dramatically fell. However, it is still common for kidney patients, even those who are waiting for a kidney transplant to receive a blood transfusion.²

Blood transfusions are not harmless. They can spread viruses such as hepatitis C and B. But, more relevant in the transplant patient, they cause an immunization-type reaction that induces a set of antibodies that will fight the new kidney transplant. This is known as the panel reactive antibody or PRA level. A patient with a high PRA – over 80% will react with just about any transplanted kidney. In other words, the higher the PRA level, the less likely one is to match with a donor. This is well observed both in the USA and in Europe. The 2010 USRDS Annual Data Report² was just published, and showed that the three year cumulative incidence of blood transfusions in patients on the transplant list with panel reactive antibodies over 80% was around 41% while those who had no antibodies was around 24-25%. A study published in Ireland in 2003 demonstrated that 100% of patients who were highly sensitized and had PRAs over 80% had received blood transfusions. Databases in the public domain show that patients who are sensitized must then wait at least one to three years longer on the list for a kidney transplant.³ The transplanted kidney does not survive as long.⁴ These patients have more complications,²

and they have a 19% higher risk of death. In all likelihood, patients who have high panel reactive antibodies may never receive a kidney transplant. They spend a longer period of time on dialysis. Our group is publishing a survey that shows that patients on hemodialysis in a dialysis center have a lower level of patient satisfaction, and that those who receive a kidney transplant have the highest level of patient satisfaction.⁵ As an informed patient and as an American taxpayer, it is important to me personally that my health care delivery system continue to allow me the opportunity to choose optimal care in consultation my doctor, particularly when that choice is cost effective. It is much less expensive over the years to sustain a patient with a kidney transplant than with dialysis². The data is compelling that blood transfusions sensitize patients to form high PRA levels, and take them out of the loop for a successful transplant. It is therefore important that the American health system continue to deploy strategies that will minimize blood transfusions. Were I on dialysis once again and waiting for a kidney transplant – a scenario for which I am always prepared in the event of transplant failure - or if I was a CKD patient hoping to preempt dialysis altogether by receiving a transplant, I would not want my hemoglobin to drop to a level that necessitated I have a blood transfusion. I would not want to be randomized to the group in a clinical trial required to have the lower hemoglobin or to receive blood transfusions to confirm that they caused high PRA levels and a worse transplant outcome. Take it from one who has lived through some of the best and the worst experiences, if you or a family member were ever confronted with kidney disease or kidney failure, I think that you too would want the latitude to choose the best treatment option in consultation with your doctor.⁶⁻⁹

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