

June 17, 2015

Aysegul Gozu, MD, MPH
Task Order Officer
Center for Evidence and Practice Improvement
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

Dear Dr. Gozu:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to provide input on the Management of Renal Masses and Localized Renal Cancer Draft Systematic Review. As the leading kidney health professional society in the world with more than 15,000 members from 114 countries (including approximately 90 percent of the nephrologists in the United States), ASN is dedicated to providing the highest quality care for patients with kidney disease.

The society's comments on the Draft Systematic Review relate to the Executive Summary (pages ES-15 to ES-16) and Key Question 3b addressing the appropriateness of nephron-sparing surgery for patients with chronic kidney disease (CKD) Stage 3 or greater.

ASN agrees with the findings and statement that overall survival and renal outcomes are favorable for nephron-sparing surgery as addressed in Question 3a. However, the Executive Summary and Key Question 3b (pages 146-147) discourages nephron-sparing surgery for those with "excellent renal function and those with the poorest renal function (Stage 3 or greater)." The society disagrees with this statement since the recommendations are largely based on a few papers and without substantial evidence to support the assertions.

The largest study of the four citations was the retrospective evaluation of the EORTC study. The reviewers interpreted that those with "lower" glomerular filtration rates (GFRs)—Stage 3 and above—did not benefit from nephron-sparing surgery (NSS) as this group did not have significantly better survival in comparison to the radical nephrectomy (RN) group. However, the majority of the study population (497 patients) had baseline creatinine <1.25 x upper limit of normal, and only 34 total patients had baseline creatinine >1.25 x upper limit of normal. Thus, this study was underpowered to allow a true assessment of treatment effect.

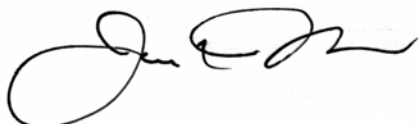
The Woldu paper also had too few patients (262 of 1306) in the Stage 3 group, with only 74 Stage 3B patients (GFR 30-44). Takagi showed benefit of NSS for those with

baseline GFR 45-59 (Stage 3A) but not Stage 3B. This was also a small retrospective study with a total of 118 patients, and only 27 patients in the Stage 3B group. Clearly the numbers are very small in the advanced CKD categories. In fact, there is a trend for better kidney function in the eGFR <30 group treated with NSS in the EORTC study and the freedom from new onset lower GFR in the eGFR 30-44 group in the Takagi paper.

In summary, the Executive Summary conclusions (page ES-15) seem to be overstated given the limited data. Until further studies are performed among those with more advanced CKD (Stage 3B and above), it is premature to have strong conclusions about groups who should have nephron-sparing surgery or radical nephrectomy.

Thank you again for the opportunity to provide input on the Management of Renal Masses and Localized Renal Cancer Draft Systematic Review. To discuss this letter, please feel free to contact ASN Senior Policy and Government Affairs Associate Grant Olan at (202) 640-4657 or golan@asn-online.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jonathan Himmelfarb', with a large, stylized initial 'J'.

Jonathan Himmelfarb, MD, FASN
President