Re: “The Impact of Insurance Status on Tumor Characteristics…”

To the Editor: We read, with great interest, the work of Fossati et al, titled “The Impact of Insurance Status on Tumor Characteristics and Treatment Selection in Contemporary Patients With Prostate Cancer” in the November 2015 issue of JNCCN—Journal of the National Comprehensive Cancer Network (J Natl Compr Canc Netw 2015;13(11):1351–1358). The authors used pretreatment prostate-specific antigen (PSA) to define which patients had low-risk prostate cancer at diagnosis. However, we feel that using PSA value in that context is of concern because, as of April 2015, the NCI Web site issued an update noting that recent evaluation of the SEER data showed a substantial number of registrar-reported PSA values to be incorrect.¹

Therefore, PSA values were not included in the November 2014 submission of the SEER data, and NCI recommended that PSA values from recent years not be used for analysis. The error in PSA reporting originated from an implied decimal between the second and the third digits of the 3-digit data field of the PSA value. That is, a PSA of 4.0 ng/mL was incorrectly coded 004 when it should have been coded as 040. To our knowledge, no update was sent to SEER users with the accurate PSA values or with statistical methodology to correct the errors in that variable. We believe that the experience of Fossati et al in dealing with the problems of the PSA values in SEER would have been helpful to other SEER researchers if discussed.

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The Authors Respond

To the Editor: In their comment on our study,¹ Drs. Alanee and Dynda highlighted the issues about PSA reliability that recently emerged within the SEER database. We agree with them that using PSA value is of concern because of the NCI update.

However, in addition to assessing the accuracy of the individual PSA value, the NCI evaluated the impact of PSA errors on current prostate cancer staging categorization. This study showed that errors in PSA coding had minimal impact on staging: the estimated percent of prostate cases in which stage was affected by PSA errors was approximately 3% to 4%, and this effect was random.² Therefore, this small and random error rate is unlikely to significantly impact our results in a meaningful way.

Further evaluation also revealed that the impact of errors in recorded PSA on any analysis of “grouped” PSA was relatively small. Specifically, NCI reviewed the impact of the errors associated with the implied decimal on the clinically relevant PSA groupings as follows: “1-9,” “10-19,” and “20+” ng/mL. They found that the errors in PSA changed approximately 5% of PSA values grouped in this categorization.

Our recently published study defined risk groups according to the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) for Prostate Cancer: low risk (PSA level <10 ng/mL, clinical stage ≤T2a, and biopsy Gleason score ≤6); high risk (PSA level >20 ng/mL, and/or clinical stage ≥T3, and/or biopsy Gleason score ≥8); or...
intermediate risk (all the remaining). Because categorized PSA values was used, it is plausible that the impact of PSA recording errors on our findings was minimal.

Finally, 2 additional aspects need to be highlighted. First, despite PSA concerns within the SEER database, our results were in line with a recent study that examined the National Cancer Data Base (NCDB). The authors of this study found that insurance status was strongly associated with disease severity among patients with prostate cancer, including those with high PSA values. Furthermore, the authors compared clinical characteristics of patients in the NCDB with patients in the SEER database: no statistically significant differences emerged between the 2 groups when PSA values were considered. Second, several SEER studies used PSA values to address oncologic outcomes in the recent years and found that despite these recently emerged concerns regarding PSA value accuracy, increasing PSA values were significantly associated with increased risk of prostate cancer mortality when included in multivariable analysis. This supports the hypothesis that PSA errors were unlikely to significantly alter study results.

The NCI is developing a protocol that will be applied by all SEER registries to further assess the error rate and allow the registries to correct PSA values of recent years. Nonetheless, based on the aforementioned observations, even if an impact of PSA value correction on the study results could be operational, the magnitude of such impact appears negligible for our study.

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References