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Seminars Section of Journal of Urologic Oncology: Introduction to “A Clinician’s Guide to Statistical Methods in Urologic Oncology”

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In this issue the *Seminars* section focuses on important statistical issues and methods that are commonly encountered in urology and which impact on our ability to derive inferences from urological research. With the explosion of information that clinicians and researchers must now keep abreast of, and the rapid pace of research on new treatments, tests and clinical outcomes, it is increasingly important that the informed consumer of the medical literature know more about statistics than whether or not $p < 0.05$. Four areas of statistical applications in medical research are highlighted in this issue, each of which represents a common research theme where basic understanding of statistical considerations can greatly aid in clinical decision-making. Of critical importance to urologists are the results of phase III clinical trials, considered the gold standard of study designs for determining the efficacy of a treatment. Dr. Halabi describes the basic principles of phase III clinical trials for prostate cancer treatments, the considerations in designing such trials, important considerations for patient selection, and how statistical procedures inform clinical inferences. The use of PSA for prostate cancer screening exemplifies the promise and problems of biomarkers for early detection. Dr. Etzioni uses PSA as an example to illustrate the critical role that statistical criteria play in the evaluation of a screening test, potential improvements in accuracy by combining markers or tests, and the issues involved in determining the utility and overall benefit of a test. Extensive evaluation of clinical outcomes in urologic oncology has been made possible by the growth of mature databases in urology departments worldwide. These databases have been and continue to be mined to identify risk factors, prognostic factors, and predictors of various clinical states. However, determining the clinical utility of such predictive factors requires a different statistical yardstick than the emphasis on p-values that dominates medical hypothesis testing, where the interest is usually in comparing two or more groups. Drs. Kattan and Gonen discuss the prediction philosophy, where the focus is on quantifying how much a new factor adds to our existing ability to make accurate predictions. For almost any clinical decision a number of clinical trials or observational studies can be found, very often with inconsistent or inconclusive results. Meta-analysis is increasingly being used as a systematic approach to synthesize a complex body of evidence and attempt to extract a clinically useful signal, and as a way to identify sources of inconsistency among studies. However, there is a great deal of misunderstanding about the role, conduct, and limitations of meta-analyses, which often makes it difficult for the reader to know whether a meta-analysis has shed light on or further obfuscated a problem. Drs. Zwahlen, Renehan and Egger discuss these issues and illustrate requirements for valid meta-analyses.

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We hope that these four papers will enhance the value of statistical findings and issues that urologists and researchers encounter in the literature and in their own work, and aid in the interpretation of important clinical studies.