

PUBLIC HEALTH & PREVENTIVE MEDICINE

GRAND ROUNDS

Sponsored by: The Division of Biostatistics

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12 PM-1 PM

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Biomarker Validation with an Imperfect Reference: Bounds and Issues

ABSTRACT

Motivated by the goal of validating a newly developed marker for acute kidney injury, we consider the problem of assessing operating characteristics for a new biomarker when a true gold standard for disease status is unavailable. In this case, the new biomarker is typically compared to another imperfect reference test, and this comparison is used to estimate the performance of the new biomarker. However, errors made by the reference test can bias assessment of the new test. Analysis methods like latent class analysis have been proposed to address this issue, generally employing some strong and unverifiable assumptions regarding the relationship between the new biomarker and the reference test. We investigate the conditional independence assumption that is present in many such approaches, and demonstrate that this assumption may be violated even when the two tests are physiologically unrelated. We explore the information content of the comparison between the new biomarker and the reference test, and show that even if the operating characteristics of the reference test are known with certainty, it is often difficult to derive any useful information regarding the new test. In particular, we give bounds for the true sensitivity/specificity when operating characteristics for the reference test are known.

Food and beverages will be provided.