

**Diagnostic test and biomarker evaluation in the absence
of a gold standard**

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3:30-4:30pm, New PI 6th Floor Multipurpose Room (6602)
Light refreshments provided

Abstract

Latent variable models have long been utilized in mental/behavioral research to summarize constructs that are represented by multiple variables and are difficult to measure. It also had significant application and development in diagnostic medicine, which has been re-energized recently due to the advance in diagnostic techniques and the discovery of novel biomarkers. Accordingly, it is important to assess the accuracy of the diagnostic tests and evaluate new biomarkers. The assessment becomes difficult when the underlying medical condition, the gold standard, is unknown due to time/cost constraints, or ethics concerns. This issue becomes more common and pressing with the growing interest on preclinical diagnosis and prevention. Moreover, with the improvement in clinical practice, there is a need to go beyond traditional binary disease status and incorporate an ordinal gold standard, and to include and examine patients' characteristics that may affect disease prevalence or test performance.

We discuss models in latent class/profile framework to address these issues. A random effect approach is adopted to account for dependence among diagnostic results, and a test for the random effect component is provided. Regression and transformation extension allows one to utilize covariate information and examine their impact. We also propose an accuracy measure as a high dimensional counterpart of the area under the ROC curve, and discuss some graphical representations of the high dimensional results. The methods are applied to two data sets, one to evaluate diagnosis performance of traditional Chinese medicine doctors, and the other to assess biomarkers for identifying preclinical Alzheimer's disease.

¹ The PI Biostatistics Seminar Series is held on Tuesdays at New York State Psychiatric Institute. If you are interested in receiving regular announcements for our seminars in the future, or if you need further information, please contact Jina James (jamesji@nyspi.columbia.edu, (212) 543-5589).

Biographical Note

Zheyu Wang is currently a doctoral student from Department of Biostatistics at University of Washington, and a biostatistician at the National Alzheimer's Coordinating Center. Her dissertation research, under guidance of Dr. Xiao-Hua Zhou, is on latent variable modeling. She also works with Dr. Margaret Pepe on risk prediction and incremental values. Prior to arriving in Seattle, she received a BS in Statistics from Peking University in China.