

**The DIVISION OF BIOSTATISTICS  
of the  
MEDICAL COLLEGE OF WISCONSIN**

Proudly Presents  
A Special Talk  
By:



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**Understanding Causal Effects of a Treatment on Survival in Observational Studies with Unmeasured Confounding**

Many clinical studies on survival outcomes based on observational data are challenged by unmeasured confounding. Instrumental variable (IV) methods are popular approaches for dealing with both measured and unmeasured confounding and are increasingly being adopted in clinical studies. However, IV methods are not well developed for survival outcomes, especially for the Cox proportional hazards model which is the most popular regression model for censored survival data. Recently, there has been widespread use of the two stage residual inclusion (2SRI) method offered by Terza et al. (2008) for nonlinear models, and 2SRI has been the method of choice for analyzing proportional hazards model using IV in clinical studies. However, the causal parameter using 2SRI is only identified under a homogeneity assumption that goes beyond the assumptions of IV, and Wan et al. (2015) demonstrated that under standard IV assumptions, 2SRI could fail to consistently estimate the causal hazard ratio. In this paper, we develop a novel IV method to obtain a consistent estimate of the causal hazard ratio for survival outcomes with a proportional hazards model specification under standard IV assumptions. Simulation studies show that when there is unmeasured confounding, both 2SRI and the standard Cox regression could provide biased estimates of the causal hazard ratio among compliers, while our method provide unbiased estimates. We apply our method to an observational study of breast cancer.

**Tuesday, November 8, 2016**  
**3:30 – 4:30 PM**  
**Medical College of Wisconsin**  
**Room M2050 – 2<sup>nd</sup> floor of the MEB**  
*Refreshments 3:00 – 3:30 PM in H2030*