Statistics and Data Science Seminar

Efficient and equitable recruitment into clinical trials using the PREDICTEE algorithm:
Application to trials of HCV vaccines

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Abstract: Randomized clinical trials are a pillar of evidence-based medicine, but are often very expensive and recruit a poor representation of the at-risk population. Here we seek to develop a recruitment strategy for trials of vaccines for HCV that would not only decrease the required sample size to achieve adequate statistical power, but also improve the demographic representation of the recruited trial cohort to enhance their equity and generalizability. Using PWID data collected from Chicago, predictive incidence models were trained and applied to a recruitment scheme which aggregates and enrolls candidates in a batchwise manner and incorporates sample size re-estimation. Dynamic weights are applied to generate a numerical score that can be used to assess a candidate’s expected probability of infection and demographic desirability, thus allowing trials to selectively recruit high-incidence PWID who also contribute to the generalizability of the trial. Simulated clinical trial recruitment using this scheme expressed a two- to three-fold increase in HCV incidence among the trial cohort compared to conventional methods. Simultaneously, the demographic composition of the recruited cohort more closely resembled the target population. This recruitment scheme also proved flexible to varying numbers of matched demographic categories, while also being robust to target populations that were highly dissimilar to the recruitment pool. This novel method of trial recruitment presents a promising approach by which costs can be minimized while assuring a
high level of demographic representation. This is joint work with Richard Guan Chiu.