Methods Seminar (first of two)
"Cluster Randomized Trials of EMR-Catalyzed Decision Support
Part I: Design and Human Subjects Issues"

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Electronic medical records (EMRs) with sophisticated clinical decision support (CDS) functions are increasingly common in large health care systems that have many affiliated clinical practice sites. Cluster-randomized trials (CRTs) of different approaches to clinical decision support are facilitated by EMRs in these systems by enabling: 1. identification of patients and problem areas that might benefit from CDS; 2. providing rich clinical data for *a priori* balancing of practices on important characteristics before allocating clusters of practices to intervention groups; and 3. providing the platforms for developing and implementing different types of CDSs; for example, CDSs for patients or providers. In this session, we will describe:

- the basic principles and differences between CRTs and RCTs, and the impacts of clustering (ICC, or rho) on study design, sample size/power, and analyses.
- human subjects issues, including principles and alternate approaches to consent

We will illustrate key points by highlighting a regional CRT of CDS in Type 2 diabetes.