

Methods Seminar (second of two)
“Cluster-Randomized Trials of EMR-Catalyzed Decision Support
Part II: Analytic and Strategic Concerns”

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As we saw in the first part of these seminars (Design and Human Subjects Issues), electronic medical records (EMRs) with sophisticated clinical decision support (CDS) functions are increasingly common in large health care systems with many affiliated clinical practice sites, and cluster-randomized trials (CRTs) of different approaches to clinical decision support are an important part of the modern researcher’s toolbox.

In this session, I will provide some insight into a few of the key analytic issues involved in developing and designing CRTs of CDS, using the regional DIG-IT CRT of CDS in Type II diabetes.

I will begin by describing the basic statistical methodology used for CRTs, including such notions as the intra-cluster correlation coefficient, the use of the design effect to modify power and sample size assessments, and some special techniques for achieving covariate balance through design. I will also discuss a few special concerns when reporting the results of a CRT.

Finally, I will present a short list of several complicating factors likely to occur in real-world applications of CRTs of CDS (drawn from the DIG-IT CRT), and give the audience the opportunity to choose a few for further discussion of interesting methodological and strategic issues.

This seminar, in combination with Part I (given by Dr Cebul and Dr Dawson) is part of a short course to be offered at the Society for Medical Decision Making meeting in Boston next month.