

## WORKSHOP TO BE GIVEN AT THE ADDICTION HEALTH SERVICES RESEARCH (AHSR) CONFERENCE

### Tentative Workshop Title

Getting SMART about Developing Individualized, Adaptive Treatment Strategies

### Tentative Workshop Description

The effective management of substance use disorders often requires individualized, sequential decision making, whereby treatment is dynamically adapted and re-adapted over time based on an individual's changing course. Adaptive treatment strategies (or adaptive health interventions) are individually-tailored treatments. Formally, they operationalize individualized, sequential, decision making via a sequence of decision rules that specify whether, how, for whom, and when to alter the intensity, type, or delivery of treatments at critical decision points in the management of substance use disorders. At each decision point, the decision rules employ patient characteristics and outcomes (e.g., preferences, response, or adherence while on previous treatment) to recommend subsequent treatment. Treatment options can be psychosocial, behavioral, and/or pharmacological. Once developed, an adaptive treatment strategy can be used in treatment planning or to supplement clinical practice.

The primary aim of this workshop is to describe and discuss the use of a novel experimental design—so-called, sequential multiple assignment randomized trials, or SMART—intended specifically for the purpose of developing and optimizing adaptive treatment strategies.

Workshop participants will:

- Learn how adaptive treatment strategies (ATSs) operationalize the tactics and strategies of individualizing treatment for substance use disorders. What are ATSs? Why do we need them?
- Be introduced to sequential multiple assignment randomized trials (or SMARTs) that can be used to inform the development of individually tailored clinical decision rules in mental health research.
- Learn about SMART study design principles.
- Learn about the types of primary and secondary scientific aims that investigators can specify in the design of, and grant application involving, a SMART.

### Long Blurb

Daniel Almirall is a Faculty Research Fellow in the Institute for Social Research at the University of Michigan. Prior to joining Michigan in January 2010, Dr. Almirall was Assistant Professor of Biostatistics & Bioinformatics at Duke University and Biostatistician in the HSR&D department of the Durham VA Medical Center.

A statistician by training, Dr. Almirall's methodological research interests lie in two, related areas: His work in the area of causal inference has focused primarily on developing models for investigating the impact of time-varying treatments (or exposures), especially methods related to estimating *time-varying effect moderation*.<sup>1-2</sup> In recent work in this area<sup>3</sup>, Dr. Almirall and colleagues have developed a weighted regression approach for investigating time-varying moderators in the presence of (a possibly large number of) time-varying confounders. In their application, the method is used to evaluate the cumulative effects of adolescent substance use treatment as a function of history of response while on treatment.

Dr. Almirall is also interested in methods and study designs used to form adaptive treatment strategies (ATS). An ATS is an adaptive health intervention made up of a sequence of decision rules that specify whether, how, and when to alter the intensity, type, or delivery of treatment at critical decision points. In this area, he devotes a portion of his time to working with behavioral health scientists interested in designing sequential multiple assignment randomized trials (SMARTs). SMARTs are randomized trial designs that give rise to high-quality data that can be used to evaluate and optimize adaptive treatment strategies. In recent work in this area, Dr. Almirall and colleagues discuss important issues to consider when designing a pilot study in preparation for a full-scale SMART.<sup>4</sup>

1. Almirall D, Ten Have T, and Murphy, SA (2009). *Structural nested mean models for assessing time-varying effect moderation*. *Biometrics*, 66(1), 131-139.
2. Almirall D, McCaffrey D, Ramchand R, and Murphy SA (2011). *Subgroups analysis when treatment and moderators are time-varying*. *Prevention Science*, in print.
3. Almirall D, Compton SN, Gunlicks-Stoessel M, Duan N, Murphy SA (submitted). *Designing a Pilot Sequential Multiple Assignment Randomized Trial for Developing an Adaptive Treatment Strategy*.
4. Almirall D, McCaffrey D, Griffin B, Ramchand R, and Murphy SA (in preparation). *Examining time-varying causal effect moderation in the presence of a potentially large number of time-varying confounders*.

### Short Blurb (without references)

Daniel Almirall is a Faculty Research Fellow in the Institute for Social Research at the University of Michigan. A statistician by training, Dr. Almirall's methodological research interests lie in two, related areas: His work in the area of causal inference has focused primarily on developing models for investigating the impact of time-varying treatments (or exposures), especially methods related to estimating *time-varying effect moderation*. Dr. Almirall is also interested in methods and study designs used to form *adaptive treatment strategies* (ATS). An ATS is an adaptive health intervention made up of a sequence of decision rules that specify whether, how, and when to alter the intensity, type, or delivery of treatment at critical decision points. In this area, he devotes a portion of his time to working with behavioral health scientists interested in designing sequential multiple assignment randomized trials (SMARTs). SMARTs are randomized trial designs that give rise to high-quality data that can be used to evaluate and optimize adaptive treatment strategies.

### Picture



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