SOCIETY NEWS

Summary of the SRNT Treatment Network Webinar: Getting SMART About Developing Individualized Sequences of Health Interventions

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On September 19, 2013, the Society for Research on Nicotine and Tobacco (SRNT) Treatment Network hosted a live webcast on sequential multiple assignment randomized trials (SMARTs)—designs that are intended specifically for the purpose of developing and optimizing adaptive interventions. The presenter was Daniel Almirall, PhD, a Research Assistant Professor in the Quantitative Methodology Program in the Survey Research Center, Institute for Social Research at the University of Michigan. Dr. Almirall works closely with Drs. Billie Nahum-Shani and Susan A. Murphy also at the University of Michigan.

The effective treatment or management of a wide variety of health disorders, including smoking, often requires individualized, sequential decision making, whereby treatment is dynamically adapted over time based on a patient's changing outcome. For example, an adaptive smoking cessation intervention that begins with counseling may intensify the frequency of counseling sessions or change the type of pharmacotherapy in response to failed quit attempts or other early indicators of relapse. Adaptive interventions (also known as adaptive treatment strategies or dynamic treatment regimens) operationalize this type of individualized, sequential, decision making via a sequence of decision rules. These decision rules specify whether, how, for whom, or when to alter the dose (amount, frequency, or duration), type, or delivery of psychosocial, behavioral, or pharmacological treatments at critical decision points in the treatment or management of a health disorder. Adaptive interventions can be designed to individualize treatment both upfront and throughout the course of care, and they can be used as guides in actual clinical practice.

Often, however, a wide variety of critical decisions must be made when seeking to develop an effective adaptive intervention. Yet, in many settings, there is insufficient theoretical basis or empirical data guiding behavioral scientists in making these decisions. For example, investigators may be interested in addressing questions such as (1) "What is the effect of starting with behavioral versus medication on longitudinal outcomes?" (2) "For nonresponders to initial treatment, is it better on average to augment or switch treatment?" (3) "Among nonresponders to initial treatment, should adherence to initial treatment be used to guide the decision to augment versus switch subsequent treatment?" or (4) "How do we define or identify individuals who are nonresponders and in need of a subsequent change in treatment?"

SMARTs use experimental design principles to obtain answers to many of these important questions. SMARTs are multistage trials that involve the same participants throughout each stage. Each stage corresponds to a critical decision point, and at each stage, subjects are randomized to a set of treatment options. The overarching goal of a SMART design is to inform the development of adaptive interventions.

An example of a SMART design, taken from a study investigating the best way to individualize sequences of treatment for children with attention deficit hyperactivity disorder (ADHD) (principal investigator [PI]: William Pelham), would be one in which participants were randomly assigned to a behavioral versus medication treatment at Stage 1. At Stage 2 (say, at the beginning of Week 9), responders would continue on the same treatment, whereas nonresponders would be randomly assigned to receive a more intense dose of the treatment they had been assigned to versus augmentation with the treatment they had not received (medication augmented with behavior therapy and vice versa). Such a SMART can be used to address questions (1) to (3) above, for example.

Dr. Almirall discussed some study design principles to keep in mind when planning or conducting a SMART, including the importance of keeping the design simple (e.g., restricting subsequent randomizations only if there are strong scientific, ethical, or feasibility considerations). He clarified some common misconceptions or confusion about SMART designs, including the concern (a) that SMART designs necessarily require large sample sizes—they do not require large sample sizes; however, as with any randomized trial design, this depends on what is the primary aim of the SMART—and (b) that SMART designs are not adaptive trial designs. In discussing how the goal of a SMART is different from the overarching goal of a randomized controlled trial, he explained how SMARTs can be thought of as a special type of factorial design, and how SMARTs fit within the multiphase optimization strategy, a framework for developing effective behavioral interventions.

The webinar was recorded and is available at http://srnt.org/mem_only/networks/treatment/treatment.cfm.

Additional information on Dr. Almirall and his work is available at www-personal.umich.edu/~dalmiral/.

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