

## COMMENTARY

# A Programmatic Approach to Socially Complex Intervention Development

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### Abstract

First used in psychiatry to study pharmacological treatments, the randomized controlled trial provides the most powerful test of the relative effectiveness of two or more interventions. Applying RCT methodology to socially complex service interventions, however, presents unique challenges that derive from difficulties in treatment standardization, attaining study sample equivalence and controlling for environmental variations. These challenges can be managed when intervention development proceeds along a programmatic trajectory that spans discovery, development, efficacy, effectiveness and practice research. Copyright © 2000 John Wiley & Sons, Ltd.

The concept of 'socially complex service interventions' (SCS) draws a distinction between treatments where a therapeutic agent, dose and route of administration can be specified with precision, and less readily defined psychosocial and service system interventions. In contrast to relatively straightforward pharmacological treatments, SCS are subject to variations from different staffing arrangements and skill levels, protocols often specified in terms of a general style or approach, subjects with varying motivational sets, and environments more or less insulated from powerful, but unmeasured contextual factors. Wolff argues that because of these uncontrolled sources of variance, the standard randomized clinical trial (RCT) design probably cannot yield valid, reliable and generalizable findings when used to evaluate socially complex services. An extensive and costly retooling is recommended to alleviate these sources of uncertainty. According to Wolff, 'Researchers and funders must accustom themselves to a more complicated (more time consuming and expensive) research design if they are to achieve the desired outcome: meaningful information to guide best practice'.<sup>1</sup>

Before committing to an ambitious program of RCT reform, however, it is useful to consider that both biological and psychosocial intervention development is a multistage

process: no single study, however elegant, can be sufficient to address the full spectrum of public health questions relative to discovering and disseminating best practices.<sup>2</sup> Defined by regulatory rather than social complexity, new drug development progresses through at least four phases. Following pre-clinical research to screen and identify candidate compounds, phase 1 studies focus on pharmacokinetics, toxicity and tolerability. Potentially therapeutic, non-toxic and well tolerated agents undergo rigorous evaluations in phase 2 RCTs using optimal treatment delivery conditions to test safety and efficacy in carefully defined patient samples. Phase 3 trials also use RCT methodology to further evaluate efficacy and safety and assess optimal dosage in larger samples.<sup>6</sup> Post-marketing or phase 4 studies will often include broadly defined effectiveness trials to evaluate performance (including functional and economic outcomes) in clinically representative samples treated in a broader and more diverse range of treatment settings. Strict inclusion and exclusion criteria are relaxed so the effectiveness of an agent might be tested in patients with comorbidities, patients with related conditions or in combination with other treatments.

As with drug discovery, psychosocial and system-level intervention development can be thought of as proceeding along predictable trajectories.<sup>3</sup> In *pre-intervention research*, potent and modifiable risk factors for an adverse outcome are isolated<sup>4</sup> or a creative solution to a clinical or organizational dilemma is envisioned and piloted. *Intervention development* research includes efforts to standardize or manualize a treatment, develop measures of fidelity or model adherence and establish utility in small open or case-controlled trials. *Efficacy research* will then utilize RCT methodology to look at a select group of individuals treated with well defined intervention protocols. These studies, designed to maximize internal validity, help define which interventions are worth exploring in a more expansive array of treatment settings and subjects. *Effectiveness research* studies, often across multiple study sites, shift the emphasis to external validity by evaluating treatment effects (including functional and economic outcomes) in diverse clinical settings with broadly representative populations. Subgroup analyses may clarify patient, treatment or contextual factors

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that favor or impede optimal outcomes. Finally, *practice research* relies on observational or experimental designs to explore questions that include how treatment resources are used, how practice variations (including structural, organizational and financial arrangements) influence the quality of outcomes and how to best disseminate evidence-based practice.

An 'hourglass' metaphor has been used to represent the overall structure and sequencing of intervention development: in this model RCTs belong at an intermediate stage of intervention development akin to the narrow stem of the hourglass.<sup>5</sup> This stem follows broader theoretical observations and intervention development activities and in turn precedes a broadening out again to more naturalistic studies in diverse 'real world' settings.

Wolff's ten recommendations for stylizing the RCT design to the characteristics of SCS represent a valuable checklist of methodological issues that warrant consideration in the design of effectiveness studies. Yet we must acknowledge that any single study will inevitably entail methodological compromises between competing concerns such as internal validity versus generalizability. A single study incorporating all of Wolff's recommendations would be at risk of collapsing

under the weight of its cost and complexity. A thoughtful stepwise programmatic agenda for intervention development may represent a more realistic remedy for the limitations of the RCT in evaluating socially complex services.

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