CJNR 2007, Vol. 39 Nº 4, 191–197

Best Practices for Research

Guidelines for Translating RCT Findings into Practice

Souraya Sidani and Laurie N. Gottlieb

The epidemiologists and methodologists have gained control of the research agenda and, more recently, the clinical agenda. Over the past 20 years, the randomized clinical trial (RCT) has become the standard against which the effectiveness of a given intervention is measured (Shadish, Cook, & Campbell, 2002). The RCT has been used extensively in testing the effectiveness of drugs, medical and surgical treatments, psychotherapies, and social programs. As the demand for evidence-based practice increases, the pressure on clinicians mounts. Many clinicians are asked to translate the RCT conditions into their practice after a trial has been completed and the effectiveness awards have been handed out. But translating RCT into practice is not easy given the inherent differences, in terms of mission and execution, between the RCT and practice worlds.

What are some of the most obvious differences between these two worlds?

The RCT is credited with providing the best available evidence on the effectiveness of an intervention. The RCT design is characterized by control over the experimental conditions. Participants are carefully selected, on the basis of strictly defined eligibility criteria, to ensure homogeneity of the sample and to control for potential confounds. To minimize selection bias, participants are randomly assigned to the treatment or comparison group. The intervention under evaluation is implemented in a standard and consistent manner across all participants assigned to the treatment group, so as to minimize random irrelevancies in its delivery that might affect the outcome. Analysis of outcome data is conducted at the group level, aimed at demonstrating statistically significant between-group differences in outcomes at post-test.

Because of careful participant selection on the basis of strictly defined eligibility criteria, the generalizability of RCT findings is limited to patients who meet those criteria (Brown, 2002). The patient population served in the practice setting comprises subgroups of patients who differ

to some extent from those included in the RCT: Patients may present with characteristics that were considered exclusion criteria (Sidani & Epstein, 2003). To what extent are RCT findings and conditions applicable to different subgroups of patients? Can the intervention be used safely, and can it produce the outcomes observed under the RCT? Few if any RCT conditions are consistent with patient-centred care. Quality nursing practice is predicated on the tailoring of care to a particular patient situation in a particular context (Radwin, 2003). Random assignment of participants to a treatment or comparison group contradicts the principle underlying clinical decision-making and practice. Clinicians are trained to select and deliver interventions that are appropriate for and effective in addressing patients' conditions and to engage patients in the decision-making process. This process relies on interventions that are acceptable to patients — consistent with their beliefs, values, and preferences.

How can random assignment inform the clinical decision-making process and the procedure for encouraging patients to take part in decision-making or for eliciting their treatment preferences? To what extent will an intervention be effective if administered on the basis of patients' expressed preferences? (Sidani, Epstein, & Miranda, 2006) The standard and uniform implementation of an intervention in the RCT context limits its relevance for and use in practice. The intervention's components, dose, and mode of delivery must be adapted or modified to accommodate patients' needs and preferences as well as the resources available in the practice setting. To what extent can an intervention's components and method of delivery be modified yet produce the intended benefits?

Results of statistical analysis, carried out at the group level and guided by the intent-to-treat principle, demonstrate an intervention's effectiveness in achieving the outcomes for the "average" participant. The average participant is one who meets the eligibility criteria and responds as expected to the intervention (Barlow, 1996). An RCT's reported results do not indicate the presence of variability in the dose of the intervention received by participants or in their responses to the intervention. Yet such variability is important to clinicians (Jacobson & Truax, 1991). Clinicians need to know who will most benefit from the intervention, at what dose level, in order to make sound clinical decisions (Sidani & Braden, 1998).

It is clear that RCT design and the reporting of RCT findings have limited relevance for practice (Ferguson, 2004). Variants of the RCT design and modifications to research strategies and methods have been suggested as means of enhancing the applicability and transferability of intervention evaluation findings to the practice setting (Glasgow, Magid, Beck, Ritzwoller, & Estabrooks, 2005; Gross & Fogg, 2001; Rothwell,

2005; Sidani, Epstein, & Moritz, 2003; TenHave, Coyne, Salzer, & Katz, 2003; Tunis, Stryer, & Clancy, 2003).

Until such variant designs and modifications are accepted as mainstream methods for the design and conduct of intervention studies, what can be done to help clinicians translate RCT findings into practice? The most commonly recommended strategy is to develop collaboration between researchers and clinicians with the ultimate aim of generating guidelines for delivering the intervention, implementing it in such a way as to preserve its integrity, and evaluating its effectiveness (Titler, Mentes, Rakel, Abbott, & Baunker, 1999). The success of this strategy depends on the availability of the information and evidence necessary to draw up practice guidelines. What information and evidence do clinicians need in order to translate RCT findings into practice? And what can researchers do to enhance the relevance of their findings for practice? To address these questions, we developed four guiding principles that researchers can use in reporting the findings of an RCT. The goal is to help clinicians identify the conditions that determine the effects of an intervention.

Principle 1: Clear Description of the Intervention

Clinicians or frontline nurses cannot translate into practice that which they cannot understand or visualize. Clinicians require clear and accurate information on the nature and essential ingredients of the intervention in order to replicate or apply it. The essential ingredients of an intervention, like the essential attributes of a concept (Walker & Avant, 1995), are the features that distinguish it from all the others. They are the elements or activities hypothesized to bring about the intended change. Delineation of the intervention's essential ingredients tells clinicians what specific elements are needed to ensure fidelity of implementation and thus achievement of the expected outcome.

In reporting on an RCT evaluating the effectiveness of an intervention, the researcher must make explicit the implicit. What is obvious to the researcher may not be obvious to others. The investigator must describe the nature of the intervention and the procedure to be followed in implementing it. This includes all the w's and h's of the intervention: where, when, who, what, why, how. In pertinent sections of the research report, the investigator can specify the overall goal(s) of the intervention; the components of the intervention and the goal of each; the tasks to be performed in delivering each component, and their sequence, if any; the mode of delivery for each component; the dose at which the intervention is to be administered; the required characteristics of the staff responsible for implementing the intervention and details of any training that might be required; and the conditions under which the intervention was tested (e.g., setting, time). The researcher can also include information on

the availability of the intervention protocol. All of these details about the intervention are critical for its accurate translation into practice guidelines and hence its faithful application in the practice setting.

Principle 2: Discussion of Variability in Intervention Dose

In the reality of day-to-day practice, variability in the implementation of an intervention is the norm. In order to tailor the intervention dose to the needs and conditions of individual patients, clinicians need to know the dose range that is safe, is acceptable to patients, and is associated with the achievement of the intended outcome. Once informed about variability in the doses administered to study participants and about the outcomes observed at different dose levels, clinicians can make modifications to suit the needs of individual patients without jeopardizing the intended outcomes.

To enhance the clinical relevance of RCT findings, researchers can report on variability in the dose to which participants were exposed and the results of dose-response analysis. First, the researcher specifies the number of participants who did and did not complete the intervention at the specified dose level and the reasons for non-completion. Next, the researcher indicates the number of participants who received each level of the intervention dose, however defined (e.g., number of contacts between participants and staff; frequency of the key activities that make up the intervention); this information points to the acceptability of the intervention dose and the dose level tolerated by most participants, and can guide modification or refinement of the dose. Finally, and most importantly, in determining the effectiveness of the intervention the researcher can supplement traditional analysis with dose-response analysis; the latter is focused on the relationships between the different dose levels to which the participants were exposed and the observed differences in outcomes (Lipsey, 1990). The results indicate (1) the minimal and optimal dose required to produce a beneficial outcome, and (2) the extent to which dose variability is still associated with therapeutic effects. Consequently, a safe and effective dose range can be delineated to guide clinical decision-making. It informs clinicians' prescription of the most appropriate intervention dose and directs their efforts to tailor the intervention to individual needs and conditions.

Principle 3: Explanation of Who Stands to Benefit the Most from the Intervention

It is not enough to simply report group findings, as is the traditional practice. Except for those working in public health settings, frontline clinicians do not treat groups. Rather, they are responsible for the care of individuals within groups. Results reported at the group level mask

within-group variability, yet this variability must be examined so that those participants who benefited the most from the intervention can be identified. Equipped with this knowledge, clinicians can determine the intervention's appropriateness for their patients and its applicability and effectiveness for patients with diverse health backgrounds.

Researchers can complement traditional group-level analysis, in which the experimental and comparison groups are compared on post-test outcomes, with subgroup analyses. The purpose of subgroup analysis is to delineate the profile of participants who responded positively to the intervention (Tunis et al., 2003). The analysis consists of describing the sociodemographic and health characteristics of participants who, as anticipated, demonstrated large improvements (Gibson, 2003; Gottlieb & Feeley, 1996). When the RCT sample is rather small, the subgroup analyses can be exploratory, aimed at identifying differences in key, conceptually relevant, characteristics among participants who, between pretest and post-test, showed improvement, no change, or worsening. Change scores are computed to represent the magnitude of improvement in outcomes, as suggested by Rogosa and Willett (1985).

Principle 4: Assessment of Clinical Significance

It is common knowledge that statistically significant findings are not necessarily clinically meaningful ones. They do not provide information on the extent to which the intervention was helpful for individual participants and made a difference in their lives (Jacobson & Truax, 1991). Yet knowledge about the impact of the intervention on participants' lives is needed for the purposes of decision-making. Clinicians use such information in planning their patients' care, in discussing the utility or effectiveness of an intervention with their patients, and in helping their patients to select an intervention that will address their presenting problem.

Researchers can take one of two approaches to examining clinical significance — statistical and individual (LeFort, 1993) — and report the results to enhance the relevance of RCT findings for practice. The statistical approach consists of computing the effect size (i.e., standardized difference in the post-test means of the experimental and comparison groups) for each outcome. The effect size is a statistical estimate of the magnitude of the intervention effect. Interventions demonstrating large effects are considered to produce outcomes that have a meaningful impact on patients' lives. The individual approach consists of reporting the number of participants in each experimental and comparison group who exhibit improvement between pretest and post-test. If a large percentage of participants in the experimental group show the anticipated level of improvement, the intervention is deemed clinically relevant.

Researchers and clinicians are partners in the delivery of nursing care. They need to form strong alliances and to create new dialogue in order to facilitate translation of RCT findings into practice. Clinicians are encouraged to voice their need for information that is relevant and that guides the prescription of interventions that respond to patients' conditions and preferences and that will maintain their integrity in day-to-day practice. Researchers must provide information and results that are meaningful for clinicians. Both stakeholder groups could discuss the appropriateness, comprehensiveness, and utility of our suggested principles for enhancing the clinical relevance of intervention research. Only through discussion and collaboration by all stakeholder groups will consensus be reached on the substance and reporting of intervention-related knowledge. The reporting of clinically relevant knowledge will promote clinicians' appreciation of research and facilitate the translation of research findings into practice.

References

Barlow, D. H. (1996). Health care policy, psychotherapy research, and the future of psychotherapy. *American Psychologist, 51,* 1050–1058.

Brown, S. J. (2002). Nursing intervention studies: A descriptive analysis of issues important to clinicians. *Research in Nursing and Health, 25,* 317–327.

Ferguson, L. (2004). External validity, generalizability, and knowledge utilization. *Journal of Nursing Scholarship, 36*(1), 16–22.

Gibson, C. M. (2003). Privileging the participant: The importance of subgroup analysis in social welfare evaluations. *American Journal of Evaluation, 24*(4), 443–469.

Glasgow, R. E., Magid, D. J., Beck, A., Ritzwoller, D., & Estabrooks, P. A. (2005). Practical clinical trials for translating research to practice: Design and measurement recommendations. *Medical Care, 43*(6), 551–557.

Gottlieb, L. N., & Feeley, N. (1996). The McGill Model of Nursing and children with a chronic illness: "Who benefits and why?" *Canadian Journal of Nursing Research, 28*(3), 29–48.

Gross, D., & Fogg, L. (2001). Clinical trials in the 21st century: The case or participant-centered research. *Research in Nursing and Health, 24,* 530–539.

Jacobson, N. S., & Truax, P. (1991). Clinical significance: A statistical approach to defining meaningful change in psychotherapy research. *Journal of Consulting and Clinical Psychology, 59*(1), 12–19.

LeFort, S. (1993). The statistical versus clinical significance debate. *Image: Journal of Nursing Scholarship, 25*(1), 57–62.

Lipsey, M. W. (1990). *Design sensitivity: Statistical power for experimental research.* Newbury Park, CA: Sage.

Radwin, L. E. (2003). Cancer patients' demographic characteristics and ratings of patient-centered nursing care. *Journal of Nursing Scholarship, 35,* 365–370.

Rogosa, D. R., & Willett, J. B. (1985). Understanding correlates of change by modeling individual differences in growth. *Psychometrika, 50*(2), 203–228.

Rothwell, P. M. (2005). External validity of randomized controlled trials: "To whom do the results of this trial apply?" *Lancet, 365,* 82–93.

Shadish, W. R., Cook, T. D., & Campbell, D. T. (2002). *Quasi-experimental designs for generalized causal inference.* Boston: Houghton Mifflin.

Sidani, S., & Braden, C. J. (1998). *Evaluating nursing interventions: A theory-driven approach.* Thousand Oaks, CA: Sage.

Sidani, S., & Epstein, D. (2003). Clinical relevance of RCT findings. *International Nursing Perspectives, 3*(1), 49–56.

Sidani, S., Epstein, D., & Miranda, J. (2006). Eliciting patient treatment preferences: A strategy to integrate evidence-based and patient-centered care. *Worldviews on Evidence-Based Nursing, 3*(3), 116–123.

Sidani, S., Epstein, D. R., & Moritz, P. (2003). An alternative paradigm for clinical nursing research: An exemplar. *Research in Nursing and Health, 26,* 244–255.

TenHave, T. R., Coyne, J., Slazer, M., & Katz, I. (2003). Research to improve the quality of care for depression: Alternatives to the simple randomized clinical trial. *General Hospital Psychiatry, 25,* 115–123.

Titler, M. G., Mentes, J. C., Rakel, B. A., Abbott, L., & Baunker, S. (1999). From book to bedside: Putting evidence to use in the care of the elderly. *Journal of Quality Improvement, 25*(10), 545–556.

Tunis, S. R., Stryer, D. B., & Clancy, C. M. (2003). Practical clinical trials: Increasing the value of clinical research for decision making in clinical and health policy. *Journal of the American Medical Association, 290*(12), 1624–1632.

Walker, L. O., & Avant, K. C. (1995). *Strategies for theory construction in nursing.* Norwalk, CT: Appleton & Lange.

Authors' Note

Comments or queries may be directed to Souraya Sidani, School of Nursing, Ryerson University, 350 Victoria Street, Toronto, Ontario M5B 2K3 Canada. Telephone: 416-979-5000, ext. 2572. E-mail: ssidani@ryerson.ca.