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# *Guest Editorial and Discourse*

## Rethinking the Research-Practice Gap: Relevance of the RCT to Practice

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The research-practice gap is not a new phenomenon in nursing. It was first observed about 50 years ago. The results of surveys conducted in various countries and at different points in time have consistently indicated that a small percentage of nurses use research-based evidence to guide their practice (e.g., Brett, 1987; Coyle & Sokop, 1990; Ketefian, 1975; Kirchhoff, 1982; Parahoo, Barr, & McCaughan, 2000; Rodgers, 2000). Attention to the research-practice gap has resurfaced at a time when evidence-based practice is viewed as a means for enhancing the quality of health and nursing care. The implementation of evidence-based nursing practice requires that nurses critically review the research evidence supporting the effectiveness of interventions, synthesize it, and translate it into practice guidelines. Yet, anecdotal and empirical observation suggests that the updating and use of research findings in everyday practice is rather limited (Naylor, 2003).

Barriers to research utilization have been identified in four areas: the social system in which nurses are employed, nurses' research values and skills, quality of research, and methods for communicating research (Funk, Tornquist, & Champagne, 1995). Various strategies have been proposed to address these barriers and subsequently the research-practice gap. For instance, unit-based journal clubs and workshops focusing on the critical appraisal of research have been established in an effort to increase nurses' research knowledge and skills. Other organizational strategies to support the research-utilization endeavours of nurses include the following: pairing of researchers and clinicians to work on developing practice guidelines, making computers available in the practice setting to facilitate access to research literature, and using research or evidence-based practice as a key value (Estabrooks, 2003; Funk et al.; LeMay, Mulhall, & Alexander, 1998). Another strategy is to improve the methods for disseminating research findings to practitioners (Oxman, Thomson, & Davis, 1995).

Despite our understanding of the factors that lead to the research-practice gap and our exploration of strategies to promote evidence-based practice, only to a limited extent are research findings being used to guide practice. Therefore we must re-think or re-prioritize the factors that contribute to the research-practice gap and adopt strategies to close it. Specifically, the perceived irrelevance of research to practice has received little attention as a barrier to research utilization. Research methods are far removed from the reality of practice and therefore generate findings that have limited applicability. The randomized controlled trial (RCT) is a case in point. It is crucial that we modify available research methods and/or design alternative ones so that they are in line with practice and produce clinically relevant findings. The changes in research methods may facilitate the updating and application of clinically relevant findings, and thereby help to close the research-practice gap and promote evidence-based practice.

## The Roots of the Research-Practice Gap

In recent reports of quantitative and qualitative studies and clinical observations, two specific barriers have been identified as hampering research utilization in different clinical settings and different countries: unclear implications for practice, and lack of generalizability and relevance to the practice setting (e.g., LeMay et al., 1998; Nilsson Kajermo, Nordstrom, Krusebrant, & Bjorvell, 2000; Retsas, 2000). This concern on the part of nurses about the limited generalizability and clinical relevance of research findings is echoed by scholars in applied disciplines including medicine, nursing, and the behavioural sciences. Scholars question the ability of available research approaches and methods to produce clinically meaningful results and the applicability of research findings to everyday practice (e.g., Clarke, 1995; Ferguson, 2004; Gross & Fogg, 2001; Lindsay, 2004; Pincus, 2002; Sidani & Epstein, 2003; TenHave, Coyne, Salzer, & Katz, 2003).

The discrepancy between the way that research is conducted and the way that practice is conducted, and between the knowledge that is generated through research and the knowledge that is needed to guide practice, is a key factor in the research-practice gap. Research approaches and methods are developed in the basic sciences. They are adopted and applied without critical analysis of their suitability and utility to the study of phenomena in applied disciplines such as nursing. Qualitative approaches to research are grounded in the social sciences, quantitative approaches in the physical sciences. The application of the methods used in these approaches may not be fully consistent with the study of health-related phenomena of interest in nursing, and with the need to form a comprehensive understanding of the patients' presenting problem, preferences, and responses to care as they occur in practice. For example, the RCT, considered the standard in intervention evaluation, is far removed from practice (Sidani, Epstein, & Moritz, 2003). It was developed to examine the impact of innovations in the field of agriculture. Its use in investigating the effectiveness of nursing interventions that are delivered to human beings in order to manage their often complex health-related problems is questionable. The RCT design is based on a perspective of science and assumptions about human beings and their response to treatment that are incongruent with those embraced by nursing. Further, the characteristic features of the RCT do not reflect the reality of practice (Sidani et al.), particularly with the current emphasis on patient-centred care. The assumptions underlying the RCT design are contradictory to those underpinning the patient-centred approach to care, in which each patient is considered a unique person, having individual needs and preferences, and responding differently to interventions. In patient-centred care, the selection and implementation of interventions are mindful of and responsive to the characteristics and preferences of individual patients (Lauver et al., 2002; McCormack, 2003).

## Closing the Research-Practice Gap: Advances in Research Methods

Faced with the discrepancy between the knowledge generated by research and the knowledge needed to guide practice, and with the questionable ability of available research approaches and methods to produce clinically relevant and applicable findings, scholars in various applied disciplines, including nursing, have cited the need for alternative research methods (e.g., Gross & Fogg, 2001; Sidani et al., 2003; TenHave et al., 2003; Tunis, Stryer, & Clancy, 2003). Over the years there has been an increase in the number of articles citing the limitations of available research methods, suggesting these be modified or proposing innovative ones. The discourse on the discrepancy between research and practice has focused primarily on the RCT design used to evaluate the effectiveness of interventions. Delivering interventions is the essence of nursing. Examining the effectiveness of interventions, therefore, is critical to nursing practice. Effectiveness is concerned with the robustness of intervention effects when implemented by various nurses, with different patient populations, in the real world of nursing practice (Whittemore & Grey, 2002).

Questions have been raised about three aspects of the RCT design with regard to its utility for evaluating the effectiveness of interventions and for generating clinically significant findings. These are: overall design, assignment of participants to study groups, and analysis of data. For each aspect, the discrepancy between research and practice and ways to minimize it are discussed.

### *Overall Design*

The characteristic features of the RCT impose artificial boundaries that limit the relevance and generalizability of the findings. The first feature is the careful selection of participants based on a set of rigorous inclusion and exclusion criteria. These criteria are a means for controlling confounding variables, which increases the likelihood that significant effects will be detected and increases confidence in attributing the effects to the intervention. Yet this careful selection limits the number of eligible participants and confines the sample to certain subgroups of the target population. The end result is lack of generalizability to the full range of subgroups that make up the population of patients encountered in everyday practice (Brown, 2002; Pincus, 2002; Sidani et al., 2003; TenHave et al., 2003; Tunis et al., 2003). The second feature, random assignment of participants to study groups, is discussed in the next section. The third feature is manipulation of implementation. The intervention is administered to one group of participants and withheld from the other; it is delivered in a standardized way, at a fixed dose. Standardized implementation at a fixed dose ensures consistency of exposure and response to the treatment, which in turn enhances the statistical power to detect significant intervention effects (Lipsey, 1990; Shadish, Cook, & Campbell, 2002). This RCT feature is not consistent with the individualized nursing interventions that make up the patient-centred approach to care. Individualization involves the adaptation of some elements and/or dose of the intervention in order to respond flexibly to patients' needs and preferences (Lindsay, 2004; Sidani et al; TenHave et al.). Furthermore, the results of an RCT in which the dose of the intervention administered is not accounted for in the analysis do not provide an accurate estimate of effects, nor do they indicate the optimal dose needed to produce the desired outcomes (Pincus). The fourth feature of the RCT is the control of factors in the setting in which the intervention is implemented. These factors may interfere with the delivery of the intervention and/or the achievement of outcomes. They are controlled experimentally by maintaining them constant across all instances of intervention delivery. Such control is unfeasible in a complex healthcare system. RCT results may not be applicable across a range of settings (Conrad & Conrad, 1994).

The current trend is to conduct a pragmatic or practical clinical trial to evaluate the effectiveness of an intervention (Tunis et al., 2003). In this type of trial, participants with diverse characteristics or backgrounds are recruited from various settings in order to ensure the representation of all subgroups that make up the population of patients seen in practice. Subgroup analysis is recommended as a way of determining the extent to which each subgroup benefits from the intervention (Brown, 2002; Sidani et al., 2003; Tunis et al.). The interventions selected for comparison in a clinical trial should be clinically relevant; that is, they should be feasible in practice and allow for flexibility in implementation and dose (Concato & Horwitz, 2004; TenHave et al., 2003). Careful monitoring of the fidelity with which the intervention is implemented (Judge Santacroce, Maccarelli, & Grey, 2004) and of the dose administered is essential. Dose-response analysis provides information about the optimal dose needed to produce the desired outcomes (Sidani, 1998). Identifying and measuring the characteristics of the setting that could influence effectiveness, and examining their impact on the outcomes, is a useful means of determining aspects of the practice setting that should be modified in order to enhance implementation and effectiveness (Sidani & Braden, 1998).

### *Assignment of Participants*

Random assignment to experimental and control groups serves to generate a balanced distribution, between the groups, of participants with similar characteristics. This initial group equivalence provides a means for controlling the influence of extraneous factors on the outcomes, and therefore for enhancing the validity of the claim that it is the intervention that caused the outcomes (Shadish et al., 2002). Random assignment has two limitations. The first relates to the notion that the initial group equivalence achieved by random assignment is probabilistic, implying that random assignment increases the likelihood, but does not guarantee, that the study groups are exactly comparable on all characteristics that may affect the outcomes (Rossi, Freeman, & Lipsey, 1999; Vandenbroucke, 2004). Because of the probabilistic nature of initial equivalence, the groups' mean scores may differ on baseline variables; however, such differences are considered to be due to chance, even if statistically significant (Rossi et al.). No matter how small they are, such between-group differences cannot be ignored, as they may be clinically meaningful and are associated with post-test differences in the outcomes, as indicated by the results of meta-analytic studies (Heinsman & Shadish, 1996; Sidani, in press).

The second limitation relates to the fact that participants have treatment preferences, which, when ignored in random assignment, may pose threats to validity. In the consent process, participants are informed about the experimental and control conditions of the investigation. They may perceive the treatment options as unequally attractive and may have a preference. Participants who do not receive their preferred treatment may become dissatisfied with the assigned treatment and fail to comply with the intervention and/or drop out of the study. The result is a biased estimate of the intervention effects (Bottomley, 1997; Torgerson, Klaber-Moffett, & Russell, 1996). Therefore, the observed intervention effects may not be reproduced when the intervention is administered to patients in a way that is consistent with their preferences, as in the patient-centred approach to care.

Recent methodological advances include modelling of potentially confounding factors as well as participant treatment preferences. Researchers can identify participant characteristics that are conceptualized to influence the outcomes, measure them reliably, and adjust for their influence statistically, even if the participants were randomly allocated (Vandenbroucke, 2004). Alternatively, they can examine the direct and/or indirect effects on the outcomes to identify the participants who benefited most from the intervention (Sidani et al., 2003). Taking participants' treatment preferences into account when allocating them to the study groups or when conducting the statistical analyses is the most recent advance in the design of effectiveness studies. Specifically, the partial RCT is a means for bringing research designs more in line with practice and for enhancing the clinical relevance of research findings (Sidani et al.; TenHave et al., 2003). It also holds promise for minimizing the threats associated with random assignment (Corrigan & Salzer, 2003; McPherson & Britton, 2001).

### *Data Analysis*

The data obtained in intervention evaluation studies are analyzed using statistical tests, which compare the mean outcome scores of the experimental and control groups. Statistically significant differences in the post-test outcome mean scores provide the evidence to infer that the intervention is effective. The model underlying these statistical tests (i.e., $t$ test or $F$ ratio) is based on the assumption that the intervention effects show up as a change, of a constant value, in the participants' post-test outcome scores. The constant change in the scores of participants who received the intervention creates the difference between the experimental and control groups expected in the outcomes measured at post-test (Bryk & Raudenbush, 1988; Lipsey, 1990). Individual differences in outcome achievement are possible; however, they are represented in the within-group variance, which is considered error variance. A large within-group variance reduces the statistical power to detect significant intervention effects (Lipsey). Yet, a large within-group variance indicates that the participants have responded to the intervention to different degrees (Bryk & Raudenbush). Information about individual or subgroup differences in response to treatment is of the utmost importance to clinicians (Jacobson & Truax, 1991). Researchers are strongly encouraged to supplement the traditional group-level analysis with analyses at the subgroup (Brown, 2002) or individual level using advanced statistical techniques such as Hierarchical Linear Models (HLM; Raudenbush & Bryk, 2001).

Reliance on tests of statistical significance to demonstrate the positive impact of an intervention is potentially misleading (Basch & Gold, 1986). Statistically significant findings do not address the size, strength, or clinical significance of intervention effects (Rothstein & Crabtree Tonges, 2000). Statistical significance indicates that the observed effects are real, reliable, and unlikely to be due to chance. Clinical significance "refers to the benefits derived from treatment, its potency, its impact on clients, or its ability to make a difference in people's lives" (Jacobson & Truax, 1991, p. 12). It should be assessed in order to validate the utility of the intervention in addressing the clinical problem of interest. LeFort (1993) provides a comprehensive overview of the various approaches for examining clinical significance. While the statistical approach (i.e., calculating the effect size) is the most common, individual approaches are gaining momentum. Individual approaches indicate the proportion of participants whose outcome improved. They therefore complement the results of subgroup- or individual-level analyses and are consistent with the patient-centred approach to care. The results of individual approaches present the findings in terms that are familiar to and consequently easily understood by clinicians. Normative approaches have great potential but require the availability of cut-off scores or normative values for the instruments measuring the outcomes of interest to nursing. Assessment and reporting of the clinical meaningfulness of results obtained in intervention effectiveness studies is key to reducing the research-practice gap.

## An Invitation

Despite all the efforts to promote evidence-based practice, research findings are still not being widely used to guide practice. The current trend is to attribute the research-practice gap to the lack of generalizability of research findings to the real world of practice, as well as to the lack of clinical relevance of research results. We will have to modify available research methods and/or design alternative ones that are more in line with practice and that produce more clinically significant results. The literature addressing this issue has increased over the years. Journals are now devoting entire issues to topics such as methodological problems in clinical research or the exploration of recent developments in research methods. An invitation has been extended to researchers to move towards an alternative paradigm for the evaluation of intervention effectiveness

(Gross & Fogg, 2001). In fact, the move to an alternative paradigm has taken place (Concato & Horwitz, 2004; Sidani et al., 2003).

This issue of *CJNR* extends the discourse on research methods in two ways. First, it invites the reader to critically appraise the utility of research methods in terms of the congruence between the assumptions that underlie them and the assumptions that underlie nursing practice, and in terms of their ability to produce clinically relevant results. Second, it encourages the reader to thoughtfully design research methods and test their ability to generate reliable, valid, and clinically meaningful results that will provide a knowledge base to guide current practice, where the emphasis is on patient-centred care. The papers in this issue of the Journal present advances in research approaches and methods that expand on those suggested under the alternative paradigm and that hold promise for the development of a sound and clinically useful knowledge base.

In two papers, the authors advance modifications to the current approach to research that are consistent with the conceptualization and operationalization of nursing practice. Redman and Lynn review the inconsistencies between research designs and methods and between the conceptualization and implementation of patient-centred care. They argue that the demand for standardized interventions and measures, for the careful selection and random assignment of participants, and for controlling or ignoring extraneous and contextual factors is incongruent with the need for interventions that are tailored to patients' needs and preferences. Redman and Lynn recommend knowledge-development approaches that pertain to the effectiveness of patient-centred, tailored interventions; the most challenging of such approaches is the generation of measures that take account of individual values and preferences. Guruge and Khanlou reconceptualize the complexity and interrelatedness of multilevel social influences on health and well-being. They propose Participatory Action Research (PAR) as a useful means for identifying issues of importance to patients and the strategies patients need in order to promote their health. These essential features of PAR are consistent with those of patient-centred care, whose emphasis is serving patients' needs, values, and preferences.

The partial RCT is considered a modified design suitable for investigating patient-centred, individualized interventions. It permits the researcher to take participants' treatment preferences into account. Miranda reports that the majority of participants are unwilling to be randomly assigned and that their treatment preferences are influenced by several factors. These findings have implications for the design of studies evaluating the effectiveness of interventions and the design of materials and measures for eliciting patient preferences.

Marcellus encourages researchers to reconceptualize attrition from an ecological perspective in which factors related to the participant, the researcher, the study, and the environment affect the participant's decision whether to complete or drop out of a study. This reconceptualization guides the investigator in selecting strategies to minimize attrition and incorporating these into the study design. Marcellus recommends the active involvement of participants in the selection of strategies, which is consistent with the paradigm shift towards patient-centred research.

Lynn and McMillen present a methodology for constructing instruments that capture the perspective of patients and the variability in their responses to measures of satisfaction with care. The methodology comprises the use of (1) qualitative methods to elicit the patient's perspective and to generate items, and (2) the scale product technique to examine the importance of the items for each individual respondent. This methodology holds promise for constructing and using measures that take account of individual values and preferences, consistent with the patient-centred approach to research and care.

Several authors address the application of alternative statistical approaches to data analysis. Fox and colleagues demonstrate the utility of hierarchical linear models in analyzing the pattern of change in outcomes. The analysis is conducted at the individual level, which is consistent with the assumption underlying patient-centred care that participants vary in their responses to a treatment. Such findings complement traditional group-level results and are useful in delineating the clinical benefits of an intervention. Lucke provides an overview of the principles and techniques characterizing Bayesian statistics, and illustrates their use in systematic quantitative reviews of studies evaluating the effects of fall-prevention programs. The applicability of Bayesian statistics to intervention effectiveness research needs further exploration.

Snowdon presents the Personal Construct Theory and its accompanying methodology, the repertory grid technique, as a means for investigating complex, multidimensional phenomena of interest to nursing. The renewed interest in this theory and technique may pave the way for quantitative exploration of the meaning and significance of individual patients' personal belief systems.

The advances in research methods presented in this issue of the Journal represent the seed of a fruitful initiative to develop research approaches and methods that are consistent with the nursing perspective, that enable the study of individualized interventions reflective of patient-centred care, and that enhance the clinical relevance of findings. Concern about the ability of available research methods to produce clinically meaningful results has prompted the move towards an alternative research paradigm. We invite nurse researchers to re-think and improve on current methodology in order to close the research-practice gap. Nurse researchers are in the best position to take the lead in this initiative. The legacy of their most prominent role model, Florence Nightingale, in carefully collecting and analyzing data, and using the results to guide practice, should be an inspiration to all.

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