

## *Discourse*

# **How Can Nursing Intervention Research Reduce the Research-Practice Gap?**

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Nursing intervention research is defined as “studies either questioning existing care practices or testing innovations in care that are shaped by nursing’s values and goals, guided by a strong theoretical basis, informed by recent advances in science, and designed to improve the quality of care and health of individuals, families, communities, and society” (Naylor, 2003, p. 382). Because nursing interventions often encompass multiple components, a systematic approach to intervention development and evaluation has been proposed. The phases of nursing intervention development and evaluation are as follows: conceptualization of the intervention, feasibility and pilot tests, efficacy trials, effectiveness trials, and widespread dissemination (Whitemore & Grey, 2002). It is important that a clear understanding of mediators and moderators of intervention effectiveness be determined during development and evaluation. Other models of intervention development and evaluation for complex health-care interventions and behavioural interventions propose similar phases (Campbell et al., 2000; Flay, 1986; Glasgow, Davidson, Dobkin, Ockene, & Spring, 2006).

Great strides have been made in nursing intervention research in the past several decades, producing evidence on the efficacy of a wide range of interventions. Yet, moving evidence from efficacy trials into clinical practice remains problematic across health-care disciplines. In the United States, the Institute of Medicine has issued a report highlighting the wide gap between evidence-based, efficacious interventions and clinical practice (Institute of Medicine, 2006). Coupled with this persistent research-practice gap are the continued health-care disparities facing health-care systems worldwide; many people lack access to evidence-based health care (Institute of Medicine, 2003; World Health Organization, 2008).

Addressing the research-practice gap will require a multifaceted and concerted effort by clinicians, scientists, communities, health-care systems,

and policy-makers. What are intervention scientists to do? Some scientists have stated that the research enterprise is at fault for failing to provide research adequate to inform clinical and health-policy decision-making and for developing interventions that are difficult to implement in diverse settings, particularly low-resource settings with vulnerable populations (Glasgow, 2008; Tunis, Stryer, & Clancy, 2003). A framework to guide intervention development and evaluation proposed by Glasgow and colleagues (1999) has the potential to address the research-practice gap. The RE-AIM (Reach, Efficacy, Adoption, Implementation, Maintenance) framework highlights the need for health-care interventions to demonstrate more than efficacy; they must also reach the targeted population, be readily adopted by providers and health-care systems, be able to be consistently implemented by providers, and be able to be maintained over time (Glasgow, Vogt, & Boles, 1999; RE-AIM, 2009).

While there are many challenges to achieving the objectives of the RE-AIM framework, two are particularly relevant to the development of nursing interventions. One challenge centres on the need for intervention fidelity in contrast to intervention adaptability; the other centres on the need for internal validity in contrast to external validity in developing and evaluating interventions. Both of these challenges greatly influence the ability of efficacious or evidence-based interventions to be implemented in clinical practice, reach the targeted population, and be effective across providers and settings.

### **Intervention Fidelity – Intervention Adaptability**

When the efficacy of an intervention is being developed and tested, it is essential that intervention fidelity be maintained across participants and/or providers so that causal outcomes can be attributed to the intervention (Bellg et al., 2004; Santacroce, Maccarelli, & Grey, 2004). However, in implementing efficacious interventions, particularly in low-resource settings, adaptability to the local context may be necessary (Green & Glasgow, 2006). This requires an elusive balance between intervention fidelity and intervention adaptability. Highly structured protocols may be impossible to implement as intended (Glasgow & Emmons, 2007) and thus may not be effective. Highly adapted interventions may not include key components of an efficacious or evidence-based intervention and thus may not be effective (Oakley, Strange, Bonell, Allen, & Stephenson, 2006).

Some interventions may have a well-specified protocol that requires standardized delivery across providers and settings (Craig et al., 2008). This condition may be effective in some settings and with some inter-

ventions. However, many settings fail in their implementation efforts despite enthusiasm on the part of clinicians for a particular intervention. An intervention may be complex and difficult to learn, may be highly specific to a particular setting, may be not modularized or adaptable, or may be difficult to implement because of limited resources (Glasgow & Emmons, 2007).

While there is ongoing debate, current recommendations call for interventions that are adaptable to local contexts. However, adaptability cannot be treated haphazardly. Strategies for addressing the fidelity-adaptability tension in intervention evaluation include: clearly identifying a limited set of key components of the intervention; specifying the theoretical link between the intervention's components and mechanisms of change; and identifying a range of reasonable adaptations of the intervention — those that retain essential elements of the original protocol (Green & Glasgow, 2006; Michie, Fixsen, Grimshaw, & Eccles, 2009). Clearly defined core components of interventions are more likely to be successfully implemented across settings. In addition, clarity in the components of interventions and mechanisms of change will facilitate adaptation to clinician, patient, or setting characteristics (Michie et al., 2009). Adaptation can thus become systematic and can result in interventions that are suitable for wide dissemination, that are responsive to a community's cultural needs, and that are effective (Castro, Barrera, & Martinez, 2004).

It is therefore important that the processes and outcomes of intervention adaptation be described and systematically evaluated. Castro and colleagues (2004) propose a process of intervention adaptation that is systematic in addressing the intervention fidelity-adaptability tension. Intervention fidelity is addressed by carefully considering the core components of the intervention and consulting with its developers. Intervention adaptability is addressed by considering the characteristics of the setting and including stakeholders (i.e., clinicians, patients, policy-makers) in the adaptation process.

The process of adaptation has relevance for the development of nursing interventions. It is critical that researchers conduct carefully planned pilot studies prior to undertaking an efficacy trial, to determine the feasibility, acceptability, and preliminary efficacy of the intervention (Feeley et al., 2009). Pilot studies can also be designed to determine the key components and adaptable components of an intervention, thus facilitating future dissemination. It may be that the early stages of intervention development will need to include a participatory research approach with key stakeholders convened to provide different perspectives on core/adaptable components. Participatory research conducted early in the development process may also facilitate dissemination to clinical practice

by ensuring that the intervention accurately reflects the context in which it will be applied (Green & Glasgow, 2006).

### **Internal Validity – External Validity**

Another challenge in meeting the objectives of the RE-AIM framework, and thus in narrowing the research–practice gap, is the emphasis on internal as opposed to external validity in evaluating interventions. As stated above, the trajectory of intervention development and evaluation specifies a development phase, then an efficacy trial followed by an effectiveness trial. Efficacy trials are essential and are aimed at determining cause and effect — assessing whether the intervention does more good than harm when delivered under optimal conditions. The emphasis of the research design is on experimental control with high standards of internal validity. If an intervention demonstrates efficacy, an effectiveness trial is conducted to assess whether the intervention does more good than harm under typical or real-world conditions (Glasgow, Lichenstein, & Marcus, 2003; Green & Glasgow, 2006). However, this intervention development and evaluation trajectory has not produced good evidence for clinical practice and policy-making (Tunis et al., 2003). Very few efficacy trials have been followed by effectiveness trials. When effectiveness trials *have* been undertaken, problems have occurred with implementation of the intervention — the intervention failing to produce the outcomes achieved in the efficacy trial (Hallfors & Cho, 2007). Thus research sometimes fails to translate into practice, particularly in low-resource settings, because interventions and methods of evaluation do not necessarily address critical contextual factors in clinical practice (Glasgow & Emmons, 2007).

While research is necessary to determine the efficacy of interventions, there is also a need for interventions that are robust across settings and can address a diversity of clinicians, patients, and settings (Braslow et al., 2005; Glasgow, 2008). Greater attention to contextual issues in feasibility and pilot studies is needed. In addition, researchers in medicine, the behavioural sciences, and psychology have recently called for “practical clinical trials” (Glasgow, Magid, Beck, Ritzwoller, & Estabrooks, 2005; March et al., 2005; Tunis et al., 2003). Practical clinical trials are distinguished from efficacy trials in that they include characteristics of effectiveness research, thus increasing the external validity or generalizability of the study. They reflect more of the complexity and context of clinical practice (Glasgow & Emmons, 2007). Key characteristics of practical clinical trials are identified in Table 1. Depending on the state of the science, more or fewer of these characteristics may be incorporated into an efficacy trial. For example, the testing of a novel intervention will require

**Table 1** *Characteristics of Practical Clinical Trials*

- Answer the questions of clinicians, decision-makers, and policy-makers.
- Use a randomized clinical trial design.
- Evaluate multiple outcomes, including cost, satisfaction, and quality of life.
- Evaluate processes of implementation.
- Compare clinically meaningful alternatives (comparative effectiveness research).
- Recruit a diverse, heterogeneous sample.
- Include multiple settings and interventionists.
- Specify training and expertise of interventionists.
- Delineate the intervention's core components and components that are amenable to modification.

greater attention to internal validity than the testing of an intervention based on an established theoretical framework being applied in a new setting (or with a different dose or with an interventionist possessing a different skill set). Practical trials offer a mechanism for merging efficacy and effectiveness research, potentially leading to evidence that meets the goals of the RE-AIM framework — interventions that reach diverse patients, interventions that can be implemented by different clinicians and in different settings, and interventions that improve health outcomes.

### **Development and Evaluation Models**

What does all of this mean for intervention science and the process of developing and evaluating nursing interventions? Development and evaluation models that specify phases of the process remain important. Interventions need to be developed systematically and need to be tested for efficacy before being widely disseminated. However, a less discrete categorization of phases and a less linear model of evaluation have been proposed (Campbell et al., 2007; Glasgow et al., 2006). The Medical Research Council in the United Kingdom recently revised its guidelines for evaluating complex interventions ([www.mrc.ac.uk/complexinterventionsguidance](http://www.mrc.ac.uk/complexinterventionsguidance)). Its new guidelines include greater attention to early pilot and development research, a less linear model of intervention evaluation, and the recognition that complex interventions may be most effective if adapted to local contexts (Craig et al., 2008). A systematic approach to intervention development remains critical. However, the context in

which the intervention is delivered needs greater consideration in all phases of development and evaluation (Craig et al., 2008). Also essential is greater attention to external validity during the intervention evaluation process (Green & Glasgow, 2006). Table 2 provides suggestions for intervention research aimed at meeting the goals of the RE-AIM framework.

<b>Table 2 <i>Directions for Future Research in Intervention Development and Evaluation</i></b>	
<b>Phase of Intervention Research</b>	<b>Directions for Future Research</b>
Development	<p>Identify theoretical mechanisms of change.</p> <p>Identify key components and adaptable components of the intervention.</p> <p>Include participatory research with key stakeholders.</p> <p>Identify potential barriers to implementation, particularly in low-resource settings.</p> <p>Determine the feasibility, acceptability, and preliminary efficacy of the intervention.</p> <p>Estimate the effect size of the intervention.</p> <p>Identify moderators of intervention efficacy.</p>
Efficacy	<p>Monitor treatment fidelity and effect on outcomes.</p> <p>Report on some aspects of generalizability.</p> <p>Determine mediators of intervention efficacy.</p> <p>Consider a practical clinical trial design.</p> <p>Incorporate some characteristics of effectiveness research (e.g., diverse sample, multiple settings, evaluation of cost).</p> <p>Include process and outcome evaluation (mixed-method research).</p>
Effectiveness	<p>Consider conducting a pilot study to evaluate adaptation before conducting an effectiveness trial.</p> <p>Compare clinically meaningful interventions.</p>

## **Conclusion**

If nursing interventions are to improve the quality of care and the health of individuals, families, communities, and society, they will have to reach a diversity of clinicians, patients, and settings. Proposed new scientific approaches to intervention development and evaluation have the potential to enhance the reach, efficacy, adoption, implementation, and maintenance of interventions. Greater attention to possible implementation challenges during the intervention development phase and increased use of practical clinical trials during the evaluation phase are recommended. Attending to these challenges may ultimately serve to narrow the research-practice gap.

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*How Can Nursing Intervention Research Reduce the Research-Practice Gap?*

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