The recent emphasis on evidence-based practice (EBP) underscores the importance of research evidence that can be used in real-world clinical situations. However, from an EBP perspective, there are some problems with traditional phase III randomized controlled trials (RCTs). In particular, as a result of efforts to enhance the internal validity of the trial to support causal inferences about the efficacy of the new treatment, RCT designs are so tightly controlled and have such stringent eligibility criteria that the trial’s relevance to real-life applications is sometimes called into question. Concern about this situation has led to a call for practical (or pragmatic) clinical trials, which strive to maximize application to real-life settings (external validity) with minimal negative effect on the ability to attribute clinically important improvements to the intervention (internal validity). Tunis and colleagues (2003), in an often-cited paper, defined practical clinical trials (PCTs) as “trials for which the hypotheses and study design are formulated based on information needed to make a decision” (p. 1626, emphasis added).

PCTs address practical questions about the benefits and risks of an intervention—as well as its costs—as they would unfold in routine clinical practice. PCTs are thus sensitive to the issues under scrutiny in effectiveness studies (phase IV trials), but there is an increasing interest in developing strategies to bridge the gap between efficacy and effectiveness and to address issues of practicality earlier in the testing of promising interventions. Achieving a creative tension between generalizability and internal validity is crucial. Glasgow and colleagues (2005) proposed several research designs for PCTs, including randomization by site rather than by people (cluster randomization) and delay-of-treatment designs. Some pragmatic trials, however, rely on quasi-experimental designs, opting to put more emphasis on external validity rather than internal validity.

Tunis and coauthors (2003) made a number of recommendations for PCTs. These include the following:

- Enrollment of diverse populations with fewer exclusions of high-risk patients
- Recruitment of participants from a variety of practice settings
- Follow-up over a longer period
- Inclusion of economic outcomes
- Comparisons of clinically viable alternatives

**Example of a nursing pragmatic clinical trial:**
Glavin and coresearchers (2010) conducted a pragmatic clinical trial to test the effectiveness of supportive counseling by public health nurses for women with postpartum depression. The program was tested in one Norwegian municipality, and women in a comparison municipality were used as the control group.
Supplement for Chapter 18 Practical (Pragmatic) Clinical Trials

Some of the researchers in the forefront of promoting PCTs have developed a framework for intervention research that specifically seeks to address a trial’s generalizability and the transferability of intervention evidence. This framework is called the RE-AIM framework (Glasgow, 2006). The framework involves a scrutiny of five aspects of a study: its Reach, Efficacy, Adoption, Implementation, and Maintenance. Reach means reaching the intended population of potential beneficiaries, which concerns the extent to which study participants have characteristics that re ect those of that population. Efficacy concerns intervention impacts on critical outcomes. Adoption concerns the number and representativeness of settings and staff who are willing to implement the intervention. Implementation concerns the consistency of delivering the intervention as intended and also intervention costs. The last component, maintenance, involves a consideration of the extent to which, at the individual level, outcomes are maintained over time and, at the institutional level, the intervention becomes part of routine practices and policies. Detailed information about this framework and advice on how to assess the five components is available at www.re-aim.org.

Godwin and colleagues (2003) prepared a useful table that contrasts features of an “explanatory trial” (i.e., a traditional phase III RCT) and a pragmatic trial. The table can be accessed at www.biomedcentral.com/content-supplementary/1471-2288-3-28-S1.doc.

REFERENCES


Example of a nursing study using RE-AIM:
Whittomore and colleagues (2009) used the RE-AIM model as the organizing framework for their pilot study of a diabetes prevention program in primary care settings.