

Symposium C5: Methodological Challenges in Intervention Research

Methodological Challenges in Intervention Research: Addressing and Maintaining Equipoise

Patricia A. Cioe, MS, RNP, University of Massachusetts Worcester, Worcester, MA

Purpose: The purpose of this presentation is to: 1.) define equipoise in intervention research, 2.) to discuss challenges related to addressing equipoise in intervention research, and to 3.) provide strategies for maintaining equipoise throughout the intervention research process.

Background: Achieving and maintaining equipoise throughout the process of intervention research may be one of the investigator's greatest challenges. Rooted in the Belmont Report and the Protection of Human Subjects documents, equipoise is the ethical foundation upon which intervention research rests.

Approach: A literature search of Pubmed and CINAHL using the keywords "equipoise" and intervention research" was conducted.

Major Points and Rationale: The ultimate goal of intervention research is to generate scientific knowledge that will provide an evidence base for practice and improve health and healthcare. It serves the common or collective good and benefits society as a whole. Research subjects may not receive direct benefit from participation in intervention research; however, protecting them from harm during the research process is of paramount importance. Equipoise has been defined as the state of being balanced or in equilibrium. In the medical literature, its definition has been the subject of great debate. In a landmark article addressing equipoise in research, Benjamin Freedman (1987) defined clinical equipoise as a state of genuine uncertainty within the expert medical community regarding the outcome of the research hypothesis. He differentiated this from theoretical equipoise which refers to uncertainty on the part of the individual investigator regarding the therapeutic merits of each arm in a trial. This distinction is important when an investigator is considering study design in intervention research.

Conclusions: Addressing equipoise in the design phase of intervention research and maintaining equipoise throughout the course of the clinical trial can be challenging. The investigator needs to employ rigor to ensure that equipoise is maintained throughout the process of conducting intervention research.