

## CHAPTER 9

### ASSESSING CLINICAL SIGNIFICANCE\*

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Defining and assessing "clinical significance" are particularly thorny issues. In this area of treatment efficacy research, there is not a set of readily agreed upon scientific conventions for demonstrating whether changes attributable to treatments in speech-language pathology and audiology are clinically significant. A number of ideas for assessing clinical significance will be proposed, but a number of decisions for implementing these procedures will remain. It should be clear that many of these ideas require further research.

First, one must recognize that "clinical significance" refers to whether a treatment that meets scientific standards for effecting behavior change is also significant in a clinically or socially relevant way. That is, one is concerned with whether treatment effects reflect *important* and *acceptable* changes in behavior. There is general agreement that criteria for determining statistically significant treatment effects do and should differ from criteria for determining clinically significant treatment effects. The problems are well known: Statistically significant treatment effects may reflect modest changes by all or most clients undergoing treatment; also one may find that there are relatively large changes in some subset of clients undergoing treatment but little or no changes in other clients. Others (Jacobson, 1988) have argued that even if large changes are demonstrated by all or most of the clients undergoing treatment, some standardized criteria for determining whether those "large" changes are important and acceptable are needed.

There are two basic approaches to assessing clinical significance: Normative comparison approaches and social validity approaches. I will argue that both these approaches are potentially useful to both group and single-subject experimental design research.

#### Normative Comparison Approaches

Normative comparison approaches have sought to demonstrate that outcomes reflected in treatment efficacy research allow clients who evidenced a psychological or a communicative disorder before treatment to be characterized as normal after treatment. That is, after treatment the "clinical population" that underwent treatment now can be characterized as "non-clinical" or within normal limits. This is a stiff test of treatment efficacy. In order to argue convincingly that treatment effects are clinically significant, then clients must appear essentially normal on some relevant outcome measure(s) after treatment. Such outcomes clearly would be *convincing* from the perspective of a skeptical consumer or a skeptical scientist, for that matter. On the other hand, this

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\*Preparation of this manuscript was supported by Grants No. G008730526 and G0087308528 from the U.S. Department of Education to the University of Pittsburgh. Address correspondence to Howard Goldstein, Department of Communication, 1117 Cathedral of Learning, University of Pittsburgh, Pittsburgh, PA 15260.