

Long-term Evaluation of Psychotropic Drugs in Major Psychiatric Disorders: Outcome Measures

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Issues in Choice of Outcome Measures

- ◆ **Appropriate for the condition(s) being studied**
- ◆ **Appropriate for primary audience (e.g. FDA, Scientists, Clinicians)**
- ◆ **Appropriate to the purpose(s) of the study(e.g. cost benefit ratio, prophylactic effects, acceptability to patients, detection of major or minor differences in efficacy)**
- ◆ **Well defined “outcomes” provided by the procedures selected**
- ◆ **Demonstrated reliability & validity in similar patients for the purpose selected**
- ◆ **Need for well trained and monitored clinical raters (with careful attention to training of “new / replacement” staff)**

Long-term Studies Require More Attention to Selection of Outcome Measures

- ◆ Characterize cross sectioned status
- ◆ Characterize course of target condition(s)
- ◆ Characterize selected cumulative outcomes (e.g. costs, adverse events)

Multiple Sources of Information

- ◆ Clinicians
- ◆ Patients
- ◆ Significant others
- ◆ Laboratory tests / medical exams
- ◆ Other data collection systems

Information on Multiple Dimensions of Outcome

- ◆ Global impressions of severity / improvement
- ◆ Symptoms of target condition(s) / diagnostic status
- ◆ Psychosocial functioning in relevant areas
- ◆ Quality of life / well being
- ◆ Side effects / adverse events (reports, laboratory tests)
- ◆ Family burden
- ◆ Costs

Evaluations Made at Multiple Time Points

- ◆ More frequent = less loss of information
- ◆ More frequent = greater cost
= greater patient / clinician burden

Information on Relevant Events

- ◆ Suicide attempts / completions
- ◆ Accidental death
- ◆ Other deaths (medical cause(s), unknown cause)
- ◆ Arrests / jail time
- ◆ Violent acts
- ◆ Use of non-study mental health services (emergency room, hospital)
- ◆ Drop out (with apparent reason)
- ◆ Need for change in treatment protocol (with apparent reason)

Long-term Studies also Need Detailed Prospective Data Suitable for Assessing

- ◆ Time to response*, remission*, recovery*, of the conditions of interest
- ◆ Time to worsening* or relapse*
- ◆ Time spent in various “stages”* of the condition(s) of interest (e.g. full symptomatic state*, partial remission*, remission*, asymptomatic*)
- ◆ Interaction of conditions of interest (e.g. alcohol abuse and major depression)

* with well defined procedural rules for assessing each variable

Conditions of Interest May Involve Such Variables

As--

- ◆ Diagnostic Status of primary condition
- ◆ Diagnostic status of co-morbid conditions
- ◆ Selected features (e.g. Negative symptoms, Positive symptoms, Suicidal thoughts/behaviors, Pain, Panic attacks)

Redudce Redundancy of Information Collection

- ◆ Select the best source(s) of information needed
- ◆ If two or more sources are used--use the same definitions of terms
- ◆ Try to avoid conflicts in outcome measures