

Monday, June 29, 2009

Workshop 5

Assessing Suicidality in Clinical Trials 1:30 p.m.– 4:30 p.m.

Assessment in Clinical Trials and Clinical Epidemiology Studies with High Risk Suicidal Individuals

Kate A. Comtois, Ph.D.
Harborview Medical Center

It is critically important that psychiatry studies, especially clinical trials, include high risk suicidal individuals as participants as suicide is the primary mortality for many psychiatric conditions. However, it is equally important that the high risk of such suicidal individuals is managed effectively so they are adequately protected. This presentation will first discuss the University of Washington Risk Assessment Protocol (UWRAP) which has been used successfully for over 15 years to assess and manage risk during baseline and outcome assessments.¹ If suicidal behavior is to be used as an inclusion criterion and outcome, it is important that we have clear and agreed upon terminology and measurement.³ Two measures – one detailed (Suicide Attempt and Self-Injury Interview² and one brief (Suicide Attempt and Self-Injury Count) are described, which collect behavioral descriptions of key aspects of self-inflicted injuries that allow for clear and consistent determination of the number, method, intent, medical severity, and lethality of suicidal behavior. The use of these measures and other methodological approaches for including high risk suicidal individuals in randomized clinical trials and clinical epidemiology studies will be discussed.

Learning Objectives:

- Understand key issues and useful assessment tools for defining and operationalizing suicidal behavior as inclusion criteria and outcome in clinical trials
- Understand the advantages of the University of Washington Risk Assessment Protocol (UWRAP) for assessing and managing risk in baseline and outcome assessments with high risk suicidal participants
- Understanding the complexity of conceptualizing suicide-related severe adverse events in clinical trials which recruit for a history of severe suicidal behaviors (attempts, hospitalizations, etc.) and strategies for addressing with institutional review boards, data safety monitoring boards, and other ethics review processes

References:

1. Reynolds, S, Lindenboim, et al. Risky Assessments: Evaluating and managing the effect of research assessments in a treatment study of suicidal behavior. *Suicide and Life Threatening Behavior* 2006; 36:19-34.
2. Linehan MM, et al. Suicide attempt self-injury interview (SASII): Development, reliability, and validity of a scale to assess suicide attempts and intentional self-injury. *Psychological Assessment* 2006; 18: 303-12.
3. Silverman, MM, Berman, et al. Rebuilding the Tower of Babel: A Revised Nomenclature for the Study of Suicide and Suicidal Behaviors Part 2: Suicide-Related Ideations, Communications, and Behaviors *Suicide and Life-Threatening Behavior* 2007; 37(3) 264-277.

Tuesday, June 30, 2009

Poster Session I
12:00 p.m. – 2:00 p.m.

Presentation date change, originally scheduled for Poster Session II on Wednesday, July 1:

Session II – 44* **Prevalence Rates of Mental Illness in Outpatients with Epilepsy**
Benji T. Kurian, University of Texas Southwestern Medical Center
Madhukar H. Trivedi, Albert Banta, Jr.

****Now Poster No. I – 79***

Substitutions:

Session I - 72 **Evaluation of the Psychometric Properties of the Medication Satisfaction Questionnaire (MSQ) in Patients with Schizophrenia**

Cancelled Presenter: Jessica Panish, Ortho-McNeil Janssen Scientific Affairs, LLC
Substitute Presenter: Amir Kalali, Quintiles Inc., and the University of California, San Diego

Wednesday, July 1, 2009

Poster Session II
12:00 p.m. – 2:00 p.m.

Substitutions:

Session II – 33 **Pooled Analysis of Sustained Response Data: Once-Daily Extended Release Quetiapine Fumarate Monotherapy in Patients with Major Depressive Disorder**

Cancelled Presenter: Johan Szamosi, AstraZeneca
Substitute Presenter: Cindy Khordoc, AstraZeneca

Session II – 49 **Development and Psychometric Exploration of a Clinical Global Impression Scale for Schizoaffective Disorder (CGI-SCA)**

Cancelled Presenter: Colette Kosik-Gonzalez, Ortho-McNeil Janssen Scientific Affairs, LLC
Substitute Presenter: David Daniel, United BioSource Corporation

Session II – 62 **Management of Missed Paliperidone Palmitate Doses Based on Pharmacokinetic Modeling and Simulation**

Cancelled Presenter: Jennifer Kern Sliwa, Ortho-McNeil Janssen Scientific Affairs, LLC
Substitute Presenter: Larry Alphas, Ortho-McNeil Janssen Scientific Affairs, LLC