

Polypharmacy in CNS Clinical Trials



UNIVERSITY OF MIAMI
MILLER SCHOOL
of MEDICINE

Philip D. Harvey, PhD
University of Miami Miller School of Medicine

Disclosures

- Dr. Harvey has received consulting fees or travel reimbursements from Acadia Pharma, Alkermes, Bio Excel, Boehringer Ingelheim, Minerva Pharma, Regeneron Pharma, and Sunovion Pharma during the past year.
- He receives royalties from the Brief Assessment of Cognition in Schizophrenia, owned by Verasci, Inc.
- He is chief scientific officer of i-Function, Inc.
- He had a research grant from Takeda and from the Stanley Medical Research Foundation.

Polypharmacy

- Treatment with multiple psychotropic medications simultaneously
- Can be Aimed at the same symptoms
 - Augmentation of nonresponse
- Can be aimed at different symptoms
 - Depression in Schizophrenia

How Common is this Strategy?

- Standard of care in cardiology
 - Alirocumab trial 35% of participants were receiving the study drug, a high-dose statin and one or more additional lipid-lowering treatments
- Very common in treatment of bipolar disorder
 - Mood stabilizer plus antipsychotic is standard of care, augmented by benzos

What are the consequences?

- Increased side effects
 - Anticholinergic
 - Antihistaminergic

What are the implications for CNS trials?

- How can you identify the effect of the study drug against the background of other treatments?
- Which other treatments can you discontinue safely, if any?
- What is the regulatory perspective on adding a medication to an existing complex regimen?