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Pediatric bipolar disorder

### Rationale, design, and methods of the systematic treatment enhancement program for bipolar disorder (STEP-BD)

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#### Abstract

The Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD) was conceived in response to a National Institute of Mental Health initiative seeking a public health intervention model that could generate externally valid answers to treatment effectiveness questions related to bipolar disorder. STEP-BD, like all effectiveness research, faces many design challenges, including how to do the following: recruit a representative sample of patients for studies of readily available treatments; implement a common intervention strategy across diverse settings; determine outcomes for patients in multiple phases of illness; make provisions for testing as yet undetermined new treatments; integrate adjunctive psychosocial interventions; and avoid biases due to subject drop-out and last-observation-carried-forward data analyses. To meet these

challenges, STEP-BD uses a hybrid design to collect longitudinal data as patients make transitions between naturalistic studies and randomized clinical trials. Bipolar patients of every subtype with age  $\geq 15$  years are accessioned into a study registry. All patients receive a systematic assessment battery at entry and are treated by a psychiatrist (trained to deliver care and measure outcomes in patients with bipolar disorder) using a series of model practice procedures consistent with expert recommendations. At every follow-up visit, the treating psychiatrist completes a standardized assessment and assigns an operationalized clinical status based on DSM-IV criteria. Patients have independent evaluations at regular intervals throughout the study and remain under the care of the same treating psychiatrist while making transitions between randomized care studies and the standard care treatment pathways. This article reviews the methodology used for the selection and certification of the clinical treatment centers, training study personnel, the general approach to clinical management, and the sequential treatment strategies offered in the STEP-BD standard and randomized care pathways for bipolar depression and relapse prevention.



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## Keywords

Bipolar disorder; effectiveness research; bipolar depression; relapse prevention

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