Author’s response to reviews

Title: The Research and Evaluation of Antipsychotic Treatment in Community Behavioral Health Organizations, Outcomes (REACH-OUT) Study: Real-World Clinical Practice in Schizophrenia

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Sharon Lawn, PhD
BMC Psychiatry

Dear Dr. Lawn,

My co-authors and I would like to thank the reviewer for her comment on our manuscript, “The Research and Evaluation of Antipsychotic Treatment in Community Behavioral Health Organizations, Outcomes (REACH-OUT) Study: Real-World Clinical Practice in Schizophrenia,” which was recently submitted to BMC Psychiatry.

We have revised the manuscript based on the reviewer and editor’s recommendations and have provided a detailed description of the modifications on the following pages. Please note that all page numbers refer to the changes-visible version of the manuscript.

We hope that you approve of this revised manuscript, and we look forward to your response. Thank you for your time and attention.
Best regards,

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Editor Comment:

1. Dear authors, the comment from Reviewer 1 remains unresolved. Please consider it again and provide further justification in the paper and potentially comment in the limitations.

Reviewer 1

1. The main problem of the article remains unresolved. While the abstract announces “there is a paucity of outcomes data… Therefore, we conducted The….Outcomes trial”, the authors state in their comment: “the objective of the study was to describe baseline characteristics of patients, not report outcomes.” To justify publication outcome data should be presented. Simply describing a group of patients with different diagnoses and different treatments without having “information on why physicians selected a particular antipsychotic medication” is problematic.

Authors’ response: We thank the reviewer for this comment and appreciate the opportunity to clarify our first response. REACH-OUT was designed to collect local, real-world data to evaluate and understand the antipsychotic treatment and practice patterns and health care
resource utilization in community behavioral health care organizations (CBHOs) in the United States. Our paper aims to describe patient characteristics and comorbidities, health care resource utilization, patient-reported outcomes, and clinician assessments and perspectives from REACH-OUT. Given the observational nature of REACH-OUT and the trial’s statistical analysis plan, we have reported outcomes data in a descriptive manner and have avoided making inferences about those outcomes. This point has been clarified in the Abstract (page 2) and in the Introduction (page 6).

In the previous set of comments, the reviewer suggested that we perform an additional analysis comparing oral antipsychotics that are available only in oral formulations (eg, clozapine) vs oral antipsychotics that are available as long-acting injectable (LAI) formulations (eg, risperidone) vs LAI antipsychotics. We did not perform these comparisons for the following reasons: 1) a limited number of subjects were receiving antipsychotics available only in oral formulations, and 2) treatment groups were not randomly assigned to control biases. We do agree, however, that the suggested analyses would be informative, and we will explore it in future investigations. The Methods have been revised (page 8) to clarify this point, and a sentence describing this limitation has been added to the Discussion (page 18).

Another important point of clarification is that selection of antipsychotic therapy was at the discretion of the treating physician. This information has been added to the Methods (pages 7 and 8) and to the Discussion (page 18). Also, REACH-OUT was not designed to collect data on why clinicians selected a particular antipsychotic medication. According to the trial’s protocol:

“Clinician participants will be queried as to why the participants who initiated a new antipsychotic at baseline were initiated on that medication (LAI or oral antipsychotic, as applicable). Reasons for initiation will include: insufficient response, patient choice, compliance issues, adverse events, tolerability, or other reasons. Free text will be used to capture other reasons.”

As you can see from this excerpt, clinicians were asked to choose from a predetermined list of reasons for initiation that were general in nature and not designed to elucidate why a particular antipsychotic therapy or formulation was selected. This information has been added to the Methods (pages 9 and 10). “Compliance issues” and “insufficient response” were the most common reasons for initiating an LAI antipsychotic, as described in the “Reasons for Initiating Medication: Clinician Perspective” section (page 16).
We hope that this response has clarified the reviewer’s question and that the limitations added to the paper at the editor’s recommendation will warrant publication of this paper. Please note that an extension of this work is currently in review at BMC Psychiatry as a separate manuscript, “Paliperidone Palmitate Injections and Other Predictors of Treatment Adherence and Remission of Schizophrenia in Community Behavioral Health Organizations: A Naturalistic Prospective Observational Study” (Anderson JP et al). This paper compares treatment pattern outcomes (eg, adherence, discontinuation) and remission between paliperidone palmitate LAI antipsychotic and oral antipsychotics. Data from the Anderson JP et al paper show that, relative to oral antipsychotic therapy, paliperidone palmitate LAI was associated with improved adherence, less frequent treatment discontinuation and switching, and improved symptom remission among patients in the CBHO population from REACH-OUT.