

Off-label medicine combinations are the predominant treatment in survey of schizophrenics

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Off-label medication use, the clinical application of prescribed drugs for indications other than those approved by the relevant drug regulatory agency (in the US, the Food and Drug Administration—FDA), is widespread in many areas of medicine but is particularly common in psychiatry. While off-label uses are legal and in many instances may be in the best interests of patients, they have not received the same degree of independent scrutiny through randomized clinical trials as have approved indications. A drug approved for marketing may be labeled, promoted and advertised by the manufacturer for only those uses for which the drug's safety and effectiveness have been established by the FDA.

In a new paper, published in the online, open-access journal *PLoS ONE*, David Pickar and colleagues, of Gabriel Sciences, report that 74.5% of 200 community-based schizophrenic patients, who were individually interviewed and evaluated (including a review of clinical records), were treated with off-label medication treatments.

Specifically, 42.5% of subjects reported that they were simultaneously treated with more than one antipsychotic drug, an unapproved treatment for schizophrenia. The most common unapproved drug combination was the use of both an antipsychotic drug and a mood stabilizer (45% of patients). This combination of drug classes was predicted by the diagnosis of schizoaffective schizophrenia, history of having physically

hurt someone and high symptom ratings.

The sample of schizophrenic patients studied in this report was derived from multiple outpatient settings and reflect demographics of seriously ill patients with schizophrenia. For example, there was a slightly higher male prevalence (59.5%); largely, patients were never married (75%); a majority live in supervised dwelling (54.5%); nearly half had had involuntary hospitalizations (47.5%), and had made a suicide attempt (48%); the mean age of onset was 19.9 years. The economic implications of off-label medication use are substantial for public sector payers as well as for the revenue of the pharmaceutical industry, whose promotion of off-label drug use is of considerable concern.

"These data underscore the limitations of both first and second generation antipsychotic drugs and the desire of clinicians to improve outcome in schizophrenic patients. The off-label status of the drug treatments are problematic as, studies required to establish support are both expensive and expose risk to the company's market by the possibility of new or serious adverse events and/or not being able to establish efficacy. Since a company is not allowed to promote an off-label use, the importance of so-called opinion leaders, who are free to independently discuss treatment approaches, increases substantially. The financial opportunities for both the company and the opinion leader can lead to blurred boundaries," observed senior author David Pickar, MD, President of Gabriel Sciences and Adjunct Professor, Johns Hopkins Medical School.

Citation: Pickar D, Vinik J, Bartko JJ (2008) Pharmacotherapy of Schizophrenic Patients: Preponderance of Off-Label Drug Use. PLoS ONE 3(9): e3150. doi:10.1371/journal.pone.0003150
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