

Should the CATIE Study Be a Wake-Up Call?

By Mark Ragins MD

Like many other people I was surprised by the media reports that the CATIE study found no substantial difference between the atypical antipsychotics and Trilafon. When I got a copy of the article in the New England Journal of Medicine, I was amazed to read how poorly all of their patients had fared.

The numbers are truly stunning: Overall, 64 - 82 % of patients dropped out of treatment in an average of 3.5 – 9.2 months. While in treatment, they only benefited symptomatically for an average of 1 - 3 months. The yearly hospitalization risk rate was 29 - 66 % although only 28% reported an exacerbation in the 3 months prior to the study. 64 - 70 % had substantial side effects, though only 30 - 36 % told their doctor about them without additional “systematic questioning.”

How could this array of wonderful medications, that I personally have used over long periods to help hundreds of people improve their lives and even recover have done so poorly? I wonder if a placebo would've done worse. No wonder there wasn't any difference between the medications; everyone did very poorly.

If my own practice did this poorly, I'd ...well, I'd decide that my treatment system was in shambles and in need of total transformation. I'd begin by investigating to see what I'd done wrong. Here's what I'd look at:

- 1) *How's the relationship between the doctor and the patient?* People tend to stay in treatment and do better with doctors they feel listen to them, care about them, and respect them, because they in turn respect, trust, and work with their doctor. Unfortunately, the authors didn't report any survey results of how the patients felt about their doctors.
- 2) *How much does the patient understand and believe in the medications?* I'm not asking if they signed a consent form. I'm asking if they internalized an explanation of how the medications would specifically help them improve their lives. People may comply with medications for awhile out of obedience alone, but long term treatment depends on really believing that they help. Unfortunately, the authors didn't report on the patients' satisfaction with their doctors' explanations or their level of understanding of their medications.
- 3) *Are the medications improving people's lives?* Our overall purpose is not just symptom relief, but helping people have better lives. These patients were described as generally unemployed, unmarried, and often substance abusing. Did the patients get jobs, girlfriends, or sobriety (or money, housing, education and legal assistance)? Unfortunately, the authors report symptom outcome measurements, but not quality of life outcome measurements.

- 4) *Were the medications integrated into other services and supports?* Medications alone are rarely an effective treatment. Integrating them into a case management team and including rehabilitation, psychoeducation, and substance abuse treatment as well as quality of life services and supports like supportive housing, employment, and education usually works better. Unfortunately, the authors don't report what other services and supports the patients received, if any.
- 5) *Were the medications part of the patients' recoveries?* Recovery based services are more effective than custodial based services. Recovery solidifies improvements and increases self-responsibility for treatment. Unfortunately, the authors don't report on either internal, subjective measures of the recovery process (e.g. hope, empowerment, self-responsibility, or attaining meaningful roles) or external indicators of recovery (e.g. engagement, risk reduction, increased skills and community supports).

Unfortunately, I don't have any answers to my questions. Although this study purports to be "real world," they didn't include any of the things I most value in my daily practice. Why not? There are scales for answering all of these questions. The authors are clearly very sophisticated, competent, well funded, and striving for relevancy, but, in my opinion, they don't succeed.

They conclude that "antipsychotic drugs, though effective, have substantial limitations in their effectiveness in patients with chronic schizophrenia." I would instead conclude that antipsychotic drugs, though effective, cannot benefit patients unless attention is paid to the doctor – patient relationship, the patients' understanding of and belief in the medication, integrating other services and supports, and being imbedded in a recovery program. I believe that these medications work for me much better than they did in the 57 sites used because our overall treatment program is better. More than anything else, this study proves that even the best and most expensive medications have little effect as used within our present system. In short, they don't work by themselves.

What I most need from our researchers is to test my clinical conclusions. What needs to be added to medications for them to work effectively?

I hear a great deal of talk about "evidence based practice" and "research informed clinical treatment." There is an increasingly frustrated group of effective clinicians urging "practice based evidence" and "clinically informed research." I don't think the CATIE study should be a wake-up call to "clinicians, patients, families, and policymakers." I think it should be a wake-up call to researchers. If we are to achieve the President's Commission's vision of a transformed mental health system, mental health research must be transformed too.