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Implications of CATIE for Mental Health Services Researchers

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Abstract

OBJECTIVE—We explore implications of the NIMH-sponsored Clinical Antipsychotic Trials of Intervention Effectiveness schizophrenia trial (CATIE) for mental health services researchers.

METHOD—We reviewed published CATIE manuscripts and related studies to determine potential implications for mental health services.

RESULTS—CATIE's important implications include the need to revise indicators of quality care and developing systems for concurrent monitoring of secondary data to promote timely interventions.

CONCLUSIONS—Mental health services researchers must build relationships with service system administrators to help state mental health authorities incorporate results from trials such as CATIE into policy and practice.

Results from the CATIE trial have several important implications for measuring and improving mental health services for schizophrenia. One challenge for services researchers is helping mental health delivery systems design quality indicators of good prescribing, including reviewing and revising indicators in the face of new data such as provided by CATIE. An additional opportunity lies in developing and testing strategies for incorporating research findings into every-day practice in the community.

The CATIE results underscore the complexities of individuals' responses to antipsychotic medications and the need to tailor prescribing decisions based on patients preferences, including the relative importance an individual puts on side effects versus symptom control, and consideration of individual characteristics such as medical status (1, 2). This suggests that evidence of good clinical care should include variety in prescribing across individuals on a prescriber's caseload (i.e., variety can be taken as proof that one size is not being tried for all). In addition, the CATIE data reinforce the value of clozapine for individuals who have not had an adequate response to other antipsychotics (3), suggesting that access to clozapine may be an important measure of quality. The CATIE trial results do not inform us about what the distribution of different antipsychotics should be, nor whether some common practices, such as prescribing two or more antipsychotic medications, are reasonable. Clinical trials addressing these open questions are sorely needed. In recent years national quality indicators have focused on access to second generation agents in general. For example, all states are currently participating in SAMHSAs Uniform Reporting System which includes only one measure related to psychotropic prescribing, the proportion of individuals prescribed a second generation antipsychotic medication, with higher

proportions considered to reflect better quality. Although initially useful to support access to second generation agents, results from CATIE suggest that high proportions of individuals taking second generation antipsychotic medications may no longer be a useful proxy for quality care. Indeed, the results of CATIE suggest that having all patients on a single SGA would be poor care, even though such a practice pattern would look good under the current SAMHSA indicator. Measures need to evolve to keep pace with new findings.

People often ask whether findings from studies like CATIE change services in the real world. Should they? Yes. Do they? Alone, generally not. Multiple studies have documented that education and research publications alone are not adequate to support changes in practice, but interventions at the system, program, prescriber, and/ or consumer levels can be effective in improving care.

System level interventions include the development of formulary policies and procedures, fiscal or regulatory incentives, and quality improvement and oversight. The complexity and variability of participants' responses to antipsychotic medications in the CATIE trial speak to the inappropriateness of restricting formularies (4) and to discouraging or encouraging switching medications (5).Instead, the resources that would be consumed by such "one size fits all" rules should be allocated to support a quality improvement approach, including the aggregation and analysis of secondary data, identification of questionable practices, and targeted interventions to support practice change. Using such a process in lieu of restricting formularies has been suggested by others as well (6). Increasingly, state public mental health systems are recognizing the need to aggregate and use secondary data to monitor care, whether done internally or through a third-party agent.

Secondary data, such as Medicaid claims data, can be used successfully to characterize current prescribing practices, medication adherence, service utilization, and health monitoring practices to identify quality problems as well as monitor the impact of interventions. For example, in a recent VA study, secondary data were used to demonstrate that the frequency of follow-up lipid monitoring for individuals with schizophrenia receiving a second generation antipsychotic medication increased following an abnormal total cholesterol level, although the median time to follow-up (about 10 months) was less than desirable for clinical care (7). The challenge for mental health services researchers is to help mental health delivery settings develop systems to monitor secondary data in a concurrent and continuing manner so that interventions to improve clinical care can happen on a real-time basis with the goal of improving outcomes and reducing morbidity.

At the same time, researchers translating research findings into practice must guard against overcorrection. For example, the results of CATIE do not suggest that, because olanzapine is associated with problems with metabolic functioning, all individuals should discontinue olanzapine. Whether the post-CATIE drop in market share for olanzapine is a result of the CATIE findings, class action law suits, a general clinical sense that this medication is making people heavy, individual dissatisfaction with weight gain, the rise of other agents, or some combination thereof is unclear. What is clear from the CATIE trial is that people tend to tolerate olanzapine longer than some of the other medications and that some individuals do not experience any weight gain or other metabolic side effects while taking olanzapine. This argues again for quality indicators based on aggregate data that look for variability in prescribing along with other events indicating appropriate care (e.g., lipid monitoring after starting an agent associated with raising lipid levels).

Systems and programs can help promote an individualized medication selection process, grounded in patient preferences, by implementing shared decision makings tools. Although better studied in cancer care and other medical conditions, services researchers are in the

process of developing and testing tools designed for mental health settings that assist consumers in communicating preferences, and practitioners in assessing and responding to preferences (8, 9). Shared decision making has the additional benefit of increasing engagement in treatment, including medication adherence. This is a promising area for future research.

The CATIE trial presents other opportunities for future services research including studies to explore the reasons for the high discontinuation rates among participants, a key outcome of the study. One reason for the variety of responses and high discontinuation rates seen among participants may have been individuals' experiences with medication side effects. Relative concern about different side effects is likely to vary between individuals, and may vary over time, depending upon an individual's preference at a given point in life. For example, weight gain or sexual side effects may be less problematic when individuals' primary goal is symptom control so that they can move to a less restrictive setting. Later, these same side effects may become more troubling as individuals become less symptomatic and pursue other goals such as romantic relationships. In a large national study, over ninety percent of participants reported side effects from their psychotropic medications with nearly two-thirds reporting a high level of distress with at least one side effect (10), suggesting that the subjective experience of side effects is an important area to consider when prescribing antipsychotic medications. Indeed, some have called for research to examine preferences for symptoms and side effects and the impact of these preferences on prescribing from multiple perspectives including the individual, his or her family, and his or her prescriber (11). Others have also noted the need to compare non-pharmacological evidence-based practices as an adjunct to or instead of antipsychotic medications (11) and ways to use results from CATIE as information to empower the therapeutic relationship when making decisions about which psychotropic medication helps an individual make progress toward their recovery-oriented goals (12).

Mental health services researchers should embrace helping mental health delivery systems incorporate results from trials such as CATIE into practice. To do this, services researchers must build relationships with service system administrators. Alone, few mental health care delivery systems have the resources to sort through and consider if or how to incorporate new information into practice. Such public-academic collaborations offer services researchers the opportunity to impact policy, improve quality of care, and further science.

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