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Interpreting the Results of the CATIE Study

To the Editor: In the December Taking Issue commentary Mark Ragins (1) expressed his concerns about the National Institute of Mental Health's (NIMH) Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) study. He is disturbed by "how poorly all the patients had fared," he complains that the study did not address several important questions, and he concludes that "mental health research must be transformed." We appreciate Dr. Ragins' interest in the study and his passion to improve mental health care, but he has misunderstood and misinterpreted the CATIE study's results.

Dr. Ragins understates the effectiveness of treatment in CATIE. He conflates medication switches (the primary outcome measure) with therapy failure. Although three-quarters of CATIE patients switched from their initial medication assignment, almost two-thirds of them continued to be followed after rerandomization to a new medication, and nearly half of all patients who en-

tered the study finished a full 18 months of follow-up. Dr. Ragins should keep in mind that dropping out of a time-consuming, double-blind, randomized research trial does not mean dropping out of treatment.

In his commentary Dr. Ragins complained that CATIE did not report on patients' attitudes toward their physician or their medication, functional outcomes other than symptoms, or the presence or absence of other rehabilitative interventions. It is true that these important variables were not discussed in the *New England Journal of Medicine* article (2), but all of them were assessed and will be reported on in the future. CATIE collected a broad range of information involving three different treatment phases (using more than eight different antipsychotics) that included nearly 1,500 people with schizophrenia who were followed for up to 18 months. This first outcome paper is but an initial installment from a remarkably rich data set.

The lack of difference between the new second-generation antipsychotics and perphenazine surprised Dr. Ragins. It also surprised us. However, such surprises are why double-blind randomized clinical trials like CATIE are needed. The CATIE results suggest that first-generation antipsychotics remain useful and deserve continued consideration by clinicians and patients. This does not mean that older, cheaper antipsychotics can replace more expensive second-generation agents. It is crucial to point out that equivalent does not mean identical: 25 percent of patients may respond to risperidone and 25 percent to perphenazine, but they are not the same 25 percent. These initial results from CATIE speak to the need for treatment options—not restrictions, such as closed formularies or fail-first requirements.

The CATIE results showed that olanzapine, perphenazine, quetiapine, risperidone, and ziprasidone differ from one another somewhat in terms of efficacy and markedly in terms of side effects. The corollary, of course, is that patients differ from

one another in how they respond to different antipsychotics. One of CATIE's most important messages is that pharmacotherapy for schizophrenia must be tailored to individuals, and one of CATIE's most important achievements will be to provide comparative data that physicians and patients can use to individualize antipsychotic treatment.

CATIE is not the last word in the treatment of schizophrenia, nor is it the end of NIMH's commitment to effectiveness research relevant to clinicians and people with mental illnesses. CATIE is the first objective comparison of multiple antipsychotic drugs carried out with patients in settings that are representative of real-world treatment settings for people with schizophrenia. It is a step toward NIMH's goal of improving the lives of people with schizophrenia and toward Dr. Ragins' "vision of a transformed mental health system."

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To the Editor: In the Taking Issue commentary published in the December issue, Dr. Ragins describes being surprised that in the National Institute of Mental Health's CATIE study first- and second-generation antipsychotics were not found to be substantially different in effectiveness; he also notes that he was "amazed to read how poorly all the patients had fared." He sees the study as a "wake-up call" and asks a

series of questions about the clinical environment in which the study was carried out—questions about the doctor-patient relationship and how medications are integrated with other therapies.

Having been the clinical director of the Illinois Mental Health Authority for the past ten years (I left my state position in September 2005), I share Dr. Ragin's concerns but not his surprise. If anything, I am afraid that the patients in the CATIE study fared better than average—definitely better than the typical patient in our public mental health system. For example, in community mental health centers (CMHCs) in Illinois, we have approximately one full-time-equivalent psychiatrist for every 1,100 patients; therefore, any discussion of doctor-patient relationships is moot. Because our Medicaid authority reimburses psychiatrists at approximately \$20 per medication visit, our CMHCs find psychiatric care, at best, a loss leader.

Our own research on continuity highlights just how bad things really are. Using Medicaid pharmacy claims for a one-year period, we retrospectively examined data for all patients who were taking risperidone (which is paid for without need for prior approval by our Medicaid authority) at discharge from our state hospitals. Although at discharge patients were given a two-week supply of risperidone, during the next three weeks, more than half did not fill a prescription for an antipsychotic, and, of those who did, half received a medication other than risperidone. Over the course of two years, less than 1 percent continuously filled a prescription for risperidone (1). In a subsequent study looking at continuity for both first- and second-generation antipsychotics, we found that 28 percent of those discharged on first-generation agents and 36 percent of those discharged on second-generation agents were never linked to a CMHC, and overall about two-thirds had dropped out before their third appointment (2).

During the ten years of my tenure, Illinois' public mental health budget did not keep up with inflation. De-

spite the budget shortfalls, we excelled on the ORYX standards of the Joint Commission on Accreditation of Healthcare Organizations, prescribing second-generation antipsychotics rather than first-generation agents to more than 70 percent of our inpatients; second-generation antipsychotics now consume several hundred million dollars of our annual Medicaid authority's budget. The decision to reduce resources for other interventions while enormously expanding the medication budget was not necessarily one that would have been supported by consumers (3), but it was a decision that we made. In hindsight it was a mistake.

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To the Editor: We strongly support Ragins' call in the December issue for a transformation of mental health research to include the development of "practice-based evidence."

Our recent naturalistic statewide study of employment rates among clients of community mental health centers, which used administrative data, is an example of the search for practice-based evidence. Our study found a 69 percent discontinuation rate for second-generation antipsychotic medications. This rate is similar to the discontinuation rates found in the CATIE study. However, our naturalistic study also found that almost half of the individuals who discontinued treatment (46 percent)

reinitiated second-generation medication within 18 months. Operating within the practice-based evidence paradigm broadened our perspective to include a fuller range of clinical practices in community settings.

Within the broader practice-based evidence paradigm, this study also provided information about the effectiveness of these medications. We found that 18 percent of individuals receiving second-generation medications were employed before discontinuing medication, but employment rates increased to 22 percent after the medication was discontinued (although this increase was not statistically significant.). A related study found that the initiation of second-generation antipsychotic medication was associated with a significant decrease in level of involvement with the criminal justice system (1).

We have argued elsewhere for increased utilization of the administrative databases that are the hallmark of our information age (2). Others have argued for balancing clinical trials with naturalistic community studies (3). Although the strengths of clinical trials are well known, their weaknesses are frequently ignored. Primary among these weaknesses is the potential lack of representativeness of the samples. In the CATIE study, for instance, only 25 percent of participants were female (4), which contrasts with the larger population of recipients of public mental health services. In our statewide study, 54 percent of adults who were receiving public mental health services for serious mental illness were female. Nationally, 52 percent of recipients of public mental health services who have a serious mental illness are female (5). The underrepresentation of women, as well as other potential selection biases, can seriously diminish the ability of such studies to reflect and inform clinical practice.

We believe that the important public policy questions raised by Ragins' critique of the CATIE study will be best addressed by a systematic program of research that incorporates both clinical trials and observational studies by using administrative

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databases. This combination of approaches to community-based research will provide a better understanding of the efficacy and effectiveness of antipsychotic medications and the broader range of clinical practices than is provided by either research paradigm alone.

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Enhancing Generalizability: Stepping Up to the Plate

To the Editor: An article by Braslow and colleagues (1) in the October issue of *Psychiatric Services* pointed out notable shortcomings in the generalizability of findings from most studies of mental health treatments that were published in four leading psychiatry and psychology journals over a 15-year period. Omitted from the article were studies from *Psychiatric Services*—the very journal chosen by the authors in which to publish their findings. I was left wondering what the findings would have been had their review included this journal.

Braslow and colleagues spoke of the need for clinical science “to shed light not only on an intervention’s ef-

ficacy but also on how well efficacious interventions actually work in diverse clinical settings, provider and patient populations, and practice circumstances.” I think of that call to action as part of the mission of *Psychiatric Services*, and thus I would hope that a comparable review of articles published in this journal would yield a better showing than did these authors’ review of outcome studies from the *American Journal of Psychiatry*, *Archives of General Psychiatry*, *Journal of Consulting and Clinical Psychology*, and *Journal of Abnormal Psychology*. This is testable: how well do we who publish in, or review for, this journal monitor ourselves in these domains?

Part of ensuring generalizability has to do with study design and execution, and part has to do with allocating some of the scarce text space to describing the demographic and organizational characteristics that Braslow and colleagues found often went unreported. One can pick at the methods used for their ratings. For example, some studies appropriately exclude one gender or do not collect information on ethnicity; the reliability of the individual ratings appears largely to have gone unassessed; raters may not have been blind to the hypotheses being addressed. However, those are concerns that should not distract from their message. The central point continues to be that much of the research on mental health outcomes after particular interventions continues to be reported in ways that sharply limit its usefulness to those who work in routine practice settings.

Over the years *Psychiatric Services* has increased its concerns about internal validity and causal inference, which have been the hallmarks of the four journals included in the review. I appreciate *Psychiatric Services’* emphasis on policy relevance and information to help mental health service providers and administrators make decisions about what works, for whom, and under what circumstances and how to get such services implemented and sustained. The articles in the October issue were good cases in point.

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In Reply: We very much appreciate Professor Essock’s insightful comments. As she rightly points out, all too often authors of mental health outcome studies report their findings in ways that limit a study’s usefulness for practitioners in usual care settings. Our study bears this out. Authors often failed to report fundamental variables related to external validity, due in part to the lack of emphasis for many journals to require or encourage the reporting of these variables. We agree with Dr. Essock that research findings need to be reported in ways that maximize their usefulness to frontline providers. If an author fails to report on key aspects on the conduct of a study, providers and policy makers are only left to guess as to the extent that study may or may not apply to their particular patients.

We do agree with Dr. Essock that our study does have limitations. For example, we were not able to ascertain whether it was justifiable for a study not to report on or to exclude minorities; such an assessment usually takes a thorough review for a study section to examine a large body of information to make that kind of determination. Nonetheless, the fact that 71 percent of the studies entirely failed to report this important variable is a significant problem. We do report on the reliability of the variables, although a number of important ones fared poorly, such as whether or not treatment was randomly allocated. We believe that our problems with reliability reflect the flawed nature of reporting in these studies—important characteristics of the design and execution were often difficult to ascertain.

Finally, we also agree with Dr. Es-

sock that including *Psychiatric Services* in a similar study would be worthwhile, and we plan to include this journal in a new study that examines changes in reported external validity from 1996 to 2005. Certainly, how generalizability has been framed and its perceived importance to the field likely have changed significantly over the last decade—but how much and in what key areas?

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Use of the COVR in Violence Risk Assessment

To the Editor: From the MacArthur risk assessment study, Monahan and colleagues (1–3) have developed an important body of work demonstrating the association between increased risk of violence and substance use among individuals with mental disorders. Complementary to this work is their report in the July issue of *Psychiatric Services* on the Classification of Violence Risk (COVR), an instrument to measure the risk of violence in persons with mental disorders, which was used in the reported study to predict the risk of violence among individuals discharged from mental hospitals (4).

The co-occurrence of substance use and mental disorders continues to draw national attention (5). Efforts undertaken to estimate the risk of violent behavior in this population have found that the elucidation of the degree of substance use is necessary to improve the accuracy of such predictions. We recently reanalyzed data obtained from the MacArthur study database, which is publicly accessible online (www.macarthur.virginia.edu/read_me_file.html), and found that the risk of violence increases with the severity of substance use. Specifically, rates of violence at follow-up (20 weeks after discharge from a psychiatric hospital) increased across three categories of substance use—no use, little use, and a level of use consistent with a diagnosis of substance use disorder—respectively from 15 to 26 to

29 percent for drug use and from 14 to 23 to 32 percent for alcohol use.

These findings imply that continued study of violence among individuals with mental disorders would be of particular benefit to augment our understanding of the risk factors for violent behavior. Such study holds promise to improve the ability of clinicians, courts, and criminal justice staff to make informed decisions about treatment.

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To the Editor: The authors of the report, published in the July 2005 issue, of the validation study of the actuarial model of violence risk assessment that was produced by the MacArthur Study (1) correctly state that the study affirmatively answered their research question about whether the model would statistically discriminate patients assessed as “high risk” from those assessed as “low risk” with re-

spect to their actual violence after hospital discharge. As a clinician, however, I would question the authors’ implied endorsement of the usefulness of the risk estimates provided by the MacArthur Violence Risk Assessment Study (2)—that is, those utilized by the Classification of Violence Risk (COVR) software (3).

Given the results of the MacArthur Study and the “unrevised” validation sample base rate for violence of 17.8 percent, one would have expected that in the validation study the COVR would have shown positive predictive power of .60 and negative predictive power of .99. However, the instrument in fact exhibited positive predictive power of .35 and negative predictive power of .91. With respect to the “revised” validation study base rate for violence of 22.9 percent, the COVR ought to have shown positive predictive power of approximately .66 and negative predictive power of approximately .99. In fact, it showed positive predictive power of .49 and negative predictive power of .91.

The observed “unrevised” positive predictive power implies that a person classified as high risk by the COVR was actually almost twice as likely to have been nonviolent than violent for the first several months after discharge. The “revised” positive predictive power, although it represents, like the “unrevised” value, an improvement on predicting to the base rate, implies that a person classified as high risk had only a “flip a coin” likelihood of being violent during follow-up. The clinician who has a patient with COVR results that classify the patient in one of the highest risk categories (56 percent or 76 percent) must wonder whether that patient’s actual risk of violence is considerably less, given the instrument’s performance in the validation study.

It also seems to me that, in vivo, the COVR will be administered not to hospitalized patients in general but only to those deemed for one reason or another to need a risk assessment. This practice could be expected to increase the base rate for violence among patients who are administered the COVR and would most likely in-

crease positive predictive power, while at the same time, unfortunately, reducing negative predictive power (a relative strength of the instrument). Such changes in positive predictive power and negative predictive power could not be computed without reliable estimates of the sensitivity and specificity of the COVR, which, again unfortunately, has shown fluctuating values for those statistics across settings (sensitivity of .96 in the development study but .68 or .75 in the validation study; specificity of .86 in the development study but .72 or .77 in the validation study).

When we also consider the fact that in applied settings there will be no Federal Confidentiality Certificates to promote patients' responding truthfully to the COVR items, I am left with the impression that, pending additional research findings, the instrument has, at best, questionable clinical usefulness.

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In Reply: Dr. McCusker concludes that the authors "correctly state that the study affirmatively answered their research question." But regarding the COVR software that was being validated, he believes that "pending additional research findings, the instrument has, at best, questionable clinical usefulness." Although our article acknowledged that many questions "await studies using the software in actual clinical settings," we believe that at the present time the software "may be helpful to clinicians." The

manual that accompanies the software makes clear that the software is a "tool" to inform clinical judgment and that "the application of clinical judgment represents the standard of care" in violence risk assessment.

Dr. McCusker's coin-flipping analogy can be seriously misleading. Given its high true-negative rate, the COVR's overall accuracy makes it vastly better than a coin flip. Only after patients were classified by the software as high risk did they have a roughly 50 percent probability of being violent. The utility of the COVR seems most reasonably evaluated against alternative approaches to risk assessment rather than against absolutist expectations. In this regard, the findings reported in the COVR validation study represent a level of accuracy equal to the highest true-positive rate reported for unstructured clinical prediction, with a much lower false-negative rate (1). The clinical predictions reported by Lidz and colleagues (1) were achieved after detailed patient interviews by nurses, residents, and attending psychiatrists. In contrast, it takes seven minutes, on average, to administer the COVR.

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Better Outcomes for Schizophrenia in Non-Western Countries

To the Editor: We read with interest the article in the November issue by Srinivasan and Tirupati (1) reporting on their study of cognition and work functioning among patients with schizophrenia in India. We were fascinated by their finding that 67 percent of the 88 patients in the study were employed and that most of them were in full-time employment in mainstream jobs with minimal or no disability or support in the workplace.

These findings will seem alien to most psychiatrists in the Western world, particularly in the United States. Schizophrenia in Western societies is conceptualized as a "chronic debilitating illness" with a poor prognosis and a poor functional outcome. However, this conventional wisdom is not entirely true. At least two major international studies, the International Pilot Study of Schizophrenia (2) and the Determinants of Outcome of Severe Mental Disorders (3), have provided convincing evidence for a better outcome in India and other "less developed" countries than in the West. The multisite study of factors affecting the course and outcomes of schizophrenia in India found that 64 percent of the participants were in remission at a two-year follow-up and only 11 percent continued to be ill (4). Such numbers are likely to be reversed in the United States.

The emphasis in Western psychiatry is on symptom control or elimination and rarely on functional recovery. Patients with schizophrenia also face severe stigma, which makes it difficult for them to find mainstream jobs and very often keeps them on the fringes of society. In addition, the general public strongly associates schizophrenia with violence. Some of the stigma has been propagated by psychiatrists and other mental health professionals. The characterization of schizophrenia as a biological "disease" that needs to be managed mostly by pharmacologic means may also contribute to poor prognosis.

It is also possible that in Western societies, expectation and beliefs about mental illness and the operation of the health care system serve to alienate patients with schizophrenia from normal roles in society and to prolong illness. In contrast, beliefs and practices in non-Western societies may encourage short-term illness and a quick return to premorbid status. Thus prognosis may also be the result of culturally based self-fulfilling prophecies (4).

It is obvious that although schizophrenia may have a biological basis, good outcomes depend on a phar-

maco-psycho-social approach, and the psychosocial aspect may well have the greatest impact on improved outcomes.

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Homeless Admissions and Immigration in a State Mental Hospital

A previous report on admissions to a state mental hospital (Chicago-Read Mental Health Center) in Chicago between 1970 and 1980 suggested an increasing rate of homelessness (1). To determine whether this increase was continuing, we gathered data from facility reports for 1996 and the last available year, 2003. We found that the proportion of homeless mentally ill persons who were hospitalized significantly increased over the three study years, from 20.2 percent in

1996 to 29.2 percent in 2003, compared with 15.3 percent in 1980 ($\chi^2=178.9$; $df=2$, $p<.001$).

In addition to finding the increase, we also found that the homeless population might be changing. Using 1996 data we compared 102 homeless patients who had no previous state hospitalizations with 158 homeless patients who were previously hospitalized. The most striking relationship, based on logistic regression, was that the odds of being a first admission were more than five times higher among foreign-born patients than among those who were native born (odds ratio=5.42, $p<.001$). This trend continued in 2003—the ratio of foreign-born persons was significantly greater among homeless patients admitted for the first time than among homeless patients who had previous state hospitalizations (21.6 percent compared with 10.8 percent; $\chi^2=4.04$, $df=1$, $p<.05$).

The increasing proportion of homeless foreign-born patients among new admissions to a state mental hospital probably reflects both the rising number of immigrants to certain areas of the United States and their economic status. U.S. census data for 1998 indicate that nearly 30 percent of recent arrivals to the United States lived in families below the poverty line, compared with 13 percent of the native born. Unemployment rates were higher, household incomes were lower, and twice as many U.S. households with foreign-born residents as native-born residents received some federal benefit. These findings underscore why foreign-born residents may be predisposed toward homelessness (2), a relationship that is receiving considerably more attention in Europe (3).

Although our findings are limited because they are based on a single state mental hospital, they are consistent with demographic changes in the country and possibly with patterns of hospitalization. For example, substantial increases in psychi-

atric hospitalization rates were recently reported for both Asians and Hispanics in Massachusetts between 1994 and 2000 (4). Although birthplace was not identified, the increase was more than likely the result of an increase in immigrants to that state.

The general psychiatric issues facing minority and foreign-born populations have been outlined by the U.S. Surgeon General (5), although the report only briefly discussed homelessness among immigrants. Our findings would suggest that state mental health planners must be cognizant of these changing populations and the potential for homelessness among the foreign born.

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