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Use of Long-Acting Risperidone

To the Editor: In their article in the September 2004 issue, Dr. Keith and his colleagues (1) recommended the use of long-acting risperidone for different patient groups, including patients with schizophrenia who are experiencing their first episode of psychosis. They discussed the rationale for using depot antipsychotics for this group: improved medication adherence, more frequent contact with service providers, and lower likelihood of relapse.

However, the use of long-acting risperidone for first-episode psychosis raises the important question of appropriate dosage, which was not adequately addressed. A MEDLINE and EMBASE search done on October 10, 2004, did not reveal any trial of long-acting risperidone in first-episode psychosis. Three different types of evidence support the use of lower dosages of antipsychotic medication for patients in this group than for patients experiencing subsequent episodes. First, comparisons of the treatment responses of patients expe-

riencing a first episode and those who have chronic, multi-episode schizophrenia have shown that the former require dosages that are as much as 50 percent lower (2). In a double-blind study of first-episode psychosis among patients with schizophrenia, 2 mg of risperidone was found to be as effective as 4 mg, with a lower incidence of fine-motor dysfunction and a lower rate of treatment dropout (3). (Chlorpromazine-equivalent dosage is not established for long-acting risperidone. However, clinical trial data show that 25 mg is an adequate dosage for most patients with multi-episode schizophrenia. For first-episode psychosis, 50 percent of that dosage should be appropriate.)

Second, when the dosage was titrated by using the neuroleptic threshold method (that is, the antipsychotic dosage was increased until cogwheel rigidity was detected), low-dose risperidone—2 to 4 mg—was found to be equally effective as higher doses, with a lower incidence of extrapyramidal side effects (4). Third, positron emission tomography (PET) studies have clarified the relationship between D₂ receptor occupancy and clinical response, with occupancies greater than 65 percent showing antipsychotic efficacy and those greater than 78 percent showing extrapyramidal side effects. A PET study of drug-naïve patients with schizophrenia showed that 3 mg of risperidone a day produced receptor occupancy of 72 percent, which is in the antipsychotic efficacy range (5). On the basis of these three studies, a target dosage of 2 to 3 mg a day is appropriate for most patients with first-episode psychosis.

Currently long-acting risperidone is available in strengths of 25 mg, 37.5 mg, and 50 mg. Because the drug is distributed in micro-spherules and not uniformly dispersed throughout the vial, it is not possible to give doses that are lower than 25 mg, which is higher than the dose required for most patients with first-episode psychosis. Unless a smaller dose formulation is available, long-acting risperidone should not be a first-line option for most patients in this group. We

recommend that the manufacturer of long-acting risperidone make it available in a lower strength of 12.5 mg to facilitate its use for patients with schizophrenia who are experiencing their first episode of psychosis.

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To the Editor: The lead article in the September 2004 issue by Dr. Keith and his colleagues styles itself as providing “practical advice” on the use of long-acting risperidone, based on a literature review and a panel discussion of international experts gathered in Dublin, Ireland, in spring 2003. As stated in the abstract, results, and acknowledgments, the entire effort was funded by an “educational grant” from Johnson & Johnson. Nowhere does it state that Janssen Pharmaceu-

tica, the manufacturer of long-acting risperidone, is a member of the Johnson & Johnson "Family of Companies" (1), nor is the educational grant described as unrestricted. It is inherently misleading for such an article to masquerade as an academic review in a peer-reviewed journal, given its funding source.

As further evidence of the bias inherent in this article, one need look no further than the next article in the same issue of *Psychiatric Services*, wherein Dr. Citrome and his coauthors present their case-control study on the risk of diabetes with use of second-generation antipsychotics (2). These investigators determined that risperidone monotherapy had an elevated, though not statistically significant, risk of diabetes and that study participants who were taking two second-generation drugs (69 percent of whom were taking risperidone) showed a significant elevation in diabetes risk. Dr. Keith and colleagues recommend a cross-over strategy for initiating treatment with long-acting risperidone that would entail at least several weeks of treatment with more than one second-generation drug. Curiously, I could not find a single mention of diabetes in the Keith article. Nor, although it purports to be a review article, does the paper cite any of the several articles on diabetes risk with atypical antipsychotics that were cited in the Citrome article. Given the morbidity of diabetes, surely it would be "practical" and prudent to alert practitioners to this risk.

I must therefore question whether the article by Dr. Keith and his colleagues should have been published by *Psychiatric Services*. Given its provenance, it would have been better suited to one of the many journals that arrive, unbidden, in our mailboxes on a regular basis.

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In Reply: We agree with all of the thoughtful, scientific points made by Drs. Pinninti and Mago until the sentence stating that 25 mg is higher than the dose of risperidone required for most patients with first-episode psychosis. Although no dose equivalency studies have been published that compare oral risperidone to long-acting injectable risperidone, the following information should be helpful. A dose of 25 mg given over 14 days is 1.8 mg a day. Peak plasma levels correlate with side effects, and peak levels for 25 mg of long-acting risperidone are approximately one-third less than with 2 mg of oral risperidone (1). Two recent posters presented data from evaluations of young patients with schizophrenia (a mean age of 23.2 years in one and 25 in the other) early in the course of their illness, which indicated that not only was long-acting risperidone effective (2) but extrapyramidal symptoms improved as well (3). My own personal observation is that patients who can tolerate 2 mg of risperidone orally can tolerate 25 mg of long-acting injectable risperidone. However, this does not obviate the point that a dose lower than 25 mg of long-acting risperidone may be helpful for some patients. As clinicians provide feedback on patients' needs, it is highly likely that the pharmaceutical industry will respond.

Dr. Parker's letter raises some critical issues about both the implications of sponsorship and the need to be all-inclusive about side effects. It was our impression that the disclosure we made in both our abstract and acknowledgment would permit readers to evaluate for themselves whether the sponsorship affected the content of the article. If Dr. Parker is correct that the readership of *Psychiatric Services* is not up to this task and that a delineation of the corporate structure of Johnson & Johnson would

have made a difference, then we are grateful that he has clarified this for readers.

We support the full evaluation of diabetes risk and all other side effects. The purpose of the article was to take people beyond the package insert to the practical, clinical use of a new medication. If there are physicians using second-generation antipsychotics who have somehow missed the extensive literature on the risk of diabetes with use of these agents and the Food and Drug Administration's class-effect warning, then once again we are grateful to Dr. Parker for calling this to readers' attention.

As to Dr. Parker's assertions about the article by Dr. Citrome and his colleagues published in the same issue, his interpretation of the findings in regard to risperidone and diabetes appear to be somewhat negative. Of the four atypical antipsychotics evaluated, risperidone had the lowest odds ratio of risk elevation, which did not reach statistical significance. As Dr. Citrome and his colleagues are correct to point out, the study was naturalistic in design and therefore it is difficult to separate cause from effect. Perhaps risperidone was so frequently associated with multiple medication use because it has been perceived (as indeed was suggested in the Citrome article) to have a lower risk for diabetes than the other antipsychotics evaluated and was therefore potentially the safest choice for combination therapy. If a 21-day period of overlap during the discontinuation-initiation of second-generation antipsychotics constitutes polypharmacy, then I am guilty of polypharmacy. I would suspect that many opponents of polypharmacy (I am one) have used a double cross-over design for discontinuation-initiation of many medications (not, of course, MAOIs). If Dr. Parker has information about the inadvisability of this kind of discontinuation-initiation strategy, we hope he will share it with the field. Finally, none of these points should be interpreted as negating the FDA's warning on diabetes, which is a potentially quite severe consequence of the use of second-generation antipsychotic medications.

Our intention in writing our article was to bring the thoughts of people with extensive experience with a new medication to a journal widely read by other clinicians. We hope that we have succeeded, and we appreciate the interest, and even the criticism, of those who have read it. We would encourage the journal to continue to provide such clinical information to its readership.

Samuel J. Keith, M.D.

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Managing Transitions to the Community

To the Editor: An article in the November 2004 issue, “Principles for Managing Transitions in Behavioral Health Services” (1), summarized a document developed by the American Association of Community Psychiatrists (AACP). Our question is, Where is the community?

Although the AACP’s principles note system fragmentation and organizational self-interest, they lack a community perspective, and they patronize nonpsychiatric professionals and consumers. The authors state that social workers have “carried the bulk of responsibility for developing transition plans.” However, they mischaracterize social work education as “limited primarily to field placement and thereby . . . most heavily influenced by prevailing practices.” In reality, key features of master’s-level social work education include knowledge of the psychosocial dynamics of well-being, skill in using the social

work process from engagement through transition, and knowledge of evidence-based research on which to build effective programs and practices. Transitions and their ramifications are fully addressed in the social work code of ethics (2), often the first document that social work students are asked to review.

Of greater concern is AACP’s ambivalent message to consumers. Although the authors note that transitions are to be “client driven,” they also state that “persons in transition should not be expected to assume responsibility to manage the complex and multifaceted aspects of their continuing care.” In today’s managed care world, clients are being asked to do just that, and professionals must support their efforts to do so.

The article on AACP’s principles ignores the many collaborating professions and stakeholders whose participation is essential in promoting community mental health. A statement of principles that disregards and denigrates those contributions is hardly helpful.

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In Reply: We welcome this opportunity to respond to the letter from Ms. Ralph and Dr. Terrell about our article on the AACP guidelines for transition management and to Dr. Segal’s critical commentary on the guidelines (1) that was published in same issue as our article.

What Dr. Segal takes issue with is difficult to discern. He appears to be concerned that current realities present difficult challenges that the guidelines do not recognize. On the contrary, the guidelines were developed to address these barriers to effective transition planning and to provide a vision and some standards for a more rational system of care. We agree that transition plans “most often reflect bureaucratic and financial considerations” and that “services are rarely integrated.” The guidelines acknowledge these realities. We believe that the guidelines present an agenda for quality improvement rather than acceptance of the status quo.

Dr. Segal’s other criticism seems to be that the guidelines advocate that all service users make transitions through all elements of the continuum of care. Although the guidelines do advocate for the availability of a complete array of services to meet the diverse needs of the service-using population, they in no way imply that these services should be prescribed without regard to individual needs. On the contrary, they emphasize the need to assess and meet individual needs and to include service users in making these determinations.

Dr. Segal also asserts that “transition” is ill defined and euphemistic. Although the term would be euphemistic if used to describe present practices, it is clearly a more appropriate term for describing the processes that the guidelines advocate. The entire AACP document is devoted to describing the meaning of transition in behavioral health services, and thus it is difficult to see how the term should be further elaborated.

In their letter above, Ms. Ralph and Dr. Terrell ask “Where is the community?” We would answer simply that the community is everywhere in this document, and that if there is some aspect of it that has not been considered, we would welcome specific suggestions.

Ms. Ralph and Dr. Terrell state that they feel that the guidelines disregard and denigrate the contributions of collaborating professionals. We were dis-

tressed and perplexed by these perceptions. The AACCP has nothing but the highest regard for its professional partners in behavioral health care and the important contributions that they make. The AACCP intended this document to be a generic, "nondenominational" set of principles to improve deficiencies in transition planning for all professions and professionals dedicated to this important task.

Ms. Ralph and Dr. Terrell also state that social work education is mischaracterized as taking place primarily in the field. We would not presume to characterize social work in this, or any other, way. The passage that they refer to is limited to the relative emphasis on transition planning in training programs and is based on numerous conversations with front-line social workers and their recollections of their training experiences. We would not pretend that this is a scientific sample, and we included it only to illustrate that all professional training programs can improve in this regard.

The authors of the letter also feel that consumers are given an ambivalent message. We think the document clearly and frequently states the value of consumer-driven transition planning. We do note that when people are incapacitated they may not be able to manage complex and multifaceted care unilaterally, and professional support is critical when this is the case. We do not think that these concepts are in conflict with one another or with the authors' perception of how clients should be supported in a managed care environment.

Wesley E. Sowers, M.D.
Barbara Rohland, M.D.

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Best Practices and the Visible Horizon

To the Editor: It is hard to argue with Dr. Schreter's reply to the letter in the November 2004 issue that addressed the disconnect between so-

called best practices and the funding limitations that often impede or even preclude their implementation (1). Nowhere is this more striking than in the recommendations of the 2002 Report to Congress of the Substance Abuse and Mental Health Services Administration (2), which promotes a longitudinal view of treatment for patients with co-occurring disorders despite the "caps" and limits on lengths of stay that are dictated by both state and federal funding.

The notion of "best practices," however, implies that nothing could be better and thus tends to limit progress in the field. After all, in the 1400s best practices included taking care not to sail beyond the visible horizon lest one fall off the edge of the earth. Christopher Columbus opted to ignore such consensus practices. More important is the identification of agreed-upon objectives and clinical outcomes toward which best practices may or may not be useful. Ultimately, it is the payers that determine what is worthwhile on the basis of their priorities. Treatment that works is always a good investment, financially and otherwise, if it is defined as having benefits that outweigh the costs no matter how high those costs may be.

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Screening for Decreased Oxygenation During Medical Evaluations

To the Editor: In the November 2004 issue, Dr. Jones and associates (1) reported on the prevalence and severity of chronic physical health problems of persons with chronic mental illness. They highlighted the

importance of pulmonary disease among such patients. In their study chronic pulmonary disease was the most prevalent physical health problem (31 percent incidence) and was the most frequent comorbid condition (50 percent or more of patients with eight other health conditions were also treated for respiratory conditions). Similar results have been reported previously, including a British study that concluded that respiratory disorders were responsible for substantial excess mortality among patients with psychotic illnesses (2).

Despite these findings it would appear that clinicians frequently do not pay adequate attention to the evaluation of oxygenation during medical examinations of patients with chronic mental illness. Recommendations for the assessment of psychiatric patients who need medical clearance generally advise physical examination and routine laboratory tests, including a toxicologic screen, CBC, electrolytes, BUN, creatinine, glucose, calcium, CPK, and prothrombin time (3). If such testing does not explain the patient's symptoms, a cranial CT is performed, followed by a lumbar puncture if the patient has a fever. However, none of these ancillary studies reflect the degree of oxygenation. Decreased oxygenation—hypoxia—may present with a number of signs and symptoms, including inattentiveness, lethargy, poor judgment, restlessness, insomnia, agitation, euphoria, and confusion, before progressing to more obvious signs of cerebral impairment (4). These symptoms are nonspecific and may be incorrectly attributed to the presentation or exacerbation of a mental disorder, particularly if the patient has a known history of mental illness.

In view of the reported incidence of pulmonary disorders among persons with chronic mental illness, it could be argued that this group's medical clearance should include some form of assessment for decreased oxygenation. For a screening test, pulse oximetry can be performed simply and noninvasively in less than 30 seconds. A sensor placed on the patient's finger or earlobe measures the percentage of

hemoglobin that is saturated with oxygen. An oxygen saturation of less than 90 percent suggests hypoxia. Pulse oximeters frequently detect problems with oxygenation before they are noticed clinically. Thus an abnormality by pulse oximetry should prompt an immediate search for an underlying cause of hypoxia.

It should be noted that oximetry results may be normal in acute dyspnea, particularly if the patient is able to compensate temporarily by hyperventilation. Oximeters give no information about the level of CO₂ and have limitations in the assessment of patients who are developing respiratory failure because of CO₂ retention. Tests such as arterial blood gas measurements are more sensitive in detecting impaired gas exchange, but they are invasive, may produce discomfort, and take longer to complete.

For patients with chronic mental illness who present with changes of mental status, decreased oxygenation should be part of the differential diagnosis on the basis of findings described above. Pulse oximetry could serve as a simple, quick, and painless screening test for decreased oxygenation provided its limitations are kept in mind (5).

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“Severe” and “Chronic”: Do These Terms Help Us Understand Patients?

To the Editor: The body of work by the journal's Editor Emeritus John A. Talbott, M.D., that was summarized in the October 2004 issue is impressive. I also congratulate Dr. Talbott on his successful efforts to offer a free subscription to *Psychiatric Services* to all members of the American Psychiatric Association (APA) as a benefit of their membership, as has always been the case for the *American Journal of Psychiatry*. This offer signals an end to a dysfunctional separation between patient populations that has always worried me.

I've always felt that the term “severely chronically mentally ill” is destructive, because, like the separation between members who do and do not choose to receive *Psychiatric Services*, it separates a stigmatized population from a more high-functioning population who also have severe and chronic mental illness but are never thought of as “severely chronically mentally ill.”

I view differences between patients from the perspective of functioning. Consider the following patients whom I've treated. During the early years of my career, when Governor Reagan was closing hospitals in California, a friend asked me to drive to the Pacific Coast Highway to sign a paper for a naked 80-year-old man who was sitting on the roadside. A few years later I was treating “young chronics,” who didn't have a new disease but were simply reacting to social reengineering. And then there

was the 70-year-old man who had been “liberated” from Pilgrim State Hospital after 40 years by the civil rights movement and consigned to rotating between the Tombs Prison and Bellevue because he couldn't get sane enough to stand trial and wanted only to go back to Pilgrim State—but couldn't because Bellevue Hospital wasn't in the Pilgrim State catchment area. I've also run high schools for girls who lived in abandoned buildings and subway stations, and I've managed programs for evaluating and paying private disability insurance for high-functioning CEOs and police officers. The differences between these individuals are a matter of function. They are all seriously mentally ill, and their illnesses are chronic.

The adjectives “chronic” and “severe” have never helped me understand who will function and who won't—and therein lies quality of life. Severity, in my experience, doesn't differentiate persons with mental illness who need case management and a lifetime system of care from those patients with severe and chronic illness who work as CEOs, managers, secretaries, and oil riggers and occasionally need help with the barriers in the health care system. For me the dividing line between patient groups is not chronicity or severity but the ability to organize and thereby function (most of the time), which is preserved among many people in both groups irrespective of diagnosis, chronicity, or severity.

I believe that sending *Psychiatric Services* to all APA members could change such attitudes over time. I thank John Talbott for helping to secure this benefit for members—and for all his efforts over the years on behalf of patients.

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