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Impractical Features of Long-Acting Risperidone

To the Editor: I am writing in response to the article in the September 2004 issue by Dr. Keith and his colleagues (1) on "practical" aspects of long-acting risperidone. I believe that a balanced discussion of long-acting risperidone should have included some acknowledgement of its "impractical" features.

Obtaining long-acting risperidone is complicated and time-consuming. There is a paperwork burden associated with procurement of the drug. Storage and administration of long-acting risperidone is cumbersome and time-consuming. The drug must be refrigerated. Our agency receives the drug at multiple sites, and it is handled by multiple persons. The chain of custody must be ensured. Assembling the components of the injection system takes time and dexterity. The actual cost of the drug includes the drug itself—about \$500 a month—plus increased cost to insurers because of the necessity of more clinic visits by patients who are receiving the drug

plus nonreimbursable clerical costs to the clinic.

Unless the mental health agency has deep pockets and an experienced billing department and has pre-purchased the drug, no long-acting risperidone is available for immediate use. The moment a patient says, "Yes, I'll take the shot," the physician must reply, "Great! Come back next week." This is no way to initiate treatment. In addition, because gluteal injection is required, I cannot be alone with my female patients or my homophobic male patients.

There are significant disincentives to the use of long-acting risperidone that should have been anticipated and considered by the manufacturer. I believe that the underutilization of fluphenazine and haloperidol decanoate had more to do with physician reluctance than patient reluctance. The cost and the problems with storage and use of long-acting risperidone are daunting obstacles for a community practitioner who is not surrounded by a bevy of nurses and clerks.

A journal that once contained the word "community" in its title should be taking a lead in demanding pharmacologic treatments that are not simply effective but also accessible.

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Dr. Amdur is medical director of Thresholds in Chicago.

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In Reply: On behalf of my coauthors, I would like to thank Dr. Amdur for raising a number of salient points. That obtaining long-acting risperidone is complicated is a mental health systems issue that needs to be addressed. When new—and presumably expensive—medications are introduced, there is almost always a "push back" from our reimbursement systems that is designed to

slow the use of the medication and thereby reduce the cost to the system. Cost and value are thus put into conflict.

Progress often comes with a price in both effort and dollars. We shouldn't expect progress to necessarily "fit" into the existing system, which most of us would agree is broken in many places. Clozapine didn't fit well initially because of its expense and the requirement for blood testing, but we managed to make it work. Our colleagues in rheumatology and oncology have mastered the "buy and bill" process. A new long-acting atypical injectable medication—a medication we have all asked to have—may not fit well initially into our current system, but as in all evolutionary progression, we need to adapt or our relevance and even our existence become less valuable to society.

Dr. Amdur's point that use of long-acting risperidone is perceived to be cumbersome and time-consuming probably refers to the required refrigeration and the actual administration of the injection. This may be the first medication in psychiatry that requires refrigeration. However, it is only one of many in other areas of medicine, and solutions must therefore be available. The actual injection is easily given. It is an isotonic water-based suspension and thus is a much easier and less painful injection than the oil-based solutions of conventional depot medications—it goes in more rapidly and doesn't need "Z-tracking." While a gluteal injection may be somewhat less convenient than a deltoid injection, it does not require major disrobing. The procedure does require appropriate safeguards and "chaperones," but as physicians we should be able to find ways to address these issues as well.

In addition, Dr. Amdur's observation that the use of conventional depot medications has declined because of physicians' resistance and the advent of second-generation antipsychotics is true in the United States but not in Europe, where long-acting injectable medications are the mechanism of choice for de-

livery of antipsychotics for 10 to 50 percent of patients, depending on the country. Because of this level of variability between the United States and other places, I believe it is an issue of choice, not a real issue. With the availability of a long-acting injectable second-generation medication, we have a different choice.

We have faced many challenges and misunderstandings in psychiatry. We thank Dr. Amdur for identifying several with long-acting injectable risperidone. We can overcome most with the combination of an ever-expanding database of science and a persistent desire to provide our patients with the best care available. Our patients with schizophrenia deserve no less from us.

Samuel J. Keith, M.D.

Ethical Challenges in the Face of a Targeted Threat

To the Editor: In this letter we describe some of the ethical challenges that emerged during an evaluation of a health care plan to assess the implementation of a disease management program for depression. In the fall of 2002, focus groups were held with enrollees of the health plan who had a diagnosis of depression with the goal of examining their experiences as health care recipients. All research protocols had been approved by the institutional review board (IRB) of the affiliated university. Before the focus groups, participants received a letter explaining the nature of the evaluation. At the start of the focus groups, consent forms were discussed, including the limits of confidentiality, and each participant signed a form. All identifying information specific to the case described here has been altered.

During one of the focus groups, a participant reported having unsuccessful surgeries, which led to complications and subsequent impairment. The participant stated during the group: "I've had times when I lay there and think about . . . buying a damn gun. . . . Just to hell with him [the doctor]. . . . What have I got to

live for? I'm not going to prison." There was enough information to indicate that this person was at high risk of violence on the basis of motivation and other stressors. We responded to these challenges by obtaining additional consents for release of information from the participant after the conclusion of the focus group. We sought immediate clinical and legal consultation—first, for a psychiatric evaluation, and second, for information about legally permissible actions to prevent the threatened violence.

The dilemma we faced was the ethical obligation for researchers to maintain confidentiality—duty to the participant—within certain boundaries (1) and the opposing duty to protect, which required notification of the identified third party because of the targeted threat (2). Other questions emerged: Do qualitative researchers establish a "special relationship" as clinicians do (3)? And what are the ethical obligations attached to that relationship? Appelbaum and Rosenbaum (3) suggested that through face-to-face interviews researchers cultivate a rapport with participants to facilitate the receipt of sensitive information. There is no case law establishing that a special relationship exists between the research participant and the researcher as a result of qualitative inquiry.

We made an effort to protect the third party by calling the local mobile crisis team for an emergency psychiatric examination of the person who made the threat. The team determined that he was not a threat. We met our IRB and legal obligations by calling the crisis team, but was that enough? Also, what additional follow-up with the participant or his health plan would be overstepping the research boundaries?

Furthermore, we found no guidance in the literature about how to handle a *Tarasoff*-related situation in a focus group. Should the focus group participants be debriefed? If so, at what point during the group should this be done, and how?

This case raised compelling ethical and practical dilemmas that qualita-

tive researchers may face. It is hoped that the case will serve as a reminder to investigators of the need to continually examine the adequacy of their research practices and protocols. In addition, we suggest that further study should be given to *Tarasoff*-related situations in focus groups.

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Identifying Life Stressors of Patients With Schizophrenia at Hospital Discharge

To the Editor: The period after discharge from a psychiatric hospital represents a critical time in the course of illness for individuals with schizophrenia. The transition from the hospital to another setting has been found to be associated with increased levels of stress and, perhaps as a consequence, with exacerbation of psychiatric symptoms, noncompliance with medication, substance abuse, and suicide attempts (1,2). In particular, the link between discharge, stress, and suicide may be important, because 20 to 40 percent of suicides among persons with schizophrenia occur within three months of discharge (3), with the risk particularly high during the first five days after discharge.

Although most studies of stress and schizophrenia focus on major life events, it has been suggested that it is more the demands of everyday life that lead to stress (4) and that daily hassles are better predictors of subjective stress than major life events (5). Schizophrenia is characterized by repeated hospitalizations and discharges. Even though it is recognized that the days after discharge are a high-stress period, there is a lack of information about the stressors that individuals with schizophrenia experience during this period.

The aim of this study was to enumerate these stressors. We assessed 110 individuals with a *DSM-IV* diagnosis of schizophrenia within a week of their discharge from an inpatient unit at the New York State Psychiatric Institute. The study was approved by the institute's institutional review board, and written informed consent was obtained from all participants. Data were collected from 1999 to 2001. Stressors were assessed by an open-ended question asking participants to indicate the three most stressful issues they were facing at the time of discharge. The 110 participants provided 279 responses (a mean $\pm$ SD of 2.54 ± 1.06 responses per person; range, zero to five responses).

The most prevalent individual stressor was psychotic symptoms, identified by 34 participants (31 percent), followed by adjustment to fu-

ture residential settings, identified by 31 (28 percent). Among categories of stressors, 47 participants (43 percent) endorsed one or more interpersonal stressors—loneliness and issues related to social activities, relationships with parents, and relationship with other relatives or significant others. Employment-related stressors—finding or maintaining employment—were the next most common, endorsed by 36 participants (33 percent), followed by stress related to concerns about general well-being or the possibility of future hospitalizations, which were endorsed by 34 participants (31 percent). Only five participants (4 percent) responded to our question by stating “I don’t know” or “No stress.”

Our findings suggest that persons with schizophrenia who are anticipating discharge experience at least one stressor. Stressors related to psychotic symptoms and interpersonal relations were frequently reported, as were stressors related to adjustment to future residential settings, general well-being, future hospitalizations, and employment. Although obtaining a job may be unrealistic for many individuals with schizophrenia, the stress associated with this issue may be present, and it reflects important predischARGE concerns. Future research focused on linking subjective experiences of stress with more objective measures of stress will be important. We are using the re-

sults of our study to develop a tool for measuring stress at discharge. When stressors are identified at discharge, interventions to help individuals manage and cope with specific stressors can be incorporated into the discharge plan.

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