

Optimal Treatment for Psychosis in an International Multisite Demonstration Project

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The Optimal Treatment Project Collaborators

Introduction by the column editors: In the past three decades several clinical strategies for the treatment and rehabilitation of schizophrenia have been empirically validated. It is generally agreed that all persons with a schizophrenic disorder should be provided with a combination of three essential interventions—optimal dosages of antipsychotic medication, education for themselves and their caregivers to cope more effectively with environmental stresses, and assertive case management to help prevent and resolve major social needs and crises, including exacerbations of symptoms (1). Despite strong scientific support for the routine clinical implementation of these strategies, few treatment programs provide more than pharmacotherapy, and even this intervention is seldom applied in the manner associated with the best results achieved in controlled clinical trials (2,3).

Only one clinical trial has attempted to determine the efficacy of providing all of the recommended treatment components to individuals with schizophrenia. In

that study, a group of 40 individuals with schizophrenia received carefully titrated antipsychotic medication, family psychoeducation, social skills training, and case management; none of the study participants who received the treatments had a relapse in the first year of the program (4). The relapse rate was 40 percent in the first year for a comparison group receiving only medications and case management; 21 percent for a group who received medications, case management, and social skills training; and 19 percent for a group who received medications, case management, and family psychoeducation.

By the second year, however, relapse rates for the groups receiving family psychoeducation and social skills training began to approach the level for the group receiving only medication and case management. The presumptive reason given for this outcome was that the benefits of the interventions dissipated with their termination (5), highlighting the importance of offering efficacious psychosocial interventions on a flexible, as needed, or maintenance basis just as medication is provided.

Building on this finding, Dr. Ian Falloon (6) demonstrated that publicly funded services could deliver evidence-based interventions for schizophrenic, affective, and anxiety disorders in routine practice, with outcomes comparable to those found in randomized

controlled trials and without the need for additional resources. Soon thereafter, Dr. Falloon recruited a large number of investigators and clinicians with ties to routine mental health services for persons with schizophrenia and established an international collaboration with the goal of implementing and evaluating optimal treatment in ordinary clinical facilities. The planning and early results of this international collaboration, known as the Optimal Treatment Project, are described in this month's Rehab Rounds.

The Optimal Treatment Project is an international, multisite study begun in 1994 to evaluate the benefits and costs of applying evidence-based, optimal biomedical and psychosocial strategies for treatment of schizophrenic and other nonaffective psychotic disorders over a five-year period. Fifty-three sites in 21 countries initially entered the project, and 35 sites continue to participate.

The participating sites were chosen on the basis of several factors, including eagerness of administrators and clinicians to develop services according to an evidence-based model and adequacy of resources to provide staff training, ongoing supervision, quality assurance, and outcome evaluation of effectiveness and costs. The participating sites also had to be able to provide a sample of cases representative of schizophrenic disorders in their respective communities, to have a history of partnership with local consumer groups such as the National Alliance

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Evidence-based strategies for treatment of schizophrenic and other nonaffective psychotic disorders used at sites of the Optimal Treatment Project

Minimally effective antipsychotic drug strategies targeted to changing symptom profiles

- Education about medications' benefits and problems
- Training in adhering to and maintaining drug regimens
- Prevention and minimization of side effects

Education about early warning signs of illness exacerbation

Education of patients and informal caregivers in stress management strategies

Education to enhance understanding of the nature of psychotic disorders and their treatments

Training in effective interpersonal communication and structured problem solving to achieve personal goals and manage life stresses

Assertive case management and outreach

Development and maintenance of effective social support, including housing, finances, health, and safety

Early detection and intensive care to resolve clinical and social crises in the settings most conducive to full and rapid recovery

Social living skills training, including training for patients and informal caregivers in skills for achieving personal goals for work and social and recreational activities

Specific pharmacological or psychological strategies for residual or emerging symptoms

Strategies for coping with persistent psychosis

Ways to manage negative symptoms

Strategies for coping with anxiety and panic

Strategies for coping with mood swings, dysphoria, and suicidal thoughts

for the Mentally Ill or the World Fellowship for Schizophrenia and Allied Disorders, and to have a commitment to assist further developments of evidence-based programs.

The Optimal Treatment Project initially intended to bring patients into the study as soon as possible after the onset of their illness and to limit project cohorts to patients whose psychotic symptoms had begun within the last ten years. However, several sites extended these limits and are examining the effectiveness of the same approach with a cohort of patients whose first episodes occurred ten or more years ago. In such cases, treatment was focused on improving the quality of life through social and occupational skill training and on providing specific pharmacological and psychosocial strategies to address persisting symptoms. However, the overall clinical goal remained the same—to assist all patients in their recovery from their disorder and from all associated disabilities and handicaps.

The optimal treatment strategies

used at these sites are listed in the box above. Therapist workbooks and patient guidebooks were used to facilitate the delivery of the optimal treatment strategies consistently (7–11). These manuals were translated into the language of each site, and modifications were made to accommodate the cultural diversity of the groups included in the project. In addition, specific strategies for encouraging the active participation of patients in treatment, enhancing relevant social and living skills, and facilitating participation in rewarding occupational activities were incorporated into the treatment program. Provision was made to add, refine, or replace strategies as more efficacious methods emerged from new clinical trials. For example, plans were made to add atypical antipsychotic drugs and cognitive-behavioral interventions for persisting psychotic symptoms as soon as their benefits had been demonstrated in replicated randomized controlled trials.

The project's approach encourages the treatment team to focus at all

times on helping patients achieve their personal goals, even during periods of crisis. Several patients have been able to continue to work or study and maintain their roles in their households despite experiencing symptom exacerbations. Patients, family members, and friends who have received education about the disorder and its treatment and have been trained in strategies for efficient problem solving can often provide substantial assistance at times of crises. This informal crisis management, combined with comprehensive daily—and nightly when necessary—treatment from the multidisciplinary professional team, including careful pharmacotherapy, has helped many patients cope with major illness episodes without suffering serious setbacks in their personalized rehabilitation programs.

In some cases, as a result of recurrence or exacerbation of psychosis, patients, caregivers, and treatment professionals improve their comprehension of how biomedical and psychosocial factors interact to produce changes in the course of psychotic disorders. This increased understanding often leads to better adherence to treatment protocols. The longitudinal nature of the project may permit the study of progress toward clinical and social recovery, as well as of social, cultural, psychopathological, and treatment factors associated with the various courses of schizophrenic disorders.

Implementation

Program development followed recommendations derived from the intervention research literature (12). After an initial period of consultation with administrators and clinicians at the program sites was concluded, multidisciplinary teams were trained to administer the optimal treatment strategies. Continuous audits of fidelity to the treatment model, annual independent reviews of the services offered at each site, and further training have maintained and improved the quality of the project.

At one site, where an excellent assertive case management program had been functioning well for many years, case managers experienced

some initial difficulty collaborating with family members who had had stress management training. For many patients, the case managers had assumed support roles often played by family members and close friends. Charts used to document fidelity to the treatment model revealed that family sessions occurred relatively infrequently at this site and that the sessions that did take place were not focused on training in problem-solving skills designed to enhance families' management of stress. The deficiency was confirmed in the quality assurance audit, which included observations of family sessions and meetings with patients and their family members and close friends, as well as with the professional team.

The patients and family members emphasized that they preferred a more equal partnership with the treatment team and that the structured training in problem solving would be helpful in achieving this aim. Feedback to the team revealed their misunderstanding of the treatment implementation. A brief audit six months later showed that a greater proportion of therapist time was spent teaching problem-solving skills to patients and families. A year later these changes had been consolidated, and patients, family members, and professionals all expressed gratitude for the benefits that had accrued from the more effective application of these strategies.

Evaluation

An aim of the Optimal Treatment Project is to provide information on the benefits and costs of treatment that will be useful to clinical researchers, as well as to clinicians, administrators, consumers, and policy makers (13). Methods of evaluation are being implemented as an integral part of clinical treatment. For each patient, a standardized, clinically relevant set of psychiatric, social, caregiver, and economic variables are measured by the clinical team throughout the treatment program, and independent evaluators make assessments using the same measures every three months (14).

For example, one patient had a stable remission of all positive and nega-

tive symptoms, but appeared to make only limited progress on his personal goals of going back to the university and playing tennis again. Assessments revealed that he was suffering from severe social anxiety that had escaped earlier detection. Anxiety management strategies helped him to cope with these symptoms, and he made rapid progress toward his personal goals.

Fifteen of the 53 original sites in the project are in the early stages of clinical training and project development. Twenty sites are currently entering patients into the five-year evaluation program. Eighteen sites ceased their participation, most in the initial phase of development. The ability to secure continued funding for evaluation has been the key predictor of sustained participation in the project. A few sites have ceased participation for other reasons, such as changes in key personnel or local political changes that eliminated support for the project.

At the end of 1997, a total of 817 patients had entered the project, and 432 had completed the first year of assessment. We hope that at least 1,000 cases will eventually complete five years of optimal treatment with evaluation.

Fidelity in applying all of the evidence-based strategies used in the project has been examined using a random selection of cases at each site. Fidelity has ranged from good to excellent, but several problems have been encountered at a few sites. The most common problems have been in applying pharmacotherapy according to the project guidelines. Problems have also been encountered in encouraging families' participation in services from which they had previously been excluded and in applying methods for skills training to help patients enhance their social networks and engage in occupational activities. Further training and supervision has usually remedied these deficits.

Preliminary results indicated that reductions in patients' utilization of hospital services in the first year of project participation were consistent with the benefits noted in the controlled clinical trials. In a subsample of 106 patients randomly assigned to

receive either the optimal treatment strategies or pharmacotherapy with case management, the rate of hospital admissions during the first year of the project was reduced by 55 percent in the optimal treatment group and by only 4 percent in the control group, compared with the rate for the year before the patients began the project (15).

Afterword by the column editors

This impressive international demonstration of empirically validated treatment and rehabilitation strategies shows that it is possible for research to move from academically supported studies of treatment efficacy to studies of community-based mental health programs where the effectiveness of services can be documented, provided that they are applied in a consistent manner.

In the Optimal Treatment Project, a major determinant of the success of service implementation at the various sites has been the work of Dr. Falloon himself. His presence, visits, consultations, clinical problem solving, and encouragement have made the difference between success and failure. It has been known for some time that one of the factors contributing to the adoption of innovations is the availability of external consultation. The project sites where Dr. Falloon has provided that input have enjoyed success in implementing optimal treatment and rehabilitation strategies. At sites where he has not been able to provide his consultation and technical assistance, program failure and withdrawal from the project have been the unfortunate consequence.

To date, international studies of treatments in psychiatry have been limited to those sponsored by pharmaceutical companies. Dr. Falloon and his colleagues are making a case for similar international replications and adaptations of an array of biobehavioral or biopsychosocial modalities. Dr. Falloon's accomplishments are all the more impressive because funding for his multisite project has come from local sources in the various countries with participating sites. No major agency or foundation such as the World Health Organization or the National Institute of Mental

Health has responded to the opportunity to support this work. Future reports will examine the clinical, social, and economic benefits, as well as problems that arise when research is applied in practice over extended periods. ♦

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