Mental Health Care From the Public Perspective: The Texas Medication Algorithm Project

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Medication treatment algorithms have been suggested as a strategy to provide uniform care at predictable costs. The Texas Medication Algorithm Project is a 3-phase study designed to provide solid data on the usefulness of medication algorithms. In phase 1, medication algorithms for the treatment of schizophrenia, major depressive disorder, and bipolar disorder were developed. Phase 2 was a feasibility study of these algorithms, and phase 3, now underway, compares the costs and outcome in 3 groups, one using a combination of an algorithm and patient/family education, a second using treatment as usual in a clinic that uses an algorithm for a different disorder, and a third using treatment as usual in a nonalgorithm clinic. *(J Clin Psychiatry 1999;60[suppl 3]:16–20)*

The mental health system in the public sector is besieged by conflicting demands to improve quality of care, increase patient access, improve patient outcomes, and, simultaneously, reduce or contain costs. Public policymakers across the country are struggling with bottom-line issues, and policy decisions are often based more on politics than on data. Medication algorithms are a possible way of bringing uniformity to treatment of psychiatric disorders at predictable costs as well as providing a standard against which treatment outcome and costs can be measured.

The Texas Medication Algorithm Project (TMAP) was designed to provide solid data on the usefulness of medication algorithms.[1] An example of public and academic cooperation, TMAP was initiated in 1995 by a group from the academic community and the state Department of Mental Health and Mental Retardation (MHMR) (1) to develop, by using scientific evidence and clinical consensus, medication algorithms for the treatment of schizophrenia, major depressive disorder, and bipolar disorder; (2) to conduct a pilot feasibility study that estimated the resources required and defined methods for implementing the algorithms; and (3) to compare the costs and outcome of treatment as usual with the use of a combination of the algorithm, patient/family education, and staff support. To fulfill the primary goal of the project—to create a system of mental health care in which all providers would be operating from the same conceptual framework—the researchers decided to create medication algorithms that were based primarily on scientific data and, in areas where there was a paucity of scientific data, on expert consensus.

Medication was selected as a focus of the study for 3 reasons. First, in clinical practice, there are few guidelines for using psychotropic drugs; thus, many psychiatrists devise their own treatment strategies. Patients in public health care systems often report that their medication regimen is changed each time they switch physicians. Sometimes the lack of established medication guidelines can be used by legislators to justify low funding levels for mental health programs. Second, the field of psychopharmacology has changed dramatically in the past several years because of the advent of new medications. Physicians may find it difficult to integrate the vast amounts of new information and synthesize this information to the point that they feel comfortable using the new agents. Finally, cost containment has become a driving factor in this era of managed care. In many private and public health care systems, cost containment has become the first consideration in choosing a medication as, for example, when patients are required to fail treatment with tricyclic antidepressants before a selective serotonin reuptake inhibitor (SSRI) can be prescribed.

PHASE 1: DEVELOPMENT OF MEDICATION ALGORITHMS

A large number of organizations representing patients and their families, physicians, psychiatrists, and other agencies who use, provide, or pay for mental health care in

Texas were included in the planning process for TMAP. Thus, the project became a collaborative effort, and those who were charged with implementing TMAP were included in the planning phase. In phase 1 of TMAP, medication algorithms were created for the treatment of schizophrenia, major depressive disorder, and bipolar disorder. An algorithm is a step-by-step process in which a formula guides the moves between steps. To create a medication algorithm, it is necessary to formalize (1) strategies, i.e., decide which medications would be used first, second, and third; and (2) tactics for using these medications, i.e., dosage, titration schedule, and length of trial. The algorithms for psychotic and nonpsychotic major depressive disorder were developed during phase 1 (Crismon ML, Trivedi MH, Pigott TA, et al., unpublished data, 1998). The schizophrenia and bipolar disorder algorithms were based on the Expert Consensus Guideline Series,[2,3] but the algorithms were subsequently modified as new medications became available.

The guiding philosophy of TMAP was that first-line treatment should be the safest and most efficacious treatment available. Simplest interventions and monotherapy would be tried before complex polypharmacy. If patients failed to respond to simple interventions, subsequent steps would tend toward greater complexity of treatment and increased risks of side effects. When appropriate, multiple medication options were provided for physicians, and patient preference could be used to guide clinical decisions. For example, the algorithm for nonpsychotic major depressive disorder includes 4 different classes of newer agents as first-line treatments; physicians use clinical judgment to select a specific first-line treatment for an individual patient. Tricyclic antidepressants were excluded as first-line treatment because of their side effect and safety profile. This decision to use the newer agents first was expected to increase the initial cost of treatment but reduce overall costs because of improved safety and reduced side effects when the algorithm was followed. Participating physicians were expected to use rating scales, and training on the use of rating scales was provided. Patient preference was another factor that was included in clinical decision-making. When the efficacy and safety of different agents were similar, the side effect profile was to be the driving force in choosing treatment. Some patients might prefer weight gain to insomnia while others may be more concerned about sexual dysfunction. Patients who are involved in the decision-making process are more likely to adhere to treatment.

After the guiding principles were established, levels of response were defined and critical decision points determined. A 0 to 25% reduction in symptoms was defined as nonresponse, a 26% to 50% response was considered partial response, and a more than 50% reduction in symptoms was assessed as response. Decision points regarding time and sequence were established on the basis of scientific data for each particular treatment.

The antipsychotic schizophrenia algorithm, which is a revision of the one published in the Expert Consensus Guideline Series,[2] currently suggests risperidone, olanzapine, or quetiapine as first-line treatment for patients both with and without a history of failure to respond to antipsychotic therapy (Figure 1). A patient who does not respond to one atypical antipsychotic is given a trial of another. If noncompliance is an issue, the patient is administered either haloperidol decanoate or fluphenazine decanoate. At stage 3, nonresponders to atypical antipsychotics are given a typical antipsychotic, and those with a history of nonresponse to typical antipsychotics are offered clozapine treatment. Various augmentation strategies are used for patients who either refuse to take or fail to respond to clozapine therapy. TMAP provides a procedure manual for every decision point from the selection of a drug dosage to treatment of side effects. Rating scales that assess symptoms, e.g., Brief Psychiatric Rating Scale, and function, e.g., Multnomah Community Ability Survey (MCAS), are used to judge response.

PHASE 2: FEASIBILITY OF USING MEDICATION ALGORITHMS

Phase 2 of TMAP involved an open-label investigation of the feasibility of using the algorithms and patient education materials routinely in the public sector.[4] Research questions included: (1) Did patients' symptoms and function improve in algorithm-based treatment? (2) Which medications were used and at what dosage? (3) What staff resources were needed to implement the algorithms? (4) How satisfied were physicians, staff, and patients with the algorithms? Patients (N = 222) in the state system who had a DSM-IV diagnosis of schizophrenia (N = 91), bipolar disorder (N = 69), or major depressive disorder (N = 62) and who needed a medication change were enrolled in the 4-month follow-up study that involved 40 physicians at 16 sites throughout Texas. Of these, 84 were inpatients and 138 were outpatients. At each site, a 2-physician team with clinical assistants implemented the algorithm and provided educational materials for 5 to 15 patients whose medication was being changed.

Symptoms and Function

Primary assessment tools included the Brief Psychiatric Rating Scale (BPRS)[5] and the MCAS,[6] which are used routinely throughout the public sector in Texas and thus were familiar to most of the TMAP physicians. A 30% decrease in the BPRS score was considered a clinically significant improvement, while a 40% reduction in BPRS score was rated as very substantial improvement for schizophrenia and bipolar disorder.[7] Symptoms improved for patients in all 3 algorithm treatment groups. After 90 days of treatment, 52% of patients with schizophrenia attained at least a 30% reduction and 35% achieved a 40%

Figure 1. Antipsychotic Algorithm*
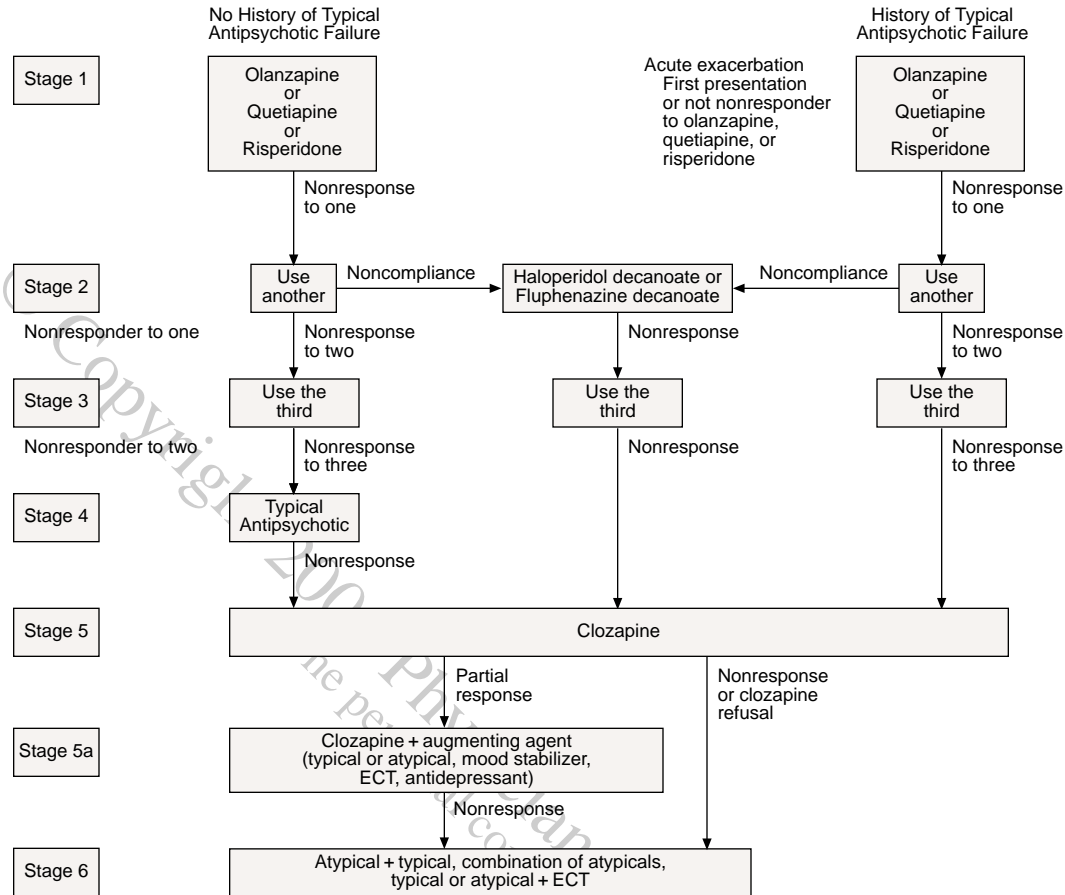
*The algorithm as it appears here is the algorithm currently in use. It is part of a series of schizophrenia algorithms.

decrease in BPRS score; 50% of patients with major depressive disorder attained a 40% reduction and 38% achieved a 50% reduction; and 55% of bipolar patients attained at least a 30% reduction and 40% attained a 40% reduction. Function also improved for all groups except outpatients with schizophrenia. Each increase of 5 to 10 points on the MCAS represents a major improvement in patient function. At baseline, inpatients with schizophrenia had a mean MCAS score of 41.2 and at endpoint, the score was 58.3. Outpatients with schizophrenia had a baseline MCAS score of 54.4 and an endpoint score of 55.2. This lack of improvement may indicate either that 4 months is insufficient time or that psychopharmacologic treatment alone is insufficient to enable patients with schizophrenia to achieve substantial improvement in functioning.

Medication and Dosage

Atypical antipsychotics were used most often to treat schizophrenia, lithium for bipolar disorder, and the SSRIs for major depressive disorder. Dosages of these agents were generally considered adequate in that they were within the range recommended in the algorithm. Of the 91 patients with schizophrenia, 62 (68.1%) received risperidone and 24 (37.3%) received olanzapine. Quetiapine was not available at the time of the pilot study. The mean maximum dose of risperidone was 5.7 mg/day and of olanzapine was 14.6 mg/day. Similarly, the mean maximum lithium dosage was 1022.5 mg/day for the 49 (71.0%) of 69 patients with bipolar disorder who were treated with lithium. Of the 62 patients with major depressive disorder, 25 (40.3%) were treated with fluoxetine and 16 (25.8%) with paroxetine. The mean maximum dose of fluoxetine was 30.0 mg/day, and the mean maximum dose of paroxetine was 26.2 mg/day.

Resource Use

The amount of time that staff spends with patients is one factor that affects overall cost of treatment, so TMAP measured the number and duration of office visits. For example, the initial outpatient visit for a patient with schizophrenia lasted 40.2 minutes, visit 2 lasted 34.9 minutes, visit 3 lasted 33.8 minutes, and visit 4, 33.3 minutes (Figure 2). During the initial weeks of administering a new

Figure 2. Texas Medication Algorithm Project: Outpatient Physician Time Per Visit*

*N varies per visit.

Figure 3. Will Continue to Use Algorithms After My Participation in TMAP
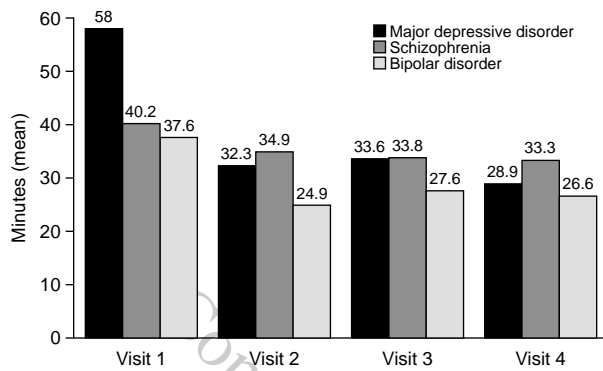
medication, patients need more physician time than they do when they are stable on a particular regimen. In addition, patients with schizophrenia often needed 30 to 40 minutes of nonphysician staff time both during and between visits.

Satisfaction With Algorithms

At the end of the phase 2 study, physicians were surveyed about their satisfaction with the algorithms. While physicians generally tend to be conservative about making changes in clinical practice, 84.7% of those surveyed either agreed or strongly agreed with the statement, "I will continue to use algorithms after my participation in TMAP" (Figure 3). Physicians treating inpatients with schizophrenia agreed or strongly agreed with the statement that using the algorithm was of assistance in making treatment decisions in 42% of the cases; for physicians treating outpatients, the percentage was 70%. Similar percentages were found for physicians treating inpatients (84%) or outpatients (55%) with major depressive disorder or inpatients (76%) or outpatients (62%) with bipolar disorder. Additionally, 72% of the physicians and 83% of nonphysician staff reported that the algorithms or the accompanying educational materials helped in clinical decision making.

Patient satisfaction was assessed by using the Texas Adult Mental Health Consumer Survey, an instrument that was developed by the Center for Mental Health Services[8] and modified for use in the Texas Department of Mental Health and Mental Retardation system. In general, patients who participated in TMAP reported being more satisfied with treatment and outcome than other patients with the same diagnosis who were treated without algorithms at the same sites. The most positive responses were clustered in the areas of empowerment, relationships with and access to physicians and other staff members, and improved functioning. For example, 64% of the TMAP patients as opposed to 45% of the non-TMAP patients agreed with the statement, "I, not staff, decided my treatment goals." Similarly, 88% of the TMAP patients and 71% of the non-
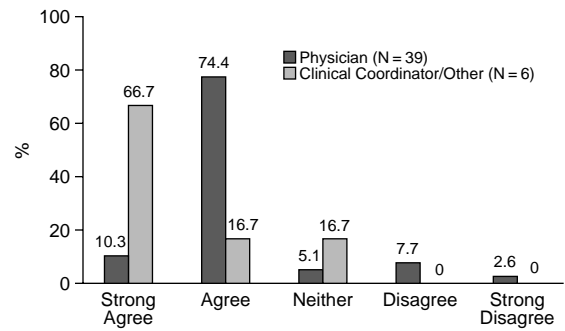
TMAP patients agreed with the statement, "Staff returned my calls within 24 hours." In terms of improved functioning, 64% of the TMAP patients as opposed to 49% of the non-TMAP patients agreed with the statement, "I do better in school and/or work," and 80% of the TMAP patients versus 65% of the non-TMAP patients agreed with the statement, "I have become more effective in getting what I need."

PHASE 3: COMPARISON OF OUTCOME WITH AND WITHOUT ALGORITHMS

Phase 3 of TMAP, which is now enrolling patients, is a prospective controlled study of 1400 patients who will be followed for 1 year to evaluate the clinical and economic impact of medication algorithms, clinical supports, and patient/family education. This phase 3 study includes 2 control groups, one consisting of patients who receive treatment as usual at a site that does not use algorithms and one consisting of patients who receive treatment as usual at a site that uses algorithms, but for different illnesses. The purpose of the second control group is to see if the algorithm culture influences the manner in which physicians treat patients whose care is not being guided by an algorithm. Patients will be compensated for undergoing independent outcomes assessments at baseline and every 3 months thereafter. In addition to evaluating changes in symptoms, quality of life, and both patient and staff satisfaction, the researchers will collect economic data on utilization of resources both within and outside the state mental health system according to a protocol developed by Kashner et al.[9] Specifically, the costs of psychiatric hospitalizations, emergency room visits, use of other psychiatric resources, and contacts with the criminal/legal, welfare, and general medical systems will be measured.

CONCLUSION

For patients with severe and persistent mental illness, including schizophrenia, bipolar disorder, and major de-

pressive disorder, medication algorithms may bring uniformity of treatment, predictability of costs, and quality of care at an overall lower cost to society. But hard data are necessary before medication algorithms can be widely accepted throughout the mental health systems in the public sector, and thus, it is important to evaluate the cost-effectiveness of algorithm treatments in a larger societal perspective. TMAP is a 3-phase project designed to provide the public health sector with data on the overall cost-effectiveness of using medication algorithms by evaluating direct and indirect costs to the system as well as symptom reduction and improvements in quality of life.

Drug names: clozapine (Clozaril), fluoxetine (Prozac), fluphenazine (Prolixin), haloperidol (Haldol and others), olanzapine (Zyprexa), paroxetine (Paxil), quetiapine (Seroquel), risperidone (Risperdal).

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