

**FINAL REPORT TO THE TRUSTEES OF THE ETHEL AND JAMES FLINN
FAMILY FOUNDATION**

Study: The Evaluation, Implementation and Utility of an Outcome Assessment Battery for Patients with Severe Mental Illness

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OVERVIEW

This is the final report for our grant, "The Evaluation, Implementation and Utility of an Outcome Assessment Battery for Patients with Severe Mental Illness." We received the three-year grant from the Ethel and James Flinn Family Foundation in December 1996, and a one-year no-cost extension in December 1999. The objectives of the grant were to design, evaluate, and apply practical and valid instruments to measure the effectiveness of treatments and programs for persons with schizophrenia and other serious mental illnesses. We completed three projects in fulfillment of those objectives. In the first, we participated in a national feasibility study of a new outcomes assessment battery (year one). The second project consisted of the design, evaluation, and implementation of our own assessment instrument (years two and three). The third was an investigation of current clinical practices and physicians attitudes in anticipation of implementing clinical practice guidelines in a community mental health center (extension year). The activities, results, and products for each of these projects have been described in our quarterly reports to the Flinn Foundation, and they are summarized in the following.

I. Evaluation of Outcomes Roundtable Assessment Instrument: a national feasibility study

During the first grant year, we participated in a national feasibility study conducted by Johns Hopkins and the University of Maryland to evaluate a new outcomes assessment survey for patients with schizophrenia. The survey, created by the Outcomes Roundtable, a group of mental health stakeholders (clinicians, researchers, patients and family members), assessed the multiple dimensions of treatment outcomes, including symptoms, functioning, quality of life, and service satisfaction.

We examined the validity, reliability, and feasibility of the outcomes survey in a sample of 40 patients with schizophrenia randomly selected from those discharged from the University of Michigan Hospital during the previous year. Baseline questionnaires were mailed to the 40 subjects. Those who returned the survey received a follow-up survey four months later. The study design also called for obtaining information about each patient from a family member and a provider.

Twenty-three of the 40 (58%) patients returned the baseline survey, and 16 of those completed the four-month follow-up. Thus, the overall response rate was 40%. Only three people consented to having us contact a family member or provider; therefore, we eliminated that segment of the study.

Although this study went to great lengths to get people to return their surveys (e.g., postcard reminders, re-sending questionnaires; phone contact), the response rates were low enough to threaten the validity of any findings. We concluded that surveying this population by mail is not a feasible method for measuring treatment outcomes. As a result, we decided to develop our own outcomes survey.

II. Design, Evaluation, and Implementation of the University of Michigan Health Opinions Survey (UM-HOS)

This project consisted of a series of studies that included: 1) design of an outcomes assessment instrument - the UM-HOS; 2) determination of the feasibility of using the UM-HOS with patients on the inpatient unit at University of Michigan Hospital; 3) examination of the validity and reliability of the UM-HOS; and 4) application of the UM-HOS in the evaluation of a new outpatient treatment program called Meds-Plus. A brief summary of each of these studies is described below.

A. Design of the UM-HOS

The UM-HOS was designed to be a self-administered outcomes assessment instrument that was practical (brief, easy to use), valid and reliable, and multidimensional (measuring symptoms, functioning, quality of life, and satisfaction with services). It incorporated questions from three widely used evaluation instruments: the Behavior and Symptom Identification Scale (BASIS-32); the Quality of Life Interview (QOLI); and the Client Satisfaction Survey (CSQ-8).

B. Inpatient feasibility study

The feasibility of using the UM-HOS for patients with schizophrenia and other severe mental illnesses was examined in a sample of 113 inpatients on the psychiatry unit of University of Michigan Hospital. The survey took 10-15 minutes to complete, and, despite the fact that patients were acutely ill, the response rate was 61%. We concluded that the survey was acceptable to patients with severe mental illnesses, and could be completed with little assistance.

C. Evaluation of UM-HOS

Our approach to validating the UM-HOS, was to examine the validity and reliability of one of its core components - the BASIS-32. Data for the validation study were obtained from two sources: 1) a study using the UM-HOS to evaluate a new clinic model, "Meds-Plus" (described in section D, below) and 2) the Lenawee County Community Mental Health (LCMH) agency, where the BASIS-32 was administered annually as a quality assurance measure.

The relatively high internal consistency of the Basis-32 subscales and 6-month test-retest correlation indicated that the BASIS-32 is a reliable measure of symptoms and functioning. However its validity - particularly for the subscales measuring impulsive/addictive behavior and psychosis - was questionable. These subscales need to be improved, perhaps with additional questions, before the instrument can be used again.

The results of this study were reported as a poster at the Association for Health Services Research Annual Meeting, Chicago, Illinois, 1999.

D. Use of the UM-HOS to evaluate "Meds-Plus," a New Multidisciplinary Outpatient Treatment Program for Persons with Severe and Persistent Mental Illness

In this study we used the UM-HOS to evaluate the effectiveness of the new "Meds-Plus" program at two sites - a University of Michigan outpatient clinic and a community mental health (CMH) center. "Meds-Plus" is a multidisciplinary (i.e., physicians, nurses, social workers) treatment program for persons with severe and chronic mental illness, whose symptoms are currently stabilized, and who, therefore need only routine medication monitoring, along with episodic psychological and social services. The program was designed to improve access, continuity of care, and patient satisfaction and to maintain or improve symptoms, psychosocial functioning, and quality of life.

Clients attending the "Meds-Plus" clinic during the first 3 months of its operation were asked to complete the UM-HOS during their first clinic visit and again after six months. Providers rated the severity of illness at these two visits using the Clinical Global Impressions scale (CGI) and the global assessment of functioning (GAF). Ninety-four patients (88% of those attending the clinics) completed the survey at their first visit, 53 (56%) completed the 6-month follow-up survey.

The results showed: 1) nearly 75% of the patients continued coming to the clinic after six months, and patients diagnosed with schizophrenia were more likely to continue than those with depression or bipolar disorder, 2) symptoms, functioning, and quality of life in these stable patients, remained stable over the six months, 3) patients were more satisfied with the services provided in "Meds-Plus" than with their former clinic, and 4) they particularly liked the multidisciplinary aspect of the program.

The study findings were presented to the clinic staff and administrators. The positive findings played an important role in the decision to continue the clinics at both of the sites.

The results were presented as a poster at the American Psychiatric Association Annual Meeting, May 15-20, 1999 in Washington, D.C.

III. Use of evidence-based clinical practice guidelines to improve treatment outcomes

The third project funded with this grant focused on improving treatment outcomes by assuring that the most effective medications are being used in community-based clinics. Over the past decade there has been a shift in the pharmacologic treatment of schizophrenia, from the older conventional antipsychotics to the new "atypical" medications. The "atypical" antipsychotics (clozapine, risperidone, olanzapine, quetiapine, and now ziprasidone) are more effective and have fewer serious motor side effects than the conventional drugs, but the atypicals are 50-100 times more expensive. As a result of the high cost, many managed care organizations have limited the choice of

antipsychotics that physicians may use. To help ensure that medication decisions by clinicians and managers are based on empirical evidence and expert consensus of effectiveness, many government and professional groups have published treatment practice guidelines and algorithms for all of the serious mental illnesses including schizophrenia. However, none are widely used, and the reasons offered for this include: the paucity of data about specific outcomes associated with the use of guidelines; failure to obtain input on guideline content and implementation from the physicians who will use them; or failure to "customize" guidelines for use in a particular setting or clinical population.

To investigate the need for, and feasibility of, implementing medication treatment guidelines in CMH clinics, we examined these issues in four counties in southeastern Michigan (Washtenaw, Livingston, Shiawassee, and Monroe). The aims of the project were to identify current prescribing practices for schizophrenia, select a set of appropriate and acceptable treatment guidelines and implement them in community clinics, and then to evaluate the impact of the guidelines on treatment for schizophrenia. Each of these activities is described below.

A. Survey of current medication treatment practices and adherence to published guidelines at Washtenaw County Community Mental Health Center (WCMHC)

The objectives of this study were 1) to describe current medication prescribing patterns at WCMHC, 2) identify demographic, clinical, and provider factors associated with variations in practice patterns, and 3) assess the extent to which current practices conform to published guidelines, and 4) examine the feasibility of using medical record data for measuring treatment practices and outcomes.

Using the medical chart abstraction form we designed, data were obtained from the records of 309 patients on demographics, symptoms, severity of illness, current medications, and utilization of services. Our conclusions can be summarized as follows: 1) variations in prescribing practices were associated with patient demographics, clinical

characteristics, and physician affiliation (academic or community); 2) very few of the current guidelines provide the operational criteria or standards of conformance needed to make them useful; 3) information currently available in the medical charts was not adequate to assess conformance to practice guidelines.

As a result of the last finding, the progress note used by physicians at Washtenaw CMH to record clinical findings during each patient encounter, has been redesigned to ensure that the information required to assess treatment outcomes will be recorded. This new form will enable us to conduct prospective studies in the future to identify which treatments work for which patients.

These findings were reported in a presentation to the Michigan Association of Community Mental Health Boards, Annual Fall Conference, September 27, 1999, Traverse City, and as a poster at the American Psychiatric Association's Institute on Psychiatric Services Annual Meeting, New Orleans, Louisiana, 1999.

B. Conduct a review of current pharmacologic treatment guidelines for schizophrenia and select a set that would be most appropriate for use in the CMHC's in southeastern Michigan

After a careful review of the most widely used treatment guidelines for schizophrenia, we selected the Texas Medication Algorithm (T-MAP) as the basis for building a Michigan-specific set of guidelines. The algorithms are specific, comprehensive, and flexible. They were developed for use in community clinics by the physicians as the Texas Department of Mental Health and Mental Retardation, and have been used and evaluated in community-based clinics.

C. Survey the attitudes of CMHC physicians toward guidelines for treating mental illness in four communities in southeastern Michigan

Physician resistance is often cited as one of the most important reasons why guidelines have not been used more widely. To increase the potential for successful guideline implementation, we asked physicians practicing in the four CMH's in southeastern Michigan to complete a survey about their opinions of guidelines in general, and specifically, the T-MAP algorithms for schizophrenia, major depressive disorder, and bipolar disorder. The purpose of the survey was threefold: 1) to assess the extent of physician agreement with each recommendation in T-MAP, 2) to obtain suggestions for modifications to T-MAP that would make the guidelines more acceptable to the CMH physicians, and 3) to provide an opportunity for physician input on the content of, and implementation strategy for, clinical guidelines.

Physicians received a copy of the T-MAP guidelines and a questionnaire, which assessed their attitudes toward, familiarity with, and past use of, each of the algorithms. The survey took about one hour to complete. (A copy of the T-MAP algorithm for schizophrenia and a sample of the questions relating to it are included in this report.) Twenty-four surveys were mailed and 13 (54%) were returned. Highlights of the findings include:

- * 90% agreed guidelines should be general and flexible versus specific and prescriptive
- * More than 50% agreed guidelines should define how to measure response to a specific agent; fewer agreed that guidelines should specify dose
- * Less than 50% agreed guidelines should specify dosage, side effect management, or augmentation strategies
- * Psychiatrists were generally familiar with TMAP, none used it
- * Great variability in level of agreement with use of specific psychotropics at certain stages
- * Disagreement as to which factors should be weighed most heavily in making

prescribing decisions

The next step in this process will be to design a Michigan algorithm, based on the results of the studies described above, that will be acceptable to physicians and managers at the CMHC's; to implement the algorithm; and evaluate it's use and impact on treatments and outcomes of care.

These results will be presented at a Symposium on Rational Psychopharmacology at the University of Michigan Health System Towsley Center for Continuing Medical Education on September 25, 2001. The results have also been submitted for a poster presentation at the American Psychiatric Association Institute on Psychiatric Services annual meeting to be held October 10-14, 2001 in Orlando, Florida.

CONCLUSION

This grant from the Flinn Foundation has enabled us to develop tools and techniques to improve the treatment and services for persons with severe mental illness in Michigan. We will continue to use the UM-HOS to evaluate the effectiveness of new programs, and we will continue to expand the use of guidelines and algorithms to assure that the most effective treatments are offered in our communities.