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Evaluation of an instructional program for improving medication compliance for chronically mentally ill outpatients

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Abstract

Outpatient medication adherence is a major problem, especially for patients repeatedly hospitalized for psychiatric disorders. This study included 39 such patients who were receiving case management services from a community mental health center. Patients were matched and randomly assigned to receive in a single session either (1) information regarding medication and its benefits, (2) guidelines for assuring adherence which encompassed all phases related to pill-taking including filling prescriptions, use of a pill container, transportation, self-reminders, doctor's appointments and so forth, or (3) the same guidelines as (2) above but given in the presence of a family member who was enlisted in support. The results showed that adherence increased to about 94% after the guidelines were given for both the individual and family guideline procedure, whereas adherence remained unchanged at 73% after the medication information procedure. These results suggest a practical means for assuring a high level of medication adherence for patients with psychiatric disorders. © 1998 Elsevier Science Ltd. All rights reserved.

Medication compliance is the degree to which patients take their prescribed medications, acceptable rates being considered to be between 80-100% (Goldsmith, 1979). Extensive research has indicated that 33% to 50% of patients fail to follow the prescription correctly and more than half prematurely discontinue the medication (see reviews by Haynes et al., 1979; O'Brien et al., 1992). Psychotropic medication noncompliance has been similarly great (e.g. Crawford&Forrest, 1974; Falloon et al., 1978) for the mentally ill, ranging from 30% to 60% non-compliance (Ley, 1988). 10% of all hospitalizations (McKenney&Harrison, 1976) and 50%

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of psychiatric rehospitalizations (McFarlane et al., 1995) are attributed to medication noncompliance.

Surprisingly, noncompliance has not generally been found to be predicted by demographic factors such as age, sex, race, education, income and religion; nor disease characteristics such as diagnosis (except for a psychiatric disorder), severity, duration, or previous hospitalization (see review by Haynes, 1976). The principal factors associated with non-compliance appear to be the complexity of the regimen, such as the number of doses and their frequency per day, external motivational factors such as family support, direct physician instruction and accessibility factors regarding the clinic and pharmacy (Haynes et al., 1979).

Because of the demonstrated importance of neuroleptics in outpatient treatment for schizophrenia, several types of outpatient programs have included medication compliance programs (Falloon et al., 1985; Liberman et al., 1986; Eckman et al., 1990) and several programs have been suggested (e.g. Shaw, 1986; Green, 1987). Controlled outcome studies for improving compliance have been scarce. Psychoeducational procedures were found effective by Glimon et al. (1993) using verbal reports of compliance, but ineffective by others when provided either to the patient or to the partner (Youssef, 1983; Deckle&Christensen, 1990; van Gent&Zwart, 1991). Pill-taking reminder procedures have been found effective with non-patients (Azrin&Powell, 1969; Epstein&Masek, 1978); family support procedures were effective in increasing disulfiram compliance of alcoholics (Azrin et al., 1982).

Several methods of measuring compliance have been used, but major problems of validity have been found for all as noted in reviews by Blackwell (1976), and Dunbar&Agras (1980) and specifically for patients' self-report (Park&Lipman, 1964; Bronson, 1991), family report (Boczkowski et al., 1985), pharmacy records (Bronson, 1991), clinical outcome measures (Hyman et al., 1995) and blood tests (Erickson, 1993; Hyman et al., 1995). Pill counts have been the most commonly used objective measure (e.g. McKenney et al., 1973; Haynes, 1976, 1982; Epstein&Masek, 1978; Logan et al., 1979) and appear to be the most valid if done unobtrusively without the patient's awareness (Pullar et al., 1989).

A great need exists for a method of improving medication compliance for chronically mentally ill patients. The present conceptualization utilizes a 'systems' approach (see Azrin, 1977) which addresses the multiple influences on successful performance of complex performance as in job-finding (Azrin et al., 1975) or the token economy (Ayllon&Azrin, 1968). This strategy was used to provide guidelines suggested by the above-noted findings for each step of the behavioral sequence from making clinic appointments to the actual ingestion of the medication including transportation to the clinic and pharmacy, reporting symptoms to the psychiatrist, assuring funds for medication payment, storing the medication, clear reminders for taking the usual multiple medications at the intended time of the day, and family support. This 'systems', or combination approach, has been advocated as well for medication compliance by Haynes et al. (1987) who concluded on the basis of their extensive review of the literature that "there has been no study that has satisfactorily shown that a single intervention of any sort is sufficient to improve long-term compliance...long-term compliance enhancement requires *combinations* of interventions" (p. 160). Methodological considerations included a controlled experimental design with random assignment, an unobtrusive objective pill count measure of compliance with inter-observer reliability and use of an active treatment control condition as well as a separate condition that isolated the family influence factor. The

unobtrusiveness of the pill count is especially critical in this area since the patient's awareness of this has been noted to influence the self-report and possibly the number of pills presented in an otherwise controlled study (Boczkowski et al., 1985) with schizophrenic patients.

1. Method

1.1. Subjects

The final study sample consisted of 39 subjects selected from the chronically mentally ill patients currently receiving case management and psychiatric outpatient services at a Community Mental Health Center. A total of 49 patients were invited to participate in this research. Of this group, three declined participation and seven were dropped from the study after the intervention was implemented for various reasons: four patients were dropped from the patient + family guidelines condition, one due to a pregnancy, one patient was abusing illicit drugs, one refused the procedure and another moved to another country; one patient in the patient-guideline condition was incarcerated after the intervention; one patient in the psychoeducational condition was dropped due to illicit drug abuse, while the whereabouts of another could not be determined at the follow-up. The most frequent drugs prescribed were Haloperidol, Lithium, Risperidone, Benztropine, Trazodone, Sertraline, Fluoxetine and Divalproex sodium. The demographic characteristics of the sample are presented in Table 1. The primary diagnoses were Schizophrenia, Bipolar I Disorder, or Major Depressive Disorder.

Table 1
Demographic characteristics of the sample ($N = 39$)

Diagnosis (DSM-IV)	N (%)
Schizophrenia	21 (53.8%)
Bipolar I Disorder	10 (25.6%)
Major Depressive Disorder	8 (20.5%)
Ethnicity	
Caucasian	25 (64.1%)
African-American	5 (12.8%)
Hispanic	6 (15.4%)
Native American	2 (5.1%)
Asian	1 (2.6%)
Sex	
Male	16 (41%)
Female	23 (59%)
	M (S.D.)
Age	38.46 (8.61)
Education	12.41 (1.58)
Dosage per day: range 1–12	5.46 (1.21)
Psychiatric hospitalizations (past year)	0.54 (1.21)
Psychiatric hospitalizations lifetime	6.05 (5.16)

with a mean of 6 previous psychiatric hospitalizations and currently receiving a mean of 5.46 (range 1 to 12) doses per day.

Inclusionary criteria to the study were as follows: (1) currently receiving psychotropic pill medication prescriptions (i.e. not solely injections) from the CMHC, (2) at least 18 years of age to assure legal adult status, (3) not diagnosed as mentally retarded to ensure comprehension of the project instructions, (4) living with an adult family member who agreed to accompany the patient to the clinic for the study sessions, (5) a primary diagnosis of Schizophrenia, Bipolar I Disorder, or Major Depressive Disorder, (6) at least one hospitalization due to a psychiatric disorder, (7) not currently receiving Clozapine since this drug entailed special monitoring and feedback which was already provided to the patient by the case manager and the psychiatrist and (8) not abusing alcohol or controlled substances as per the case manager's and subject's report. Information regarding the criteria were obtained from the patients' files except for the family participation criterion which was obtained through a phone call.

1.2. Research design

The research design was a standard combination of a within-subjects and between-subjects design. The within-subjects feature derived from obtaining pre-intervention measures against which the subsequent follow-up measures were compared to provide a measure of change for each subject. The between-subjects feature was a standard group design in which three conditions were compared: (1) patient + family guidelines condition, (2) patient guidelines condition and (3) a psychoeducational condition. The subjects were divided into triads matched for (1) DSM-IV diagnosis and (2) the number of doses per day within each triad since these two factors have been found to be correlated with the degree of medication compliance, thereby providing greater equivalence between treatment groups. None of the subjects exhibited paranoid ideation regarding their medications (e.g. their medications were poison). Subjects within each triad were then randomly assigned to one of the 3 experimental conditions. For the seven patients who dropped out, each was replaced by the same random draw with the same matching criteria.

1.3. Measures

1.3.1. Pill count

Medication compliance was ascertained by a count of the number of pills in the subject's possession and compared to the number that should have been present if the prescribed number had been used over the designated time period. The formula for this calculation, as also used in previous studies, was:

$$\% \text{Compliance} = \frac{\text{number of pills taken}}{\text{number of pills prescribed}} \times 100$$

In calculating the number of pills taken, the number of pills remaining (as determined by a count of the pills in the container) is subtracted from the number obtained from the pharmacy (as determined by the pharmacy record). This apparently valid calculation appears to be the method used in previous studies (e.g. Youssef, 1983). This formula assumes that no pills were

remaining at the time that the prescription was refilled. Otherwise, the formula yields an inflated indication of non-compliance. For this reason, a pill count was also taken at a pre-intervention session one month prior to intervention. The revised formula for the number of pills taken was the number of pills remaining in the container in the pre-intervention session plus the number obtained from the pharmacy in the interim minus the number counted at present, divided by the number of pills prescribed for that period $\times 100$.

A second source of error in the use of the above formula was the assumption that the number of pills in the most recent single pharmacy container represented the actual number of unused pills. However, our pilot study with 18 patients, which also included intensive interviews and some home visits, revealed that leftover pills were often present in other containers. Use of the unrecorded pills in these other containers by the subjects would also lead to an overestimation of non-compliance. Consequently, the present procedure urged the subjects to bring in all containers that contained any pills.

The pill count was conducted out of sight in an adjoining room where a photocopy was taken of the pills so that independent counts could be made later from the photocopy by two staff members for reliability assessment. The photocopy was taken by emptying all pill containers onto a transparent sheet placed on a photocopier surface. The inter-rater reliability by the two staff members was $r = 0.99$. The pill count was taken at the pre-intervention, intervention and follow-up session. Pre-intervention compliance was calculated by the above formula based on the difference counts obtained between the pre-intervention and intervention session and similarly by the difference counts between the intervention and follow-up session for the post-intervention measure of compliance.

1.3.2. Symptoms Checklist 90-R (SCL-90-R) (Derogatis, 1977)

The SCL-90-R is a 90 item self report questionnaire regarding psychiatric symptomatology yielding 9 primary symptom dimensions and 3 global indices of distress. A number of medication compliance studies (e.g. van Gent&Zwart, 1991; Glimon et al., 1993) have used this instrument as a measure of psychoactive status. This questionnaire was administered prior to intervention and at follow up.

1.3.3. Treatment credibility

To assess the patients' benefit expectancy level for each treatment, a treatment credibility questionnaire (Borkovec et al., 1987) was given at the end of the intervention session for all three conditions. The questionnaire utilized a 9-point Likert scale for the following three questions: (1) "Did the information we discussed today make sense?", (2) "How successful do you think this information will be?", (3) "How willing would you be to recommend this information to others?". Subjects were also asked to rate "What percentage of improvement in your mental condition do you expect if you follow these guidelines", from 0 to 100%.

1.3.4. Guideline adherence questionnaire

A questionnaire was completed by the subjects in the 2 guideline conditions at the follow-up session in which they rated their adherence from 0-100% to each of the guidelines that had been listed in the Medication Guideline pamphlet.

1.4. Procedure

All qualified subjects who had a forthcoming appointment with the clinic psychiatrist were contacted by phone requesting the subject to attend a session on the same day immediately following their visit with the psychiatrist. Subjects in the patient + family guideline condition were also asked to have a family member who was currently residing with them in the home to accompany them to the session. The intervention session lasted for 1 h for all 3 experimental conditions, approximately 45 min of which were spent on the medication guidelines or information. The investigator phoned all subjects and family members (if applicable) in all three treatment conditions 7 days post intervention to answer questions. A follow-up assessment session was provided 2 months after the intervention. To obtain timely assessment at this 2-month follow-up, a home visit was made for those subjects who failed to make the clinic visit at the intended time.

1.5. Patient + family guidelines condition

The patient and family member assigned to the patient + family guidelines condition were given a pamphlet titled 'Guidelines to Taking Medications', and read aloud each of the guideline steps. The specific guidelines were: (1) to use a transparent 28-compartment pill box, which was given to them, consisting of 4 compartments designating 4 time periods for each of the 7 designated days in a week in which to store the pill medications. The subject and family member together were instructed in its use by (a) displaying a sample pill box filled with various pills, (b) then demonstrating the proper use of the pill box given to the subject with their own medications in the appropriate compartments for the first day and (c) having the subject place the medications in the appropriate compartments for the remaining 6 days. The other guidelines beside (1) use of the compartmentalized pill box were: (2) taking medications at the same time, place, or occasion each day. (3) Taking medications in the presence of the family member. (4) Having both the subject and the family member check the pill box, which was to be located in a visible location, throughout the day to ensure that medications were actually taken. (5) Having both the subject and the family member take their respective medications together when possible. (6) The family member giving compliments to the subject for taking medications. (7) Identifying and stating to oneself the positive consequences of pill taking (e.g. "I feel less tense when I take all my medications"). (8) Refilling the prescription 1 week before medications were used up. (9) Calling the clinic for an appointment, or for a prescription refill, well in advance, or for the psychiatrist to authorize the patient's pharmacy to refill the prescription. (10) Seeking financial assistance to help pay for medications if this was a burden (a list of clinic-affiliated agencies providing free or discounted prescribed medications was provided). (11) Speaking to the pharmacist to obtain information regarding possible precautions and a medication description sheet. (12) Jointly refilling the pill box at the start of each week with all medications. (13) Taking the pill box with them when away from home. (14) Discussing side effects, effectiveness, symptoms and expense of the drugs with the psychiatrist by means of (i) having the family member attend all of the subject's medical appointments and (ii) writing down symptoms, side effects, questions and so forth on a provided sheet of paper to be given immediately to the psychiatrist at the start of each visit.

(15) Providing strategies to temporarily relieve side effects as they occur. (16) Having all prescriptions filled at the same pharmacy. (17) Having the family member ensure transportation to the clinic and pharmacy for the patient. (18) Avoiding the consumption of alcohol because of drug interactions. (19) Asking the subject and family member to review all of the above steps if they noticed a symptom change or side-effects. The separate patient and family pamphlets utilized a fill-in format whereby they wrote down their willingness (e.g. 'yes') and the specific actions they would take (e.g. name of the family member, pharmacy, time and place and occasion for taking medication, transportation assistance, etc.) to implement each guideline. The staff member assisted them in formulating the fill-in answers for each guideline, encouraged a commitment of adherence to each, and were given the pamphlet to keep as a reminder.

1.6. Patient guidelines condition

The patients in the patient guidelines condition received identical instructions to the those in Section 1.5, except that the guidelines entailing family member support were omitted and no family support was solicited; no family member was present. Additionally, these subjects were neither encouraged nor discouraged to enlist the assistance of a family member with regards to medication administration or to give the pamphlet to family members to read.

1.7. Psychoeducational condition

In the psychoeducational condition, the subjects individually met with the staff member without the family member. An informational pamphlet describing psychotropic medications was given to the patient and read aloud by the investigator. This essay reviewed the major types of neuroleptic, antidepressant and mood stabilizer drugs, outlined their histories, discussed the factors related to drug efficacy, potency and side effects of each drug and briefly outlined the mechanism of action for each. The subject was encouraged to ask questions and to describe the experiences (e.g. side effects, benefits, etc.) with their own psychotropic medications. The examiner gave empathic or informational, but non-directive responses to any patient concerns or questions.

The above procedures ensured comparability between conditions as to the amount of time and attention provided to the subjects: all received a pamphlet which was read aloud to them and taken home and all were contacted again within 7 days to answer questions.

2. Results

2.1. Demographic comparisons

The three groups of subjects did not differ from each other on any of the demographic or medication-related variables shown in Table 1 (diagnosis, sex, age, etc.) using one-way ANOVAS or χ^2 analysis except for a lower number of lifetime psychiatric hospitalizations for the psychoeducational condition ($M = 2.58$, $S.D. = 1.56$) than either the family + patient

Table 2

Mean percent compliance with prescribed medication pre-intervention and at follow-up for the patient + family guidelines, patient guidelines and psychoeducational procedures; $N = 39$

Condition	Pre-intervention,		Follow-up,		Pre versus follow-up	
	<i>M</i>	(<i>S.D.</i>)	<i>M</i>	(<i>S.D.</i>)	<i>t</i>	<i>p</i>
Patient + family guidelines	76.24	(25.26)	95.03	(6.38)	2.49	<0.05
Patient guidelines	69.52	(29.21)	92.01	(9.54)	3.20	<0.01
Psychoeducational	73.37	(26.53)	73.62	(23.07)	0.05	n.s.

guidelines ($M = 7.92$, $S.D. = 5.66$) or patient guidelines ($M = 7.38$, $S.D. = 5.47$) conditions (both $ps < 0.01$).

2.2. Medication compliance

Table 2 and Fig. 1 show the compliance rates (% of pills taken of those prescribed as determined by pill count) for the three treatments. A 2(time) \times 3(condition) repeated measures ANOVA with a repeated measures on time yielded a significant interaction effect $F(2, 36) = 3.27$, $p = 0.05$ indicating a differential pre versus follow-up treatment effect between treatment conditions. Analysis of simple effects revealed no significant pretreatment differences between the three groups. Within-groups analyses from pretreatment to follow-up (see Table 2) indicated significantly increased compliance for both the patient + family guidelines and

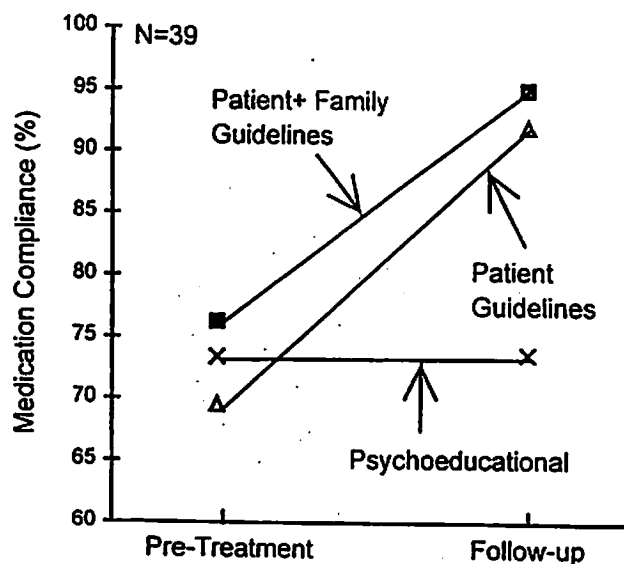


Fig. 1. Medication compliance before and 2 months after being given instructional guidelines either to the patient alone (patient guidelines) or to the patient and a family member (patient + family guidelines) as compared with providing general information regarding psychotropic medication effects (psychoeducation). Compliance was measured as the % of the pills taken of those prescribed.

patient guideline conditions; the patient psychoeducational group showed no change remaining constant at approximately 73% compliance pre-and post-intervention. Between-group analyses were conducted at follow-up using the pre-treatment compliance scores as covariates. The family + patient groups showed significantly greater compliance ($M = 95.03\%$) than the patient psychoeducational group $F(1, 25) = 12.01$ $p < 0.01$; the patient guideline group also showed a significantly greater compliance ($M = 92.01\%$) than the patient psychoeducational group $F(1, 25) = 12.90$ $p < 0.01$. The two guideline groups did not differ from each other $F(1, 25) = 0.62$, n.s.) at follow-up.

Examination of the individual subjects' data for near-perfect compliance at follow-up revealed that the proportion of patients showing compliance ratios of 90% or greater was 100% (13/13) for the patient + family guideline condition, 92% (12/13) for the patient guideline condition and 46% (6/13) for the psychoeducational condition. At pre-intervention, the corresponding % of near-perfect compliance for patients were 46, 38 and 53% respectively. χ^2 analysis indicated that the differences were statistically significant combining the 2 guideline conditions versus the psychoeducational at follow-up ($\chi^2 = 10.40$, $p = 0.001$).

2.3. Treatment credibility

In response to the treatment credibility questions (Borkovec et al., 1987), that were given at the end of the intervention session, the mean rating on the 9 point Likert scale was 8.87 (S.D. = 0.47) as to whether the guidelines/information 'made sense', 8.54 (S.D. = 1.0) as to whether they 'would be successful' and 8.59 (S.D. = 0.99) as to whether they would 'recommend this information to others', and estimated a mean 84.36% (S.D. = 21.74%) 'improvement' in their condition resulting from the provided guidelines/information. No differences between conditions emerged, all F s being statistically non-significant for all the credibility questions.

2.4. Symptom checklist (SCL-90^{-R})

Each of the 3 summary and 9 clinical subscales of the SCL-90^{-R} were subjected to a 2(time) \times 3(condition) repeated measures ANOVA with repeated measures on time. Neither the interaction nor the main effects between conditions or across time were statistically significant.

2.5. Medication management guideline adherence

The mean percentage of time that the subjects in the two guideline conditions ($N = 26$) reported in the questionnaire at follow-up that they had adhered to each of the specifically suggested guidelines was as follows: (1) ensured adequate payment (92.31%), (2) filled prescriptions at the same pharmacy (88.46%), (3) took medications at the same time, place, or occasion (83.41%), (4) used the compartmentalized pill box (78.40%), (5) refilled the pill container at the start of each week (73.2%), (6) refilled the prescription one week beforehand (62.31%), (7) reported side-effects, symptoms, insufficient effects and other concerns to the psychiatrist (59.27%), (8) checked pill box throughout the day (56.0%), (9) spoke to the Pharmacist regarding administration precautions (48.0%), (10) took the pill container when away from home (46.92%) and (11) wrote questions/concerns beforehand for the psychiatrist

(23.08%). Additionally, the mean percentage of time that the subjects in the patient + family guideline condition ($N = 13$) reported at follow-up that they had adhered to the guidelines specifically suggested for this condition was as follows: (1) a family member ensured transportation to the pharmacy (58.21%), (2) a family member ensured transportation to the clinic (57.69%), (3) family member was present when taking medications (55.0%), (4) family member gave compliments for taking medications (46.31%), (5) The family member and patient took medications together (45.53%).

2.6. *Correlates of medication compliance*

To determine demographic predictors of pre-intervention compliance, all demographic characteristics listed in Table 1 were analyzed by r for continuous variables or phi for categorical variables for their degree of correlation with the measured pre-intervention level of compliance. None of these correlations were statistically significant including age, number of hospitalizations, number of dosages per day, sex, diagnosis, education, number of side effects and ethnicity. To determine whether the degree of adherence to specific guidelines was associated with the degree of medication compliance, Pearson product moment correlations were performed at the follow-up for each of the suggested guidelines in the two guideline conditions ($N = 26$). It was found that the pill-count measured degree of medication compliance was (1) significantly associated with the reported percentage of times the pills were taken at the same time, occasion and place each day ($r(22) = 0.40$, $p < 0.02$) and (2) borderline significantly related to the reported percentage of use of the pill container ($r(22) = 0.32$, $p = 0.06$). None of the other guideline usage reports was significantly correlated with the pill-count compliance measure.

2.7. *Follow-up duration*

Although the follow-up measures were scheduled to occur precisely two months after intervention, some unavoidable variation occurred because of the failures to keep the clinic appointments at that time. The actual mean duration of follow-up was 69.46, 70.77 and 69.31 days, for the three intervention conditions, the difference not being statistically significant ($F(2, 36) = 0.05$, n.s.).

3. Discussion

The present level of medication compliance of the guideline subjects was near-perfect indicated by the mean of 94% of pills taken or by the 96% of patients taking 90% or more of the pills. The psychoeducational procedure served as a 'placebo' control, showing no increases in compliance.

Probable reasons for this high level of effectiveness appear to be the (1) specific nature of the guidelines, (2) the 'systems' approach of providing guidelines for all aspects of obtaining utilizing medication and (3) requiring the patient to indicate in writing and verbally their agreement/strategy for following each guideline versus passive reading or listening. The two

guideline practices most closely associated with high compliance were (1) use of the compartmentalized pill box and (2) taking medications at a predesignated time, place or occasion. Most of the other guidelines were reported to have been followed much of the time.

Two findings were surprising. First, the Patient + family guidelines condition did not show more benefit than the Patient guidelines condition. A possible explanation is that a 'ceiling effect' occurred; near-perfect compliance (92%) was attained when the patient alone was given the guidelines leaving little further room for improvement (95%) by involving the family. Alternatively, the patients in the patient guidelines condition may have given their family the guideline pamphlet, although not explicitly instructed to do so. The second surprising finding was the absence of improvement in clinical symptomatology as measured by the SCL-90^{-R}, associated with the increased compliance. This self-report measure may be insufficiently sensitive to the present degree of medication change, as has also been found in previous medication compliance studies (Deckle&Christensen, 1990; van Gent&Zwart, 1991; Glimon et al., 1993).

The results of this study indicate that medication compliance can be dramatically improved through this systems approach by providing patients with specific guidelines and strategies regarding medication administration. These procedures include using a pill box that provides adequate space for a full week's dosage, compartmentalized for the time of day and day of the week, rechecking the transparent pill box to assure all pills were taken, taking medications at the same place, time, or occasion each day, ensuring transportation to the doctor and pharmacy, reporting side effects and other symptoms to the doctor, providing resources to ensure that adequate payment for medications is available, obtaining information regarding side effects and the mechanisms of action from the pharmacist, filling all medications at the same pharmacy, taking the medication in the presence of a family member, using the same pharmacy for all prescriptions, rehearsing the specific benefits of compliance, renewing the prescriptions and refilling the pill container well in advance and enlisting family support and reminders for each step.

Special care was taken to adequately address methodological concerns. All subjects meeting inclusion criteria were invited to participate in the study, with only three choosing to decline thereby assuring representativeness of the study to the population of chronically mentally ill patients receiving case management services at a Community Mental Health Center. The instructions were written and standardized. Comparability of subjects between conditions was achieved by matching subjects by DSM-IV diagnosis and dosages per day prior to random assignment and pre-treatment compliance was comparable between conditions. An objective measure of medication compliance was obtained and inter-rater reliability for this measure was excellent, with the independent rater being blind to a subject's assignment and the specific aims of the study. Treatment credibility measures were obtained and indicated that all conditions were equally and highly credible. Measures of reported adherence to each guideline by the subjects were obtained and suggested that most of the recommended guidelines were followed by a majority of subjects. All conditions received equal intervention time and patient-staff interaction. Additionally, the psychoeducational condition served as a 'placebo' control as indicated by its high expectancy-of-benefit score. Previous outcome studies of medication compliance have not generally addressed all of these methodological concerns.

The present instructional program appears to offer a highly effective and practicable means of attaining medication compliance for psychiatric outpatients and may be applicable to non-psychiatric patients as well. The ease, cost-effectiveness and practicality of this procedure makes these guidelines of particular interest to psychiatrists, case managers, social workers, discharge planners and others who serve this population.

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