Prediction of Dose–Response Relations Based on Patient Characteristics

Wolfgang Lutz
University of Berne

Jenny Lowry
Loyola College

S. Mark Kopta
University of Evansville

Danielle A. Einstein
Westmead Hospital, University of Sydney

Kenneth I. Howard
Northwestern University

The recent discussion of evidence-based, adaptive treatment planning highlights the need for models for the prediction of courses of treatment response. We combine a dose–response model with growth curve modeling to determine dose–response relations for well-being, symptoms, and functioning. Hierarchical linear modeling was used to model each patient's expected course of improvement. The resulting predictions were cross-validated on two samples of psychotherapy outpatients. The results give further empirical support for the dose–response model and the phase

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Correspondence concerning this article should be addressed to: Wolfgang Lutz, Department of Psychology, University of Berne, Muesmattstr. 45, CH-3012 Berne 9, Switzerland. E-mail: wolfgang.lutz@psy.unibe.ch

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model of psychotherapy as well as for the usefulness of patient treatment response profiling for individual treatment management. © 2001 John Wiley & Sons, Inc. J Clin Psychol 57: 889–900, 2001.

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Recently, a growing demand has emerged for the use of empirically based information to guide mental health policy. Two different research methodologies have been developed to provide such empirical data. Each strategy has its own strengths and weaknesses.

Randomized clinical trial (RCT) methodology addresses a confirmatory-deductive goal and emphasizes the primacy of theory. It produces evidence to support or reject theoretical hypotheses. In general, this design investigates treatment efficacy questions that relate to patients suffering from a single, specific disorder. The main methodological concern is internal validity; that is, can observed differences between treatment groups on the dependent variable be unambiguously attributed to the influence of the independent variable (i.e., treatment) rather than to other factors such as preexisting differences between subjects?

The sine qua non of the RCT methodology is the random assignment of subjects to treatment and control conditions. Random assignment is supposed to produce equivalent groups with regard to uncontrolled potential causal variables (e.g., chronicity, age). The objective of this method is to ensure that chance is the only rival explanation for observed mean differences between groups. The RCT also tends to feature manualized, structured psychotherapies conducted by specially trained therapists so that treatment is applied reliably. Strict inclusion/exclusion criteria are used to obtain homogeneous patient samples.

A number of problems arise when this methodology of "true experiments" (Campbell & Stanley, 1966) is applied to patient populations. The main criticism usually concerns aspects of external validity (cf. Howard, Moras, Brill, Martinovich, & Lutz, 1996; Kopta, Lueger, Saunders, & Howard, 1999; Seligman, 1995). First, random assignment does not correct for self-selection. Patients who enter and remain in treatment are not a random sample of any defined patient population (e.g., they are self-selected on the basis of their willingness to volunteer for the study and to accept the experimental conditions). Due to the multitude of potentially causally relevant independent variables, the typically small sample size is rarely sufficient to ensure that random assignment equates groups with regard to possible confounds in any particular study. Second, in conducting research with patients, it is virtually impossible to avoid missing data (attrition) because patients routinely fail to provide complete information at all data points and fail to attend all treatment sessions as defined by the research protocol. Missing data always compromises random assignment to groups and makes secondary analyses necessary (e.g., Howard, Krause, & Orlinsky, 1986). Third, the manualization of treatment, the special training as well as monitoring of therapists, and the specification of the number of sessions compromise the external validity (generalizability) of RCT findings with regard to psychotherapy as practiced in actual clinical settings. Thus, the RCT is usually an artificial situation that may not accurately represent cause–effect relations in clinical practice.

The second type of treatment-focused methodology is the naturalistic quasi-experiment that tends to be employed in "effectiveness research." This exploratory-inductive methodology emphasizes the primacy of data and seeks to provide post hoc

theoretical descriptions for observed patterns. The strength here is preservation of external validity. Large patient samples with multiple problems who self-select their treatments are studied with more general, unobtrusive measures. This approach usually fails to eliminate alternative plausible explanations for the results. Thus, external validity is emphasized at the expense of internal validity. Statistical methods are usually used to explore or minimize the effect of potentially confounding variables.

We believe that optimal scientific support for a treatment should entail positive findings across both types of methodologies. Therefore, outcome results from both naturalistic mental health service research—which validates the effectiveness of psychotherapy as it is practiced in the field—and RCT research—which can confirm the efficacy of new therapies—are needed (Barlow, 1996; Goldfried & Wolfe, 1998; Lambert, 1998; Newman & Tejeda, 1996).

Even if psychotherapy for a given disorder has been found to be efficacious and effective, no therapy has been shown to work for every single patient with a particular problem. Independent of the research design, there is considerable within-treatment outcome variation (cf. Lyons & Howard, 1991) and an extensive overlap of outcome score distributions for treatment and control groups (Chassan, 1967; Howard, Krause, & Vessey, 1994). Thus, even if tests of average effects yield statistically significant differences between treatment and control conditions or between alternative treatments, estimates of success probabilities for the single case are invariably modest and imprecise.

These estimates of success probabilities for the single case are the kind of information that a practitioner needs. However, treatment-focused methods provide findings only about the average patient. Clinicians are not interested in the average patient. They want to know if their applied psychotherapy is working for the particular patient that they are currently treating.

To provide this kind of information, a case-based approach (Kazdin, 1982) is needed that can be applied to a single patient. Howard et al. (1996) introduced the technique of patient profiling. This allows for such empirically based, individualized psychotherapy management. This patient-focused method has its theoretical origin in the dosage and the phase models of psychotherapy. On the basis of a meta-analysis, Howard, Kopta, Krause, & Orlinsky (1986) described a dosage model of psychotherapeutic effectiveness that demonstrated a positive relationship with diminishing returns between the log of the number of sessions (dose) and the normalized probability of patient improvement (response). Subsequent dose–response work has provided evidence for the differential responsiveness to psychotherapy of various symptoms (Barkham, Rees, & Stiles, 1996; Kopta, Howard, Lowry, & Beutler, 1994), interpersonal problems (e.g., Horowitz, Rosenberg, Baer, Ureño, & Villaseñor, 1988; Maling, Gurtman, & Howard, 1995), and diagnoses (Howard, Kopta, Krause, & Orlinsky, 1986; Pilkonis & Frank, 1988).

The phase model (Howard, Lueger, Maling, & Martinovich, 1993) extended the dosage model. This model proposed three progressive, sequential phases of the psychotherapeutic recovery process: (a) remoralization, the enhancement of well-being; (b) remediation, the achievement of symptomatic relief; and (c) rehabilitation, the reduction of troublesome, maladaptive behaviors that interfere with adaptive life functioning. Following these two models, the decelerating curve of improvement for a patient could be attributed to the sequential change and increasing difficulty of treatment goals over the course of psychotherapy. Both the phase and dosage models rely on group data to provide outcome information for an average patient. However, research has shown that patterns of improvement for individuals vary substantially from the general trend (Barkham, Stiles, & Shapiro, 1993; Kadera, Lambert, & Andrews, 1996; Krause, Howard, & Lutz, 1998; Martinovich, 1998).

Patient profiling (Howard et al., 1996; Lutz, Martinovich, & Howard, 1999) addresses this problem. Assuming an underlying log-linear course of recovery, each patient's course over treatment can be modeled as a log-linear function of session number. More specifically, patient profiling utilizes a hierarchical linear modeling strategy (HLM; Bryk & Raudenbush, 1992) to model a patient's change over treatment as a log-linear function of session number; it uses seven pretreatment clinical characteristics to predict a patient's course of improvement (Table 1). Using the results of such an individualized growth curve analysis for a large sample of outpatients in psychotherapy, a single patient's course of treatment can be predicted as soon as intake information is available. Furthermore, ongoing therapeutic effectiveness can be assessed for a single patient by tracking the patient's actual progress in comparison to the expected progress based on the seven pretreatment clinical characteristics. Patient profiling's predictive accuracy is impressive, predicting the observed treatment response of 75% of 890 patients in a cross-validity study (Leon, Kopta, Howard, & Lutz, 1999).

Figure 1 presents a sample case, characterized by the 25th percentile "failure" boundary and "normal range" boundary that are derived from percentile ranks based on patient norms at intake. In addition, a 75th percentile bound (expected "successful" course) is included. These boundaries provide benchmarks against which to evaluate treatment progress.

The patient was a 26-year-old single, Caucasian woman in full-time employment suffering from a single episode of Major Depressive Disorder. The patient commenced psychotherapy with a Mental Health Index score (MHI; which is a global mental health score) of more than 1 *SD* below the average outpatient. At each assessment point, her overall status improved. However, the rate of improvement at Session 11 was lower than expected. This situation indicated the need for a progress review and a possible change in

Table 1
Seven Predictors of Improvement Selected from Lutz, Martinovich, and Howard's (1999) Hierarchical Linear Modeling Procedures for Patient Profiling

Variable	Description
Subjective Well-being	A scaled score. Items assess overall distress level, health, general energy level, emotional adjustment, life satisfaction, and everyday functioning.
Current Symptoms	A scaled score. Items assess frequency of symptoms experienced in the past month. Scale was based on DSM-III-R diagnoses. A minimum of three items corresponds to each of the seven subscales.
Current Life Functioning	A scaled score. Items assess extent to which psychological problems interfere with areas of life functioning including finances, relationships, work, and performance of routine tasks.
Global Assessment of Functioning	Clinician rating of overall functioning on a scale from 1 to 100.
Past Use of Therapy	An individual Likert-scale item measuring amount of previous therapy.
Duration of Problem	An individual Likert-scale item measuring the amount of time the problem for which the patient is currently seeking treatment has been a concern.
Treatment Expectations	An individual item measuring expectation of improvement in psychotherapy.

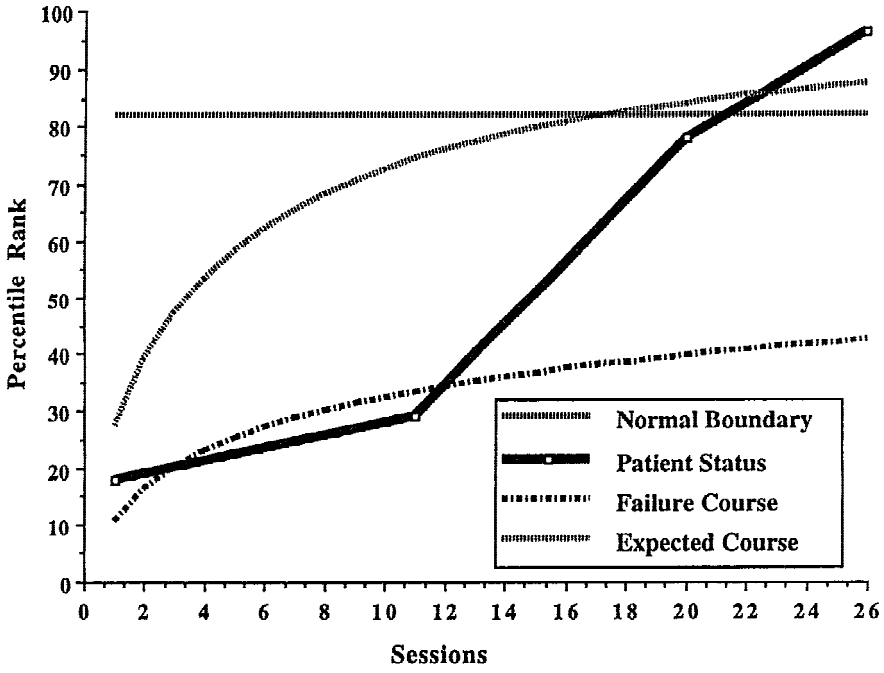

Figure 1. Treatment course for a case where outcomes data led to a change in treatment strategy.

the applied treatment. Following the review, the patient demonstrated greater improvement by Session 20 that continued and exceeded expectations by Session 28.

Thus far, patient profiling has employed only a global measure of outcome, that is, a general index of mental health. However, for the technique to be more useful in clinical practice, it should utilize more specialized measures in order to map a range of treatment goals (i.e., enough treatment to accomplish what?). This study first evaluated patient profiling in its application for modeling the different outcome phases—well-being, symptoms, life functioning—over time. Consistent with the phase model, the first hypothesis was that the percentage of patients improved or the probability of improvement for one patient (response) across sessions (dose) would be highest for well-being, followed by symptoms, and then life functioning. With regard to Hypothesis 2, dose–response relations were compared among the different clinical syndromes (e.g., depression, anxiety) with the expectation that patterns of response would vary as indicated by previous research on syndromes (Howard, Kopta, Krause, & Orlinsky, 1986) as well as individual symptoms (Barkham et al., 1996; Kopta et al., 1994). Finally, for Hypothesis 3, dose–response relations for the MHI were compared to dose–response relations for general improvement reported by Howard, Kopta, Krause, & Orlinsky (1986). It was predicted that these dose–response relations would demonstrate similar patterns.

Pretreatment and outcomes assessment questionnaires were administered to two samples of patients at intake and at a minimum of two session points during treatment. For a third sample, only pretreatment information at intake was available. Observed and expected trajectories were calculated for well-being, symptomatic distress, life functioning, clinical syndromes, and global mental health. The percentage of patients improved at specified dosage points within samples were calculated to create dose–response relations. The relations then were compared among the phases and the clinical syndromes.

Method

Participants

This study included three samples from a diverse national sample of psychotherapists and outpatients in individual psychotherapy whose treatment was monitored and managed with the assistance of the COMPASS® tracking system (for a description, see Sperry, Brill, Howard, & Grissom, 1996). The first two samples consisted of two subgroups of 445 subjects, randomly selected (without replacement) from an original database of 890 patients; these therapists and patients had completed the COMPASS® materials at a minimum of three sessions, including intake. All participants possessed an MHI *T*-score below 60. People with an MHI *T*-score below 60 are more likely to have scores representative of a patient population rather than a nonpatient population. That is, they are considered to be outside the normal range of functioning and meeting a treatment criterion of medical necessity (Jacobson & Truax, 1991). Sample 1 was primarily female (79.7%), Caucasian (89.2%), employed full-time (69.1%), and married (57%). The mean age of this sample was 37.2 years, with an *SD* of 9.8. Sample 2 shows the same pattern, primarily female (67.0%), Caucasian (88.6%), employed full-time (72.6%), and married (55.1%). The mean age of this sample was 37.5 years with an *SD* of 9.6.

Sample 3 consisted of 11,002 patients, also receiving psychotherapy in a range of clinical settings across the United States, but where only assessment at Session 1 was available. Its composition is comparable to that in Samples 1 and 2. The sample was primarily female (66.8%), Caucasian (84.8%), employed full-time (72%), and married (57%). The mean age was 36.5 years with an *SD* of 10.1. The statistics for all three samples are representative of the psychotherapy outpatient population in the United States (cf. Vessey & Howard, 1993).

Measures

The COMPASS® tracking system measures progress in outpatient mental health treatment based on both the patient's and clinician's perspectives. COMPASS® has been applied to a diverse national sample of therapists and psychotherapy patients to support the monitoring and management of their treatment. Validity and reliability coefficients for the COMPASS® scales are satisfactory (Howard, Brill, Lueger, O'Mahoney, & Grissom, 1995; Sperry et al., 1996). COMPASS® includes a global outcome criterion, the MHI, which consists of the sum of the Current Well-Being, the Current Symptoms, and the Current Life Functioning scales. For the Current Well-Being scale, patients rate their overall distress level, health, energy level, emotional adjustment, life satisfaction, and everyday functioning. The Current Symptoms scale is a 40-item scale in which subjects rate the frequency of symptoms experienced over the past two weeks. It reflects the Diagnostic and Statistical Manual of Mental Disorders-III-R (American Psychiatric Association, 1987) diagnoses of the following disorders and/or syndromes: adjustment disorder, anxiety, bipolar disorder, depression, obsessive-compulsive disorder, phobia, and substance abuse. The Current Life Functioning scale is a 24-item inventory in which patients rate the extent to which emotional and psychological difficulties are interfering with functioning in six main areas (e.g., work, family, self-management).

Procedure

For Samples 1 and 2, patients and psychotherapists completed the COMPASS® scales at intake and at a minimum of two session points during treatment. The second administra-

tion occurred between Sessions 3 and 9, with the other administrations occurring between Sessions 10 and 15. COMPASS® information for Sample 3 was available only for the intake session. Patients were informed that their responses would be used to track their progress and assess the quality of their treatment. The clinical treatment settings provided the questionnaires which, after completion, were returned to COMPASS® Information Services for scoring.

Analyses and Results

Previous researchers (Howard et al., 1996; Lutz et al., 1999) have used HLM on outpatient samples to model each patient's expected course of improvement across sessions as a function of pretreatment clinical characteristics of the patient. Seven variables were selected to predict the individual courses of treatment for the MHI (Table 1). The present study used these seven predictors to calculate each patient's expected course of improvement across sessions. Improvement was assessed using the MHI, Current Well-Being, Current Symptoms, Current Life Functioning, and five subscales of the Current Symptoms scale: adjustment disorder, anxiety, bipolar, depression, and obsessive-compulsive.

First, HLM was conducted on all of the aforementioned dependent variables for Sample 1 ($n = 445$), the derivation sample, with the seven profiling predictors entered. Next, the fixed effect regression coefficients generated from Sample 1 were used to predict the course of treatment for the patients in Sample 2 (first validation sample). To confirm the accuracy of these predictions using the same regression coefficients, the observed courses were calculated for patients in Sample 2. For the calculation of observed courses for Sample 2, we used ordinary least square estimates for intercepts and slopes based on each patient's observed data over the course of treatment. This method has the advantage (compared to pre- and postevaluation of improvement) of multiple points of assessment being taken into account for the parameter estimation and leads to a more reliable description of individual courses of treatment (e.g., Gibbons et al., 1993).

In order to classify predicted and observed treatment courses as improved or not improved, we used a reliability-based improvement criterion (cf. Jacobson & Truax, 1991). Reliable improvement was defined as a change of 1.04 *SEM* (85%, one-tailed confidence bound) in the observed course from intake to the specified dosage point. Then, using the expected and observed courses for each patient, observed and expected rates of improvement over sessions were defined for the different outcome variables. At specified dose levels, the percentage of patients improved then was calculated, resulting in dose–response relations for the MHI, three outcome phases, and symptom subscales. The resulting observed and predicted improvement rates were compared to evaluate the accuracy of the predicted rates derived from intake information.

Table 2 presents the predicted and observed improvement percentages across sessions for the first validation sample (Sample 2, $n = 445$) for the MHI and the three phases. The predicted percentage improved for each scale was calculated for the first validation sample (Sample 2) based on the fixed effect coefficients from an HLM analysis on Sample 1.[1] The predicted percentages were reasonably similar to the observed percentages across the scales, with 44% of predicted percentages being lower than observed, 44% higher, and 13% the same. With regard to the phase model, Hypothesis 1 was confirmed. Observed and predicted improvement percentages across phases demonstrated

[1]Cause of the selection criteria for the two samples with repeated measurements, there was actually no real information on Session 0 for these data sets out of a managed care companies data pool. Therefore, at Session 0 we assumed the same amount of cases being above an MHI *T*-score of 62 as in the full sample of 11,002 cases.

Table 2
Predicted and Observed Dose–Response Relations for the Validation Sample (Sample 2, n = *445) for Current Well-being, Current Symptoms, Current Life Functioning Scales, and the Mental Health Index*

Session Number	Subjective Well-being		Current Symptoms		Current Life Functioning		Mental Health Index	
	P (%)	O (%)	P (%)	O (%)	P (%)	O (%)	P (%)	O (%)
0	15.3	15.3	12.2	12.2	13.8	13.8	14.3	14.3
2	40.2	33.3	16.6	28.6	18.4	30.2	23.3	35.1
4	63.6	66.1	48.1	50.7	37.8	45.5	58.6	57.0
6	69.9	74.7	59.0	58.2	44.4	49.6	69.4	63.4
8	71.2	77.7	63.9	61.1	50.2	51.7	73.4	66.1
10	72.6	79.4	67.5	64.5	51.7	53.7	75.5	67.1
26	76.8	84.4	77.3	68.8	59.9	58.5	84.0	73.0
52	78.1	85.7	80.9	70.2	62.4	60.3	86.1	74.2

P = predicted percentage improvement; O = observed percentage improvement.

the expected sequence, with Current Well-being being the highest, followed by Symptoms, and then Life Functioning.

Table 3 presents predicted percentage of patients improved compared to observed percentage of improved across sessions for the current symptoms subscales for Sample 2. The predicted percentage improved was generally higher than the observed percentage improved on all five subscales, suggesting a tendency to overestimate the dose–response relationship. However, the predicted percentage improved was again a good estimate of the observed percentage improved on all scales, with no differences greater than 10%. The findings in Tables 2 and 3 support the use of HLM for the prediction of patient improvement across treatment for different treatment goals.

In descending order, improvement percentages were as follows: adjustment disorder, depression, obsessive-compulsive symptoms, bipolar, and anxiety (Table 3). Supporting

Table 3
*Predicted and Observed Dose–Response Relations for Sample 2 (*n = *445) for the Current Symptoms Subscales*

Session	Adjustment Disorder		Depression		Obsessive-Compulsive		Bipolar		Anxiety	
	P (%)	O (%)	P (%)	O (%)	P (%)	O (%)	P (%)	O (%)	P (%)	O (%)
0	13.8	13.8	12.1	12.1	10.5	10.5	8.4	8.4	8.6	8.6
2	28.6	28.5	21.4	30.6	16.3	25.4	16.1	22.6	15.4	22.6
4	49.1	50.9	50.2	51.4	40.9	44.9	43.2	43.2	38.4	39.8
6	58.5	56.5	58.9	58.7	50.3	49.5	51.7	48.2	47.0	46.2
8	63.5	59.7	62.4	61.5	54.7	52.7	54.9	51.2	50.5	50.9
10	66.1	61.7	64.4	62.7	56.9	53.5	56.6	52.5	53.2	52.8
26	73.9	66.5	72.7	66.6	64.0	58.2	62.6	57.8	61.8	58.5
52	77.3	68.5	74.9	68.8	66.8	59.4	66.5	60.3	65.1	60.4

P = predicted percentage improvement; O = observed percentage improvement.

Hypothesis 2, the discovery of differences in syndromes' improvement rates was consistent with previous findings (e.g., Howard, Kopta, Krause, & Orlinsky, 1986; Kopta et al., 1994), suggesting that different syndromes, as well as symptoms, change at different rates across treatment. For example, percentage improved for depression and adjustment difficulties were higher early in treatment and continued to increase across sessions; In contrast, percentage improved for anxiety problems showed less change across sessions in this sample. Given the large sample, all statistical tests would show significant differences between the scales. Therefore, we omitted these additional analyses.

The predicted improvement percentages across sessions for the larger validation sample (Sample 3, $n = 11{,}002$) are presented in Tables 4 and 5. Hypothesis 3 was confirmed. Sample 3 patients' global mental health, as assessed by the MHI, improved at a similar rate compared to the original dose–response relations reported by Howard, Kopta, Krause, & Orlinsky (1986) (Table 4). For instance, the percentage of patients improved at Session 0 and at Session 26 were nearly identical for these two independent samples. The results in Table 4, like those shown in Table 2, also are consistent with the phase model and support Hypothesis 2 in that across sessions, percentage of patients improved was highest for well-being, followed by symptom distress, and lowest for life functioning. The findings reported in this study provide support for both the phase and dose–effect models of psychotherapy.

Confirming Hypothesis 2, findings for the larger validation sample (Sample 3, $n = 11{,}002$) are presented in Table 5 and Figure 2 with regard to the symptom subscales. In descending order, percentage improved was adjustment disorder, depressive symptoms, obsessive-compulsive symptoms, bipolar symptoms, and anxiety-related symptoms. This finding is consistent with the ordering for Sample 2 except for small differences between the bipolar scale and the obsessive-compulsive scale.

Discussion

This study extended patient profiling methodology to modeling progress in psychotherapy for different syndromes and phases of recovery. The results were stable across different samples using validated fixed effect regression coefficients derived from

Table 4
Predicted Dose–Response Relations for the Validation Sample (Sample 3; n = *11,002) for Current Well-being, Current Symptoms, Current Life Functioning, and Mental Health Index; Modeled from Sample 1 (*n = *445)*

Session	Subjective Well-being (%)	Current Symptoms (%)	Current Life Functioning (%)	Mental Health Index (%)	Dose–Response Relation[a] (%)
0	15.3	12.3	13.7	14.3	14
2	32.0	16.0	17.9	21.2	24
4	59.7	41.7	35.5	50.1	30
6	67.4	51.2	41.7	60.2	41
8	70.9	56.0	45.2	65.2	53
10	73.2	59.3	47.4	68.0	62
26	78.9	68.6	53.7	75.6	74
52	81.2	72.5	56.3	78.6	83

[a]From: Howard, Kopta, Krause, & Orlinsky (1986).

Table 5
Predicted Dose–Effect Relations for the Validation Sample (Sample 3; n = *11,002) for the Current Symptoms Subscales: Modeled from Sample 1 (*n = *445)*

Session	Adjustment Disorder (%)	Depression (%)	Bipolar (%)	Obsessive-Compulsive (%)	Anxiety (%)
0	13.8	12.1	8.5	10.5	8.6
2	21.3	20.1	15.7	16.0	14.3
4	48.2	45.7	40.2	38.9	34.2
6	57.1	53.4	48.5	47.4	42.3
8	61.6	57.3	52.4	51.7	46.3
10	64.2	59.6	55.2	54.3	49.2
26	71.9	66.6	62.4	61.8	57.3
52	75.3	69.5	65.8	65.3	60.9

growth curve modeling procedures. It was impressive that the coefficients derived from Sample 1 produced dose–response relations in comparison with Sample 2 (which used at least two other session points beyond intake) and Sample 3 (which used only intake information).

The findings reported here provide further confirmation of both the phase and dose–response models of psychotherapy. The improvement percentages across sessions for the MHI and the dose–response curve based on Howard, Kopta, Krause, & Orlinsky's (1986) meta-analysis are remarkably similar. This finding is especially noteworthy since the comparisons involved completely different samples, outcome variables, and treatment

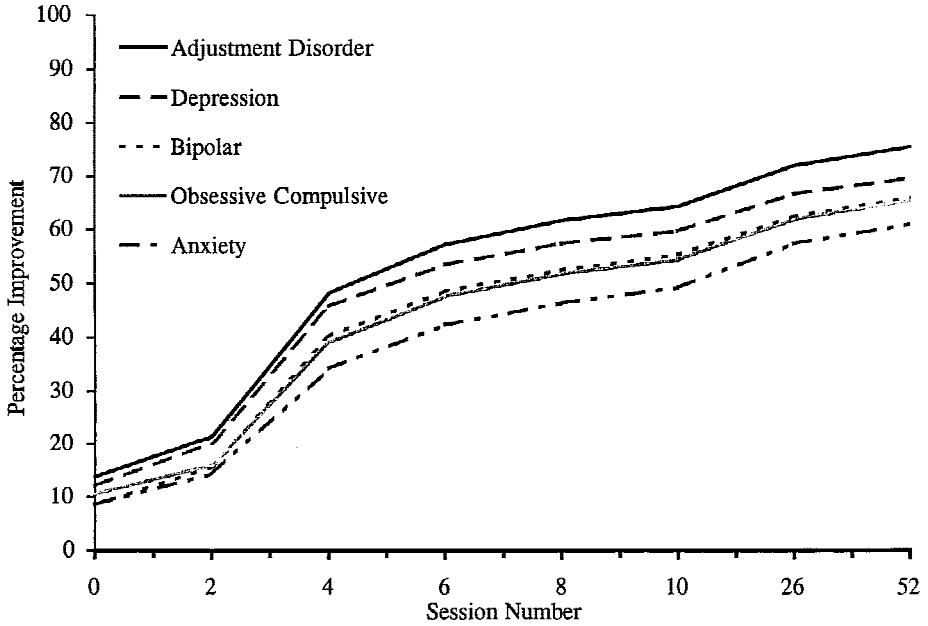

Figure 2. Graphical representation of the predicted dose–response relations for Sample 3 (*n* = 11,002) for the current symptoms subscales.

philosophies. With regard to the phase model, the different phases of the model showed different rates of improvement in the same order as had been found in earlier work (Howard et al., 1993). The highest percentage of patients improved across sessions was for well-being followed by symptoms, and finally by life functioning.

Progress was made in this study with regard to predicting the course of treatment for an individual patient. However, several other issues need to be investigated. Not all individual patients follow a log-linear dose–response relationship over time. It is important to search for other characteristic patterns of improvement. Thus, there is a need to theoretically and empirically define different possible courses of treatment for different types of patient clusters. There also is a need to search for practical decision rules, which could be applied in real clinical settings to improve treatment.

This study illustrates the value of patient profiling in delineating the different relevant dimensions of change in psychotherapy and in predicting specific patients' responses to treatment. With regard to its clinical value, patient profiling provides the opportunity to reshape treatment interventions for individual patients who are not progressing as expected. By providing dose–response information on large groups of patients, it allows for the discovery of general lawful relationships for the course of improvement across psychotherapy.

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