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# Chapter 5

## **Assessing adherence to guidelines for common mental disorders in routine clinical practice**

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## Abstract

**Objective:** To measure the overall level of adherence to clinical guidelines with a set of cross-diagnostic process indicators in a randomly selected sample of outpatients who started an acute phase treatment for a common mental disorder in a routine clinical setting.

**Design, Setting and Participants:** We developed a generic set of quality measures to assess the implementation of guidelines in daily practice. This set was tested in a retrospective cohort study in a randomly selected sample of 300 outpatients who started an acute phase psychiatric treatment for various psychiatric disorders. Patients were treated with pharmacotherapy, psychotherapy or a combination of both.

**Main Outcome Measure:** Scores on cross-diagnostic process indicators.

**Results:** Most indicators were positive in a high to very high percentage, indicating that most treatment elements in this routine clinical practice setting were delivered according to the guidelines for the acute treatment phase. We observed significant lower scores in the combined treatment group as compared with the two other treatment groups on the indicators 'correct treatment module' and 'stepped care' ( $P \leq 0.005$ ). Patients receiving psychotherapy had the best results on the separate indicators. Overall, only a minority of the patients in this sample was treated in complete accordance with the guidelines and treatment manuals.

**Conclusions:** Assessment of guideline adherence is feasible with this cross diagnostic set of process indicators and hampering factors of implementation could be easily detected. Future research should focus on the relationship with treatment outcomes.

## Introduction

Over the past decades the selection of treatment for patients with psychiatric disorders has gradually shifted from an approach based on clinical expertise towards evidence-based medicine. In many countries, psychiatric organizations and services have now formulated and implemented evidence-based guidelines for the pharmacological and psychological treatment of psychiatric disorders or follow those from international organizations. The implementation of evidence-based guidelines is expected to improve the (cost) effectiveness of pharmacological and psychological treatments of mood and anxiety disorders in clinical practice. [1,2]

Although evidence based guidelines are widely used nowadays, the generalizability of the results from the randomized clinical trials that form their building blocks can be questioned, as those trials typically demand controlled conditions and use stringent inclusion and exclusion criteria for patient selection. [3-5]

At the moment there is insufficient evidence whether patients in routine psychiatric care benefit from treatment according to evidence based guidelines. In general, the effects of guidelines on patient health outcomes are often far less studied and data are less convincing. Increased adherence to guidelines may or may not be necessarily associated with improved clinical outcomes. [6-9]

Additionally, there has been little work on cross-diagnosis approach to guideline-based quality assessment, since most guidelines have been developed for specific, single diagnoses. For implementation in standard clinical settings, limited quality management resources require efficient, summary means of tracking quality [10,11].

In order to determine whether treatment according to guidelines is indeed associated with improved treatment outcomes in clinical practice, the adherence to these guidelines needs to be assessed first. Studies focusing on the adherence to guidelines are so called process-focused studies. In the last ten years several studies, assessing the adherence to guidelines in clinical practice have been published. However, these studies show great variety in their approach. Some studies focused on choice and dosage of medication, others assessed provision of case-management or outcomes. The number of indicators used to assess adherence varied from one to 49 between studies.

Because of the wide variety of approaches, comparing adherence-rates between studies is rather problematic. This is even further hampered by the fact that the terms used to describe the degree of adherence vary greatly. Some studies used levels as outcome, i.e. low, moderate to high level of adherence; other studies used percentages to describe the level of adherence. Most adherence studies focused on the adherence to guidelines for a specific disorder, like depressive disorder, bipolar disorder or schizophrenia. The majority of studies assessed only one specific treatment modality, predominantly pharmacotherapy, in frequency followed by pharmacotherapy in combination with psychotherapeutic interventions. Finally, many adherence studies used administrative data, for instance from insurance companies. [12-45]

To our knowledge there are no studies that have assessed clinical guideline adherence across multiple disorders and treatment modalities in a routine clinical setting. Such an approach can be very useful to assess the overall level of adherence in these settings and to identify both general and specific factors that influence adherence to guidelines in routine clinical practice. In order to assess the overall level of adherence to guidelines we developed a set of cross diagnostic process indicators based on the guidelines for the treatment of specific common mental disorders (i.e. mood, anxiety or somatoform disorders).

With this set of indicators we retrospectively examined the overall level of adherence to clinical guidelines in a randomly selected sample of outpatients who started an acute phase treatment for a common mental disorder in a routine clinical setting.

As patients and setting in routine clinical practice usually do not resemble randomized clinical trials which form the building stones of evidence based guidelines, we expected the degree of guideline concordant treatment in our clinic to be limited.

## **Methods**

### **Rivierduinen**

The use of evidence based guidelines and outcomes measurement is integrated in routine practice in Rivierduinen, a regional mental health care provider (RMHCP) in the Netherlands. Rivierduinen provides secondary mental health

care for an area with over one million inhabitants. In the Netherlands access to mental health care is not limited by insurance or financial status. Health insurance is compulsory for all citizens, and for patients without medical insurance, like illegal immigrants and homeless, psychiatric services provide all care free of charge.

The implementation of guidelines and a system for Routine Outcome Measurement (ROM) started in 2002, in collaboration with the department of psychiatry of the Leiden University Medical Hospital. All new patients suffering from mood-, anxiety-, and somatoform disorders and who master a sufficient body of the Dutch language are eligible for ROM. Patients have an extensive baseline assessment, including a structured diagnostic interview, and follow-up assessments.

The local stepped care-based programs closely follow the national evidence based guidelines from the Dutch Association of Psychiatry ([www.nvvp.net](http://www.nvvp.net)) or when available, the more recent Multidisciplinary Guidelines, developed by the Dutch associations of psychiatry, psychology and general practitioners ([www.trimbos.nl](http://www.trimbos.nl)) and were slightly adjusted to the local setting. Multifaceted interventions were applied to enhance the implementation of the guidelines.

### **Patients**

Between January 2004 and January 2006 in total approximately 3000 patients started treatment for a unipolar depressive, anxiety or somatoform disorder. We selected 300 patients, 10% of the total number, aged between 18 and 65 years, who were assigned to receive treatment for the acute phase of a DSM-IV depressive, anxiety or somatoform disorder in the period between January 2004 and January 2006 at the Leiden outpatient department of RMHCP Rivierduinen. For each year we included 100 consecutive patients who had had at least one treatment session with their therapist after the diagnostic phase and who mastered a sufficient body of the Dutch language to complete the ROM assessments.

### **Treatment**

A treatment modality (medication treatment, psychotherapy or a combination) was allocated during the routine multidisciplinary intake. Allocation was based on the information gathered during the intake phase, the ROM baseline assessment, patient preferences and of course the directions from the clinical guidelines.

In the case of pharmacotherapy (PhT) patients were treated by a psychiatrist or by a resident in psychiatry, supervised by a psychiatrist. In the case of psychotherapy (PsT), patients were treated by a registered psychotherapist or psychiatrist or by a resident in psychiatry, supervised by a registered psychotherapist or psychiatrist. In the case of combination therapy (CT), patients were treated by a registered psychotherapist or psychiatrist or by a resident in psychiatry, supervised by a registered psychotherapist and psychiatrist.

### **Routine Outcome Monitoring (ROM)**

During the intake phase patients are assessed with a standardized diagnostic interview (M.I.N.I International Neuropsychiatric Interview plus [46], rating scales and self-report measures. After three to four months an outcome assessment is scheduled, including the rating scales and self-report measures. A large number of instruments has been selected for ROM. Two kinds of self-report measures and rating scales are employed: generic and disorder-specific. Generic measures, such as the Brief Symptom Inventory, [47] are completed by all patients. Specific measures such as the Panic Appraisal Inventory [48] are only administered when the patient meets criteria for a panic disorder for example.

In order to avoid an extra burden on the therapist, and to bypass the difficulties therapists encounter collecting data on a routine basis, independent research nurses perform ROM. The therapists are informed about the results of ROM and can discuss the results with their patients. To facilitate the administration of the MINI interview, rating scales and the completion of self-report measures, dedicated software "Questmanager" has been developed. The assessment in the intake phase can take up to two hours, depending on the psychopathology present: 35 minutes for the MINI-plus, 40 minutes for the rating scales and 45 minutes for the self-report measures. An outcome assessment after three to four months includes all the above with the exception of the MINI and the DAPP-SF, which are administered only at the baseline assessment. A ROM outcome assessment session takes on average one hour. ROM has been performed in over 8000 patients and virtually no patients refuse the assessment. [49]

### **Indicators**

In order to assess the adherence to guidelines in our routine clinical practice in the acute phase of treatment across different disorders and treatment

modalities, we defined a number of more generic guideline and treatment manuals derived indicators. At this stage, we decided not to develop indicators for a more detailed assessment of the delivered treatments, like compliance to pharmacotherapy or whether psychotherapy sessions strictly followed the manuals, because these data were not available in a consistent manner. After studying the applicable clinical guidelines and treatment manuals, the indicators were defined through consensus by a group of senior psychiatrists from RMHCP Rivierduinen and the department of psychiatry of the Leiden University Medical Center. We conducted a pilot-study to assess the feasibility of our approach, as recommended in the literature. [50] Six generic, dichotomous indicators were defined to assess the concordance of acute phase treatment with clinical guidelines. We also defined two indicators to assess the use of ROM, which were specific for the local programs of care. The following indicators were defined:

Treatment indicators:

- i. Was the combination of primary DSM-IV diagnosis and the provided treatment-modality according to the guidelines?
- ii. Was the stepped care principle followed?
- iii. In the case of medication treatment, was the minimal adequate dose of the chosen drug prescribed?
- iv. In the case of medication treatment, was the duration of the treatment at least six weeks?
- v. In the case of psychotherapy, was the duration of the treatment at least 12 weeks?
- vi. In the case of psychotherapy, was the frequency of the psychotherapy at least one session every one and a half week?

ROM indicators:

- vii. Had ROM been performed during the diagnostic phase?
- viii. Had ROM been performed at least once during the first treatment module?



As psychotherapy sessions in routine clinical practice often fail to obtain a frequency of once a week, because sessions are canceled due to holidays or personal circumstances from both patient and therapist, the consensus panel judged a minimal frequency of one session every one and half weeks to reflect the frequency as demanded by guidelines. For the same reasons we decided to use a minimal duration of twelve weeks for the psychotherapy, as the shortest duration of psychotherapy mentioned in the guidelines is eight weeks (for instance panic management or exposure in vivo for panic disorder).

The indicators for psychotherapy are not applicable to Eye Movement Desensitization and Reprocessing (EMDR). Duration and frequency of this form of psychotherapy are not well defined and hence this treatment modality was not rated in our study.

In addition to the percentage of treatment for which an indicator was positive, we also assessed the percentage of patients for whom the delivered treatment had a positive score on all treatment indicators. Patients receiving combination therapy had to meet six indicators where patients receiving pharmacotherapy or psychotherapy had to meet four indicators.

### **Data collection and Assessment**

Data on the first treatment step were available from ROM and additional data were collected by a retrospective chart review. Indicators were listed on a form and were rated 1 if the criteria were met and 0 if not. Data and scores were entered in a database. Anonymity was maintained, and data were used only in aggregate form: accordingly, the participating institute did not require the patient's consent to the use of these data. The study was submitted to and approved by the institutional review board.

### **Statistical analyses**

Analysis was performed using SPSS 12.0.1 (SPSS Inc., Chicago, IL, USA). The Chi-square test was used to examine the differences between scores on the process indicators in the three subsequent years.

## Results

### Patients

Patient characteristics of the 300 patients in our study are presented in Table 1. A total of 66,0% of the 300 subjects was female. The male/female ratio and mean age were not different between the diagnostic categories. The mean age was 37, 0 years (SD 11, 1). The majority of patients was suffering from a mood disorder (46, 3%), followed by an anxiety disorder (36, 0%). A small group was diagnosed with a somatoform disorder (17, 7%). When patients had comorbid disorders, we assessed the disorder that was chosen as treatment focus by the board of therapists at the intake conferences.

Of the 300 patients, 46,0% was treated with psychotherapy, 36,0% of the patients received pharmacotherapy and a minority 13,7% received a combination of pharmacotherapy and psychotherapy. A group of 13 (4, 3%) patients was defined as receiving miscellaneous forms of treatment and was excluded (i.e. light therapy, supportive care etcetera).

### Scores on the indicators

The first indicator showed that on average 94,7% of all patients received treatment for their diagnosis in accordance with the guideline (table 2). The PsT group did better on this indicator (99,1%) than the PhT (92,6%) and CT (86,5%) group ( $P \leq 0,005$ ). The second indicator, assessing whether the provided module was according to the principle of stepped care, showed positive results in 91,9% of all patients. The CT group scored significantly less on this indicator compared to the two other treatment groups ( $P < 0,000$ ).

The duration of pharmacotherapy was at least six weeks in 68,2% of the patients. The PhT group was more likely to receive the minimal duration of six weeks of pharmacotherapy compared to the CT group (72,0% versus 56,2% respectively, not significant.)

The minimal adequate dose was prescribed in 90,9% of the patients and there were no differences between the PT and CT groups.

The minimal duration of 12 weeks of psychotherapy was achieved in the majority of patients in the PsT and CT group (74,1% and 81,2% respectively). However, the frequency of one psychotherapeutic session every one and a half week was only met in 27,6 % of the patients with PsT and in 25,0 % of the patients with CT.

The first indicator for ROM showed that assessment during the diagnostic phase was performed in about 50 % of the patients. However, fewer patients in the CT group were assessed during this phase (35,1%) than in the PsT and PhT group (55,6% and 53,8% respectively) ( $P \leq 0,009$ ). The second indicator showed that only a minority of patients was measured during the therapeutic phase (23,4%). In the next step we determined percentages of patients treated completely in accordance with the guidelines and who received all ROM measurements; i.e. for whom all the indicators for the course of treatment were scored positive. This was only the case in a minority of patients. The PhT group had a significantly higher score of 12,0 %, compared to the PsT and CT groups (1,7% and 2,7% respectively;  $P < 0,000$ ).

Assessing guideline-adherence without ROM resulted in higher percentages with positive scores on all the indicators, especially in the PhT group. More than half of the patients (54,6%) in the PhT group was treated according to the guidelines, and only 8,5% of the patients in the PsT group and 2,7% of the patients in the CT group.

## Discussion

To our knowledge this is the first study assessing guideline adherence across multiple disorders and treatment modalities in a routine clinical setting. We consolidated disorder-specific guideline based process indicators into a smaller, and easy to use, set of cross-diagnostic indicators. Contrary to our hypothesis, most indicators were positive in a high to very high percentage of patients, indicating that most treatment elements in this routine clinical practice setting were delivered according to the guidelines for the treatment of the acute phase of common mental disorders.

We observed significant lower percentages of positive scores in the combined treatment group as compared to the two other treatment groups on the indicators describing the correct treatment module and the principle of stepped care. These results suggest that patients receiving combined treatment or the combined treatment itself may be more complex, possibly forcing therapists to deviate from the guidelines to provide optimal treatment.

Overall, the patients receiving psychotherapy had the best results on the separate indicators, except for the frequency of psychotherapeutic sessions.

This is rather surprising, as we already chose a lower frequency than demanded by the guidelines to take some absences of patients and therapists into account. This discrepancy between guidelines and clinical practice raises concern as several guidelines state a preference for psychotherapy because of the equal efficacy in combination with the absence of significant side effects and the benefits for relapse prevention. [51]

Although most indicators were positive in the majority of patients and across different treatment modalities, only a minority (less than 10%) of the patients in this sample was treated in complete accordance with the local treatment manuals, which included ROM. When ROM was not taken into account, percentages were still low. The fact that so few patients are treated according to the guidelines is rather disturbing, as guideline concordant treatment is generally thought to result in better patient outcomes. On the other hand, the correlation between guideline concordant treatment and patient outcomes in routine clinical practice is still subject of an ongoing debate in the literature, and some studies suggest that the correlation may be moderate. [7,8]

We believe that our study has several strong points. Our patient sample was derived from a routine clinical outpatient setting where guidelines have been intensively implemented and reliable information regarding patient characteristics, the delivered treatment and therapists was available. There are, however, also some limitations to consider. The influence of guidelines on treatment was only examined in one specific center and only in newly treated patients in the acute phase of their disorder. Another potential limitation is the absence of relative weighing and the limited coverage of treatment by the indicators.

In our study we demonstrated that assessment of guideline adherence across common mental disorders in clinical practice is feasible with a cross diagnostic set of quality indicators and can be used to detect hampering factors in implementation. We suggest that quality monitoring in smaller clinical settings could benefit from the use of cross-diagnostic process indicators. Further research into patient, therapist and institutional factors influencing the concordance of treatments with clinical guidelines in routine clinical practice is needed.

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## **Case vignettes to illustrate the use of indicators (positive score on the indicator is 1, negative score is 0)**

### **Case vignette 1**

Patient A., a 24-year old male with no previous history of psychiatric illness, was referred to our outpatient clinic by his general practitioner for treatment of depressive symptomatology. During the diagnostic phase patient A. was assessed with ROM. He was diagnosed with a severe depressive disorder. Therefore the psychiatrist chose to start treatment with the selective serotonin reuptake inhibitor (SSRI) citalopram at 20 mg citalopram daily. After approximately seven weeks the therapist referred the patient to assess symptoms with ROM again, to establish whether treatment had been effective or not.

Scoring of the indicators was as follows: ROM was performed during the diagnostic phase: 1, the combination of DSM-IV diagnosis and the provided treatment-module was according to the guidelines: 1; the provided module was in accordance with the principle of stepped care: 1; the minimal adequate dose of the specific medicine was prescribed: 1. The duration of the pharmacological treatment was at least six weeks: 1; ROM was performed in the therapeutic phase: 1. There was a positive score on all six indicators and hence patient A was considered being treated in complete concordance with the guidelines.



**Case vignette 2**

Patient G. was a 56-year old female outpatient with no previous history of a psychiatric illness. The clinical diagnose was a panic disorder. Treatment was started and consisted of Cognitive Behavioral Therapy (CBT) and citalopram 10 mg daily, with no further dosage increase. For unknown reasons the SSRI was stopped within four weeks by the clinician. The frequency of the CBT was on average one session every 3 weeks. After five months, patient G. was assessed with ROM to measure the effect of the CBT.

Scoring on the indicators was as follows: there was no ROM during diagnostic phase: 0; the combination of DSM-IV diagnosis and the provided treatment-module is described in the guidelines: 1; the provided module, however, was not according to the principle of stepped care (combination therapy is not the first step): 0; the minimal adequate dose of the specific medicine was not prescribed: 0; the duration of the pharmacotherapy module was less than six weeks: 0; the duration of the psychotherapy module was at least 12 weeks: 1; the frequency of psychotherapy was less than one session every one and a half week: 0; the assessment of guideline adherence showed that patient G. was treated in limited concordance with the guidelines: only three out of the eight indicators for combination therapy were scored positive.

**Case vignette 3**

Patient V. was a 40-year old woman referred to our outpatient clinic because of unexplained physical complaints. ROM during the diagnostic phase confirmed the clinical diagnose of an undifferentiated somatoform disorder. Patient V. was referred to a psychotherapist to start CBT. The therapist delivered CBT for more than 12 weeks with an average of 1 session every one and a half week. During the psychotherapeutic treatment there was, however, no record of a ROM assessment.

Scoring on the indicators was as follows: ROM was done during diagnostic phase: 1; in accordance with the guidelines and with respect to the principle of stepped care the combination of DSM-IV diagnosis and the provided treatment-module was according to the guidelines: 1; the provided module was in accordance with the principle of stepped care: 1; the duration of the psychotherapy was at least 12 weeks: 1; the frequency of psychotherapy was at least one session every one and a half week: 1; ROM was performed in the therapeutic phase: 0; the assessment of guideline adherence showed that this patient was treated almost in complete concordance with the guidelines as there was a positive score on five of the six indicators.

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**Table 1** Patient characteristics

	PsT <sup>a</sup>	PhT <sup>b</sup>	CT <sup>c</sup>	Miscellaneous	Total
<b>total – n</b>	138	108	41	13	300
<b>age - n</b>	36,0 ±11,0	39,1±11,1	35,1± 10,9	37,3± 10,6	37.0 ± 11.1
<b>female – n</b>	101 (73,2%)	62 (57,4%)	28 (68,3%)	8 (61,5%)	199 (66%)
<b>mood disorder – n</b>	34 (24,6%)	77 (71,3%)	17 (41,5%)	11 (84,6%)	139 (46.3%)
<b>anxiety disorder – n</b>	64 (46,4%)	25 (23,1%)	17 (41,5%)	2 (15,4%)	108 (36.0%)
<b>somatoform disorder-n</b>	40 (29,0%)	6 (5,6%)	7 (17,0%)	0 (0,0%)	53 (17,7%)

<sup>a</sup> psychotherapy

<sup>b</sup> pharmacotherapy

<sup>c</sup> combination therapy

**Table 2** Scores on process indicators (%) for the three treatment modalities

Process indicators	N (Eligible patients per indicator)	Psychotherapy	Pharmacotherapy	Combination therapy	Total
<b>General</b>					
<b>The combination of DSM-IV diagnosis and the provided treatment-module is according to the guidelines</b>					
Number assessed		117	108	37	262
Number adherent		116 (99.1%)	100 (92.6%)	32 (86.5%)*	248 (94.7%)
<b>The provided module is according to the principle of stepped care<sup>1</sup></b>					
Number assessed		116	100	32	248
Number adherent		115 (99.1%)	91 (91.0%)	22 (68.8%)*	228 (91.9%)
<b>Routine outcome monitoring</b>					
<b>Routine Outcome Monitoring in diagnostic phase</b>					
Number assessed		117	108	37	262
Number adherent		65 (55.6%)	57 (52.8%)	13 (35.1%)	135 (51.5%)
<b>Routine Outcome Monitoring in therapeutic phase<sup>1</sup></b>					
Number assessed		116	100	32	248
Number adherent		36 (31.0%)	15 (15.0%)	7 (21.9%)	58 (28.9%)
<b>Pharmacotherapy</b>					
<b>Duration of the treatment-module is at least six weeks<sup>1</sup></b>					
Number assessed			100	32	132
Number adherent			72 (72.0%)	18 (56.2%)	90 (68.2%)

Table 2 continued

Process indicators	N (Eligible patients per indicator)	Psychotherapy	Pharmacotherapy	Combination therapy	Total
<b>Minimal adequate dose of the specific medicine has been prescribed<sup>1</sup></b>					
Number assessed			100	32	132
Number adherent			90 (90.0%)	30 (93.8%)	120 (90.9%)
<b>Psychotherapy</b>					
<b>Duration of treatment-module is at least 12 weeks<sup>1</sup></b>					
Number assessed		116		32	148
Number adherent		86 (74.1%)		26 (81.2%)	112 (75.7%)
<b>Frequency of psychotherapy is at least one session every one and a half week<sup>1</sup></b>					
Number assessed		116		32	148
Number adherent		32 (27.6%)		8 (25.0%)	40 (2.0%)
<b>Positive score on all process indicators:</b>					
Positive score on all process indicators:		2 (1.7%)	13 (12.0%)	1 (2.7%)	
Positive score on all process indicators (without ROM)		10 (8.5%)	59 (54.6%)	1 (2.7%)	

\*P≤0,005 tested with Chi-square test

<sup>1</sup> patients are eligible for this indicator only when they receive a treatment-module according to the guideline

