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Summary and discussion

A. Summary

The overall aim of this thesis was to develop a set of reliable, valid and easy applicable indicators to assess guideline adherence in the treatment of mood, anxiety and somatoform disorders. This would be important for optimizing treatment in routine clinical practice. In **chapter 2** we describe a study on poor treatment response in a typical Dutch routine outpatient setting for patients with mood, anxiety and somatoform disorders. The analyses were carried out on baseline Routine Outcome Monitoring (ROM) data gathered from 2004-2006 from a discovery cohort of 892 adult patients with Mood, Anxiety or Somatoform (MAS) disorders. Subsequently analyses were replicated on baseline ROM data gathered from 2007-2009 from a replication cohort of 1392 MAS patients. As expected we found a considerable number of patients with a poor treatment response, warranting further research into guideline adherence. Predictors for poor response as measured with the Brief Symptom Inventory (BSI) and Clinical Global Impression (CGI) were higher age, having a somatoform disorder, comorbid MAS disorders, dysfunctional personality traits (i.e., tendency to selfharm, intimacy problems, affective lability), and a low reported general health status. Analyses like the ones described in this chapter suggest that treatment protocols could be more individualized. However, before starting to develop special programs for patient groups at risk for poor results, it is clear that one should first assess to what extent guidelines were implemented and followed in routine clinical care, since guidelines were developed and implemented as tools to optimize treatment.

In **chapter 3 we** report the results of a survey among the boards of all Dutch mental health institutes, focusing on the degree of implementation of guidelines and adherence to guidelines in clinical care. Most mental health institutes reported to use evidence-based guidelines. However, institutes were not able to present data on the extent to which guidelines were followed in day-to-day treatment practice. Most institutes acknowledged that the information they provided was not based on actual data, but on estimations. Furthermore, it appeared that an instrument to evaluate guideline adherence did not exist. In **chapter 4** we describe the development and validation of a set of cross-diagnostic adherence indicators based on the Dutch multi-disciplinary guidelines for the treatment of unipolar mood disorder, anxiety disorders and somatoform disorders. We used this set of indicators to retrospectively

examine the adherence to clinical guidelines in 300 MAS outpatients who started treatment, in the period from 2004 to 2006 in a routine clinical setting at Rijnveste, Leiden. For each year we studied the first 100 patients who started treatment with pharmacotherapy, psychotherapy or a combination of both. The same set of indicators could be used for all patients, irrespective of diagnosis. Scores on most indicators ranged from fair to good over the three different years. Also, interventions to increase the number of ROM baseline assessments patients had paid off, as the score of this indicator showed a significant increase over the three years (from 29% to 69%). However, indicators assessing whether patients received ROM follow-up measurements and indicators assessing the frequency of psychotherapeutic sessions showed low scores in all three years. This study showed that assessment of guideline adherence is feasible with a cross-diagnostic set of process indicators. In chapter 5 and 6 we subsequently examined therapist and patient factors potentially influencing adherence in routine clinical care.

In **chapter 5** we investigated whether treatment modality (pharmacotherapy, psychotherapy or the combination) was a factor influencing guideline adherence. We used the same set of cross-diagnostic process indicators and the same patient sample as in chapter 4. For all treatment modalities adherence was fair to good if analyzed separately per indicator (average score per indicator 65, 5%), but low if analyzed for all indicators per patient together (average score of the three treatment groups 5,5%). There were also differences between treatment modalities: scores in the combined treatment group as compared to the other treatment groups were significantly lower on the indicators "correct treatment module" and "stepped care". Patients receiving psychotherapy had the highest scores on the indicators concerning "correct treatment module", "stepped care" and ROM, when compared to the other treatment modalities.

In **chapter 6** we examined what patient-related clinical and psychosocial factors as assessed in ROM could potentially influence guideline adherence. We used the same sample of outpatients as in our previous studies and used questionnaires included in Routine Outcome Monitoring (ROM), the Brief Symptom Inventory (BSI) and the Social Functioning 36 (SF-36), and demographic variables. Using multivariable regression analysis, we identified independent predictors of guideline adherence. Patients with low scores on the vitality subscale of the SF-36 were at the highest risk to receive low guideline-concordant care. Post-hoc analysis showed that especially patients

receiving psychotherapy and displaying low vitality scores had the highest risk to receive low guideline-concordant care. We did not find an association with socio-demographic variables or comorbidity.

In **Chapter 7** we undertook a proof-of-principle study to examine whether not only ROM data, but also routinely collected administrative data of outpatients treated for MAS in Rivierduinen, could be used to assess adherence with our set of disorder independent process indicators. We used routinely collected administrative data on the treatment of MAS patients, collected between January 2009 and April 2013. With the administrative data, five of the eight previously tested cross-diagnostic indicators could be assessed. Scores on the indicators showed a great variance, ranging from 93.8% (duration of pharmacotherapy) to 29.6% (frequency of psychotherapy). Easy extractable parameters, like age, gender and diagnosis were found to predict adherence in this dataset. A diagnosis of anxiety or somatoform disorder was associated with higher odds of suboptimal duration, suboptimal frequency of psychotherapeutic treatment and the absence of a baseline ROM measurement as compared to a diagnosis of depression.

B. General discussion

In the next paragraphs we will discuss our findings in a broader perspective. We will first discuss our findings on patients who showed poor treatment response as measured with available ROM data. We then discuss the feasibility of assessing guideline-adherence and the literature regarding the development of adherence indicators, including the potential use of these indicators in mental health care. In the third part we discuss the reliability and validity of our set of indicators for use in clinical practice. Finally, we discuss our results in the context of national and international initiatives and we compare our findings on factors influencing adherence, like therapist and patient factors, with the available literature. This section will be completed with a discussion of the limitations of our studies, the implications for future research and some final remarks.

1. Factors associated with poor treatment response

In chapter 2 we showed that after two years about half of the patients with mood, anxiety and somatoform disorders in our routine outpatient clinics had a poor treatment response. This means that despite two years of being in care many patients were still suffering from the complaints they sought treatment for, and much effort of patients, clinicians and organization was spent in vain. Is it possible to improve this situation?

This question can be approached from different angles. One may first look at the discrepancy between the efficacy and the effectiveness of treatments. As showed for major depression by van der Lem et al. [1], the effects of treatment in randomized controlled trials (efficacy) are superior to those in routine clinical practice (effectivity). Does this difference points to a way to improve results? Should we follow the strict structures of RCTs? Not necessarily, as patient selection may play an important role in the better results of randomized controlled trials, with less complicated patients being included. On the other hand, an important contribution to the superiority of randomized controlled trials over routine clinical practice is probably the effort that is put in both patient's and clinician's protocol adherence (thesis van der Lem, page 130). A second approach is to try to identify patient factors associated with poor response. In the study described in chapter 2 we identified several of these patient factors: being elderly, suffering from comorbid MAS-disorders, a somatoform disorder, cluster B personality traits and a poor general health. As discussed in chapter 2, these findings are to a large extent in accordance with other studies. We suggest that a next step could be the identification of the most effective treatment for patients with these characteristics. However, guideline adherence may be an important factor influencing whether patients actually receive this treatment and in the correct manner.

Therefore, a third approach is to investigate guideline adherence. It goes without saying that treatments that are not carried out correctly have a smaller chance to be successful. Therefore, assessing guideline adherence should be the first step. Unfortunately, however, to date, standardized assessment of adherence is virtually absent in routine mental health practice (chapter 3).

2. Assessing guideline adherence in clinical practice: is it feasible?

Because of the absence of generally accepted procedures for systematic and standardized assessment of guideline adherence, we decided to develop a set of cross-diagnostic indicators. These indicators were based on the guidelines for mood-, anxiety- and somatoform disorders in the Netherlands and the programs of care derived from them in the mental health hospital Rivierduinen and the Leiden University Medical Centre (LUMC). As discussed in chapter 4, after reviewing the literature and consulting experts and clinicians, we formulated five indicators for pharmaco- and psychotherapy and three more general indicators concerning the stepped care principle and the screening with Routine Outcome Monitoring (ROM). We focused on indicators that we thought to relatively easy to assess, are not too detailed and can be used in routine clinical practice settings (see table 1).

Table 1. Overview of the indicators. All were used in the first indicator study (chapters 4 - 6). The * marked indicators were used in the second study (chapter 7).

General indicators:

The combination of DSM-IV diagnosis and the provided treatment module is according to the guidelines $\!\!\!\!\!\!\!\!\!\!\!\!\!\!\!\!\!\!$

The provided module follows from the stepped care principle

Routine outcome monitoring:

Routine outcome monitoring in diagnostic phase? *

Routine outcome monitoring in therapeutic phase? *

Pharmacotherapy:

Duration of therapy at least six weeks *

The minimal adequate dose is prescribed

Psychotherapy:

Treatment lasts at least 12 weeks *

Frequency of the session is at least one session every one and halve week *

in the second study (chapter 7), we used a frequency of one session every two weeks)

Our choice for a cross-diagnostic approach, i.e. using the same indicators irrespective of the presence of mood-, anxiety- and/or somatoform disorders, may at first sight seem less obvious. However, depression, anxiety and somatoform disorders often occur as comorbid disorders [2,3]. In addition, patients with depression, anxiety and/or somatoform disorders are treated with the same treatment regimes: antidepressants, (variants of) cognitive behavioral therapy or a combination of both, and importantly, in many clinical settings also by the same group of clinicians. Therefore, diagnosis-specific assessment of guidelines may be less informative on the state of routine clinical practice. Moreover, diagnosis- or treatment-specific analyses of the data remain a possibility afterwards, because information about both is available.

Other investigators have also used a cross-diagnostic approach. Wang et al. [4] assessed adherence to pharmacotherapy and psychotherapy in depression, general anxiety disorder and panic disorder and Young et al evaluated the quality of care for depressive and anxiety disorders [5]. We will discuss these studies in more detail later.

We investigated the usefulness of the indicators in two studies. In the first study we gathered data on the indicators along with other patient data from the patient files of samples of outpatients with depression-, anxiety- and/or somatoform disorders from three consecutive years (2004, 2005 and 2006). We demonstrated that at least some indicators showed a change in adherence over

time (ROM-assessments) and others differed between treatment modalities (chapters 4 and 5). However, because at that time data extraction had to be done manually, it was a very time-consuming process and certainly not feasible for routine practice.

Therefore, we subsequently looked for an easier way to assess guideline adherence in clinical practice. This came theoretically within reach when routinely collected administrative data of patients became available for analysis. These data were, of course, more easy to assess and could be obtained from very large numbers of patients. These data were used in our last study (chapter 7). We were able to adapt five of the eight original indicators so that they could be applied on these administrative data. Besides the degree of guideline adherence, these administrative data also provide additional demographic data and information about the clinical diagnosis that can be included in the search for factors associated with adherence.

Taken together, these results show that we have a set of at least five relevant indicators of guideline adherence that have the potential to become useful in clinical practice and in research. Of course, additional studies are necessary to investigate whether the indicators can pick up the effects of interventions to improve adherence and how the indicators perform in other settings in the Netherlands.

3. Reliability and validity of the indicators

In this section we will discuss some aspects of the reliability and validity of our set of indicators. Because our studies clearly had a proof-of-principle approach, we only addressed some main issues of reliability and validity. Future research, with data from Rivierduinen and LUMC, but also from other centers and by other researchers, is necessary to more extensively examine reliability and validity.

3.1 Reliability.

In the first study (chapters 4 - 6) we investigated the inter-rater reliability by adding a second assessor who randomly assessed patient records with the

set of indicators. Inter-rater reliability was consistently high, despite the fact that data were sometimes difficult to retrieve and handwritten patient files were difficult to read. The data that were used for the last study (chapter 7) were purely administrative; therefore, inter-rater reliability was not relevant. However, reliability of administrative data is a point of concern. There is usually no routine assessment of the accordance of the administrative data with clinical practice available. In this respect it is particularly true that "the chain is as strong as the weakest link".

In the context of our studies we did not look at other aspects of reliability like intra-rater, inter-method and internal consistency reliability.

3.2 Validity.

One of our aims was to assess the degree to which the guidelines for the treatment of MAS-disorders were implemented. Therefore, we translated the basic building blocks of these guidelines in indicators with face-validity, for instance the correct first treatment step for the diagnosis the patient got, and subsequently the application of the stepped care principle. At the level of treatment modality, our set measured essential parameters like the minimum adequate dose of psychotropic drugs or the frequency of psychotherapeutic sessions. We also included two indicators for the use of routine outcome monitoring. To further enhance face and content validity, we sought the advice of a panel of senior psychiatrists from RMHCP Rivierduinen and the Department of Psychiatry of the Leiden University Medical Centre to ensure that our set of performance indicators was based on the national guidelines and also tailored to our local setting. We used their comments to further construct indicators with high face and content validity.

4. Guideline adherence: comparisons with the literature.

4.1 Dutch studies.

Dutch studies on guideline adherence are still rare, especially in mental health settings. The only other studies in secondary mental health outpatient care were carried out by Van Dijk et al. Contrary to our approach, they focused only on anxiety disorders [6,7]. Guideline adherence was assessed with a set of process indicators comparable to ours. However, in some aspects their indicators

required more detail, like whether specific forms of psychotherapy were applied for specific anxiety disorders and whether the required form of psychotherapy was correctly performed, such as with homework assignments in CBT. Van Dijk et al. also assessed the duration of the provided psychotherapy. Contrary to our design, however, they did not study the frequency of psychotherapeutic sessions. With respect to pharmacotherapy they evaluated, just like we did, indication, dosage and duration. They did not include an indicator for ROM measurements. Although there were differences in assessment, the results of van Dijk et al. in anxiety disorders are comparable to those of our crossdiagnostic approach. They found baseline adherence rates of between 30 and 85 percent, comparable with our assessment. Similar to our findings, indicators for pharmacotherapy showed higher adherence rates when compared to indicators of adherence to psychotherapy [6,7].

As van Dijk et al. wanted to evaluate the effects of stimulating guideline adherence, they studied changes in adherence over time. They found improvement rates in applying the correct treatment ranging from 10 to more than 70 percent after promotion of the use of guidelines. In our study, we found a clear effect of the interventions in Rivierduinen aimed at promoting and implementing ROM.

Van Dijk et al. compared the effects of active guideline implementation with various control conditions (one in which the implementation of guidelines was not actively stimulated and another in which adherence to guidelines was compared to non-adherent treatments). The results support the theory that proper implementation of guidelines enhances treatment results [8-10]

Van Dijk et al. [10] also studied predictors of treatment response, but results from these studies are rather difficult to compare with ours. They studied the one and two-year response in 81 patients with anxiety disorders, in contrast to the two-year response in 5346 patients with mood-, anxiety- and/or somatoform disorders in our study. Another difference is that van Dijk et al. could compare a treatment setting in which guidelines were implemented (intervention condition) with a setting where guidelines were only disseminated (control condition). After one-year follow-up, intervention-condition patients showed a greater decrease in anxiety symptoms, higher rates of response and remission and a greater decrease in the rate of phobic avoidance. After two years, only phobic avoidance remained significantly improved. In chapter 2 we describe our study on poor treatment response in routine clinical practice as measured with the BSI and CGI. We found that higher age, having a somatoform disorder, comorbid MAS disorders and dysfunctional personality traits (i.e., tendency to self-harm, intimacy problems, affective lability), and a low reported general health status were predictive of insufficient treatment response after two years treatment according to guidelines.

Interestingly, guidelines were introduced in Dutch primary care much earlier than in secondary mental health care. Thus, Dutch primary care physicians have a longer experience in guideline implementation. This may be the reason that a much higher adherence to guidelines for the treatment of depression and anxiety disorders is reported in a Dutch primary care study: 39% total adherence versus 5.5% in our study [11]. Unfortunately, the methodology used to assess adherence was not explicitly addressed in this study. We are not aware of Dutch studies on improvement of adherence in primary care.

4.2 International literature.

In the last two decades several large projects were carried in which the effects of guidelines on treatment outcome were investigated: the Texas Medication Algorithm Project, the Berlin Algorithm Project and STAR*D. The results of all three projects demonstrated clearly that the implementation of guidelines improves treatment results, but, as discussed in chapter 1, these projects did not study whether the *degree* to which psychiatrists and therapists adhere to the guidelines influences outcome as well. Besides, the treatment settings differed very much from routine clinical practice.

Adherence in routine clinical practice was the subject of a study in 2000 by Wang et al [4]. They cross-diagnostically assessed adherence to pharmacotherapy and psychotherapy in depression, general anxiety disorder and panic disorder, but with only two indicators: 1) whether the patients received medication and had four or more visits to a specialist or 2) whether patients had eight or more visits to a therapist in the absence of medication. The study population consisted of the 3,032 respondents of the Midlife Development in the United States (MIDUS) study, a national, representative telephone-and-mail survey conducted in 1996. The overall adherence of 14,3% Wang et al. found is higher than our overall adherence of 5,5% (see chapter 3), but their methods differed

in many aspects from our studies. First, data were collected by a telephone and mail survey, whereas we extracted patient data from files or routinely collected administrative data. Second, the set of indicators used by Wang et al. is more limited than our set. Also, we included not only depression, general anxiety disorder and panic disorders, but also all other anxiety and somatoform disorders. Finally, we studied adherence specifically in a secondary mental health setting, while the above-mentioned study included patients from various settings.

In 2002 Wang et al. published a study assessing adherence in psychiatric disorders in general, using administrative data and indicators like minima number of visits and adequate dose of medication [12]. The authors now found an adherence rate of 38,9%. Again, we cannot adequately compare this study with ours, due to differences in methodology [12]. Young et al. also evaluated the quality of care of the treatment of depressive and anxiety disorders in 1636 adults in the US, with a cross sectional telephone survey. They used a very loosely defined set of indicators, like "any primary care visit", "any medication use" Data were from a cross-sectional telephone survey conducted during 1997 and 1998 with a national sample [5]. Again, methodological differences do not allow to really compare this study with ours.

Another US study by Chermack et al. [13] compared psychotherapy, pharmacotherapy and their combination, like we did, but only for a single disorder. The authors examined treatment of the acute phase of depression in the Veterans Administration (VA) healthcare system, and included measures of medication treatment, psychotherapy, and combined treatment according to The Healthcare Effectiveness Data and Information Set (HEDIS) guidelines [13]. Guideline concordance for medication therapy was defined as prescription of antidepressants for at least 84 of 114 days. Guideline concordant psychotherapy was defined as 12 or more outpatient visits in 114 days. The definition of Guideline concordant combination therapy followed adherence as defined for medication therapy and psychotherapy. The authors did not include indicators like medication dose and the choice of the correct treatment step as we did. Of the studied sample, 35% received guideline concordant care (in particular medication therapy).

Comparison of our studies with those from the Netherlands and abroad, mainly from the US, shows an emerging field in which important differences exist between studies with regard to methodology, type of data and settings. Nevertheless, the general impression is that of low adherence to guidelines in general.

5. Factors associated with guideline adherence

In this section, we try to integrate our findings on factors influencing guideline adherence (in our case treatment modality and patient characteristics) with those reported in the literature. Once again, we should be aware of the important differences in methodology, type of data and setting.

In chapter 5 we reported on differences in adherence to guidelines between treatment modalities. We found that patients receiving combined treatment were significantly more at risk for guideline deviations. In chapter 6 we examined the clinical and psychosocial correlates of guideline adherence and found that patients with low vitality were at risk for deviations from the guidelines. In chapter 7 we found that parameters, like age, gender and diagnosis could predict adherence in psychotherapeutic treatment. A diagnosis of anxiety or somatoform disorder was associated with higher odds of suboptimal duration and suboptimal frequency of psychotherapeutic treatment and the absence of ROM in the diagnostic phase compared to depressive disorder disorders.

5.1 Treatment modality

In chapter 5 we reported that there is less treatment adherence for the combination therapy modality, than in each of the treatments given separately. Not only the more complex nature of this combined treatment may play a role, but also the more complex psychopathology of the patients. In clinical practice, patients often start with one modality, for example pharmacotherapy, and when this is insufficient a combination therapy is started. Often a psychiatrist or resident in psychiatry is responsible for the prescription of the medication and a psychotherapist provides the psychotherapy. In clinical practice, this splitting of the treatment over two persons might jeopardize a clear direction or evaluation and therefore decrease guideline adherence. To the best of our knowledge, no other studies have paid attention to whom is conducting the combination therapy.

5.2 Profession of the therapist

In our project in a routine clinical setting, we did not study the influence of the profession on adherence to guidelines. Interestingly, using case vignettes, Tiemeier et al. [14] found that patients seeing psychiatrists are most likely to receive adequate treatment, as compared to patients seeing psychotherapists or clinical psychologists. Whether the treatment was in agreement with the Dutch guidelines, was scored by 15 panelists using a modified group judgment method (RAND). Kniesner et al. [15]used insurance data to study the influence of type of provider and found similar results. Definitions of treatment adequacy came from guidelines for the treatment of major depression established by expert panels of the Agency for Health Care Policy and Research and the American Psychiatric Association. Possible explanations for the influence of the pathology treated by the different professions.(more severely depressed patients possibly receiving more strict treatment)

5.3 Therapist's attitudes towards guidelines and ROM

An important factor influencing therapists' adherence to guidelines may be their attitude towards working with guidelines. To investigate the attitude of therapists working at Rijnveste GGZ Rivierduinen with regard to working with guidelines in clinical practice, we performed an anonymous survey in 2004, 2005 and 2006 (unpublished data). We asked the psychiatrists, residents in psychiatry and psychologists about their attitude towards working with guidelines in general, the extent to which they actually used them, their involvement in the implementation process and the perceived accessibility of the guidelines. They were moderately positive about all these topics. However, many of the therapists believed that their patients are too complicated to be treated completely according to the guidelines. For them, the guidelines felt like a straightjacket. We found no remarkable differences in attitudes over the three consecutive years.

We also performed an anonymous survey on the attitude with respect to working with ROM (unpublished data). Overall, therapists were moderately positive. We also organized a group meeting with this group of therapists in which they were encouraged to freely express their ideas concerning the use of routine outcome monitoring. At that time, most therapists found the timing of the ROM assessments and the selection of questionnaires too rigid. Besides, they experienced frequent discrepancies between ROM results and their clinical impression of the progress the patient had made. They were also afraid what effects the use of ROM data as a potential benchmarking instrument might have and wondered whether the objectives of managers and insurance companies were in line with the interest of the patients (and the therapists)?

This more reluctant and defensive attitude may also have played a role in the so-called "Doorbraakprojecten", [16]. These were evaluation projects in primary care, focusing on guideline implementation. They were organized from 2004 to 2009 by the Dutch Trimbos Institute, in collaboration with the Stichting Kwaliteitsinstituut voor de Gezondheidszorg of the Centraal Begeleidings Orgaan (CBO). The results showed some improvements at the process level of care and on patient outcomes, but much smaller than expected. Possible explanations given for these disappointing results include resistance of mental health care workers against changing their practices and reluctance to be evaluated [17,18]. Other authors also report resistance to working with guidelines, skepticism about the outcomes and a tendency to stick with previous practice [19,20]. It may be the same sort of resistance to standardization that was also found when the DSM-III was introduced [21]. This is in contrast with the results of a cross-sectional electronic survey among 703 general practitioners (GPs) in the Netherlands on perceived barriers to guideline adherence in general, which revealed that Dutch GPs have a positive attitude towards the guidelines of the Nederlands Huisartsen Genootschap (NHG) and report high adherence and low levels of perceived barriers. Barriers to adherence were restricted to external factors, in particular patient restrictions due to disability, behavior problems and preferences [22]. As the GPs started earlier with the guidelines, a hopeful perspective may be that the concerns expressed by mental health workers may be temporary.

5.4 Patient-therapist interaction

In our project we did not examine the interaction between patients and therapists as a factor influencing treatment adherence. However, the relationship between adherence and factors like diminished patient vitality, age, gender and specific diagnosis, as reported in chapters 6 and 7 could be mediated by the interaction between patient and therapist. To date, only a few studies have

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examined the relationship of patient-therapist interaction and compliance with guidelines. Most of them were conducted in primary care. Certain patient characteristics such as poor social resources of the patients, alcohol abuse, and psychotic features were associated with inaccurate judgments from the therapists [14,23]. Also, the progress expected by the patient himself seemed to influence the therapists' decisions [24].

Patients' acceptance of treatment guidelines, in particular in mental health, should be taken into account, as patients' noncompliance with medication treatment may influence therapists in their use of guidelines [25]. Physician adherence to guidelines appeared to vary with different types of "patients" and with the length of clinical experience of the therapist [26]. One study on depression found that therapists feel that factors hampering guideline adherence have to do with their patients' psychosocial circumstances, attitudes and beliefs about depression and its care [23]. Another group of researchers asked 7000 psychiatrists who treat patients with bipolar disorder about guideline adherence. The most frequently cited reason for not following the guidelines was that they do not address particular features of their clinical populations [27].

Should adherence to guidelines always be perfect? Some deviations are inevitable due to particular circumstances and characteristics of patients, for instance co-morbidity making prescription of a psychotropic drug impossible or a sudden change in psychosocial circumstances interfering with psychotherapy. In such cases, the therapist should document his arguments for non-adherence. If these arguments can be extracted from patient files and aggregated, they might help to further refine the guidelines.

5.5 Patient characteristics

It is plausible that patients' characteristics not only influence guideline adherence in general practice [22], but also in mental health. With our ROM data (chapter 6) and the parameters available in the administrative data (chapter 7), we were able to examine the association of clinical and psychosocial characteristics of patients with guideline adherence. In our sample of patients suffering from mood, anxiety and somatoform disorders, low scores on the vitality subscale of the SF-36 were associated independently with low

adherence to guidelines. A diagnosis of anxiety or somatoform disorder was associated with higher odds of suboptimal duration and suboptimal frequency of psychotherapeutic treatment and the absence of ROM in the diagnostic phase compared to depressive disorder disorders. No relationship was found with other sociodemographic variables, co-morbidity and the scores on the BSI subscales.

A number of other studies [27-33] also examined the relation of psychometric and socio-demographic patient factors with guideline-adherence in mental health. Younger age, male gender, lower socioeconomic status, minority status, poorer social functioning, co-morbid psychiatric disorder, poor insight in mental condition and (severe) side effects of psychotropic medication appeared to be associated with adherence problems. So far, these factors have not been systematically examined and replicated in other studies. Other studies found that age and gender were associated with adherence to specific indicators [13,34]. Adequate duration of pharmacotherapy was found for instance to be more likely in older females [34]. One study found that higher age was associated with insufficient assessment of therapy outcomes during treatment [35].

Interestingly, we could not replicate these findings, although we studied the same parameters, except for the side effects of psychotropic medication. The discrepancy may be explained by differences in the studied samples and the methodology. The other studies included patients with a broader range of disorders, like psychotic disorders and substance abuse, and with a different socio-economic background.

Taken together, these results demonstrate the influence of patient factors on guideline adherence, but this should be studied more extensively. It should also be investigated in what way patients at risk for diminished guideline adherence should be approached in routine clinical practice to improve adherence.

In conclusion, our studies and others demonstrate that various factors are associated with guideline adherence. However, much more research is needed to establish where guidelines adherence should be improved and where the guidelines themselves need improvement or adaptation to these factors.

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5. Limitations

In this section more general limitations of this thesis project will be discussed. More specific limitations for the different studies were already mentioned in the separate chapters.

Firstly, the first data for the studies included in this thesis were gathered in January 2004 and the last data in April 2013. In the nearly ten years this period of data acquisition lasted, the outpatient care of patients with mood-, anxiety- and somatoform disorders has changed. This is especially true for the organization of the care, most of the changes being the consequences of waves of changes in the reimbursement by the insurance companies and changes in the organization of the clinics in attempts to increase efficiency or refocus. Furthermore, the composition of the teams of psychiatrists and psychologists is likely to have changed during this period. We do not know whether these specific changes in the organization indeed influenced guideline adherence and if so, in what way: the studies in the chapters of this thesis span different time periods and differ in the way the data are acquired.

Secondly, the analyses described in chapters 4 through 6 are based on a relatively small number of patients: 100 in each year from 2004 to 2006. These numbers were large enough to investigate the feasibility of the indicators, but unfortunately rather small for further analyses. The reason was that all data for these studies had to be extracted manually from the notes in the patient records. Even after the introduction of electronic patient files in 2006, data for this study still had to be collected manually, as they were written as plain text in the electronic files. Obviously, collecting data in this manner is a very time consuming process. One might wonder why we undertook such a laborious task, as this would not easily lead to possible future large-scale application. The reason is that at the start of our project, it was expected that electronic patient files would soon be available, including files from which detailed information about patient and treatment characteristics integrated with ROM could be extracted automatically. However, this never was realized during the study period. To date, it is still unlikely that such data from electronic files will become easily available in the next future. Fortunately for this project, administrative data from January 2009 through March 2013 were made accessible for analyses and these data enabled analyses of guideline adherence in a much larger group of 5346 patients, although with a smaller number of indicators.

Thirdly, we originally planned to study whether guideline-concordant care is associated with a larger treatment effect. However, several factors made this not possible. A substantial proportion of our 2004-2006 sample (36%) did not have a complete set of first and subsequent ROM assessments. Consequentially, the sample with complete data (N=192) was too small to make a study of the association between guideline adherence and treatment effect possible. The 2009-2013 sample was much larger, but it was technically impossible to couple administrative data with ROM data.

Fourthly, we choose to score the indicators using a dichotomous approach (1 if the criterion was met and 0 if not). This approach was chosen for practical reasons, but also results in a loss of information. For example, the minimal duration of pharmacotherapy had to be six weeks (according to the guideline) and five weeks of pharmacotherapy resulted in a score of 0 instead of a more differentiated percentage of adherence. Also, information on the considerations to deviate from the guidelines was not included.

Fifthly, as we studied a small number of patients in the 2004-2006 study, the number of therapists treating sufficient numbers of patients to be able to make reliable statements at the level of the individual therapists was too limited. In the 2009-2013 sample, a study on the therapist level would have been possible as patient numbers were sufficient, but data on individual therapists were unfortunately not available.

Sixthly, a growing proportion of patients in Dutch mental health care has roots in other countries and often in cultures very different from Dutch society. It is evident that this may influence assessment and adherence to guidelines. In this study we only included patients who mastered Dutch. Future studies will have to take the effects of culture into account.

Seventhly, in our studies we could not include guideline-naïve groups (patients nor therapists) as in Rivierduinen such groups were non-existent.

Finally, the guidelines formulated for the treatment of MAS-disorders typically follow a stepped-care approach, with usually many steps involved. In this thesis, however, we only studied the first treatment steps. Clearly, treatment in secondary mental health care usually involves more steps. There are indications, however, that it frequently takes a long time before these next treatment steps are made and that in many patients those steps are never made at all.

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6. Implications for future research

Based on this project, some potential building blocks for future research on guideline adherence can be advised:

First of all, an electronic file in which standardized treatment data can be stored and automatically retrieved is necessary. More precise: this file should contain not only data on anamnesis and life history of the patient, but also data on the type and course of treatment and the treatment steps. These data should be arranged in such a way that the various possibilities per topic can be entered in a database via a menu, allowing statistical analysis. For instance, the antidepressant chosen should not be written down in plain text but selected from a menu. With respect to the details of treatment: these should also be entered in a menu or interactive screen in such a way that treatment processes can easily be compared with the guidelines. The process indicators we developed can serve as starting point for such a menu.

ROM should not only be done as a standard component of the intake procedure but also of the follow-up and certainly at the end of each treatment step. Furthermore, ROM data should be routinely coupled to treatment data. A next step could be to standardize the analyses of guideline adherence to allow comparisons between settings, specific patient samples and even countries.

The moment data from electronic patient files and ROM-data of large patient groups can be coupled and aggregated, it becomes possible to study guideline adherence in much more detail. In outpatient departments, the data can be used to evaluate and improve routine practice. It will then become possible to do more systematic research on the factors hampering adherence and how to overcome them, first by analyzing routinely gathered data and next by systematically evaluating different approaches. This type of data may prove to be very useful for the development of staging and profiling approaches, ultimately leading to more personalized treatments.

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