Adequacy of Treatment for Patients With Schizophrenia Spectrum Disorders and Affective Disorders in Lombardy, Italy

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Objective: **This study assessed whether patients being treated for schizophrenia spectrum and affective disorders in Lombardy receive adequate treatment and sought predictors of adequate treatment.** ***Methods:*** **Patients were aged ≥18, were residents of Italy's Lombardy region, and were treated in 2007 for schizophrenia spectrum and affective disorders (N=44,462). The patients were assessed as part of a retrospective analysis of pharmaceutical and mental health services databases. Adequacy of 12-month treatment from the first psychiatric contact in 2007 was assessed at the patient level. A hierarchical log-binomial regression model was fitted to estimate relative risk and 95% confidence intervals for association between patients, characteristics of the departments of mental health (DMH), and receipt of minimally adequate treatment.** ***Results:*** **About half the patients with serious mental disorders did not receive adequate care; 45.5% of patients with depressive disorders, 55.7% of those with bipolar disorders, and 49.3% of those with schizophrenia spectrum disorders received minimally adequate treatment. Diagnosis of a schizophrenia spectrum disorder or bipolar disorder and male gender predicted adequate treatment, whereas employment and high comorbidity predicted inadequate treatment. Patients who received mental health services in the past year were significantly more likely to receive adequate treatment compared with those who had received services in the past five years or new patients.** ***Conclusions:*** **Minimally adequate treatment is a useful indicator to monitor quality of care in Italy's regional mental health system. These data should be used at regional and local levels to implement clinical audits, to create benchmark measures, and to define new quality-improvement projects to meet specific DMH needs. (*Psychiatric Services* 62:1079–1084, 2011)**

Serious mental illness, including schizophrenia spectrum and affective disorders, is the main focus of mental health systems, particularly in community-based mental health systems. As Leff (1) asserted, the success or failure of community care is judged by the results achieved with these patients and their families. Furthermore, community care is not simply a network of community mental health facilities; more important, it involves the delivery of appropriate and evidence-based treatments (2).

Previous studies have shown that a substantial proportion of people receiving treatment for serious mental disorders do not receive adequate care (3–8), not even in well-developed mental health systems. Thus the identification of this population is a critical first step toward improving the appropriateness of care and health outcomes of those with serious mental illness.

To assess quality of care, we need to define a set of common indicators that allow comparisons between different mental health systems and between different levels of care within the same mental health system (that is, primary care versus specialized care). The concept of minimally adequate treatment has been used extensively (3,9–12) and is suitable for the purposes of such comparisons. In this concept minimally adequate treatment is defined as receiving either pharmacotherapy (two or more months of a psychotropic medication plus four or more visits to any type of medical doctor) or psychotherapy (at least eight psychotherapeutic sessions) (9).

Reform of mental health care in Italy began with a change in legislation (Law 180) that closed the psychiatric hospitals in the 1980s and promoted community-based care. The 1978 legislation charged the regions of Italy with the responsibility of managing the transition toward community psychiatric care. In the decades that followed, each Italian region set up its own mental health system (13,14). From an evaluative point of view, each region represents

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a single evaluation unit that is relatively homogeneous in terms of policies, resources, and service delivery.

The aim of this study was to assess the quality of treatment for serious mental illness in Lombardy, the largest region of Italy. We analyzed data for the entire Lombardy population that received mental health services. Our goal was to estimate the proportion with serious mental illness who received care consistent with available evidence-based treatment recommendations. Furthermore, predictors of receipt of minimally adequate treatment were identified.

Methods

Setting

Lombardy is the largest and the most affluent region in Italy, and in 2009 its population was 9,742,676 (16.2% of Italy's population). Lombardy is located in the northernmost part of the country and includes the metropolitan area of Milan, Italy's second largest city.

In Lombardy, the department of mental health (DMH) is the national health service that provides mental health care to the catchment area's population through a network of community services that include ambulatory care, outreach teams, hospitals, and day treatment and residential facilities. Each DMH is organized to provide a full range of psychiatric care, from acute emergency treatment to long-term rehabilitation, and generally includes one or more of the following facilities: community mental health centers, general hospital psychiatric units, day treatment centers, and community residential facilities.

Data source

The data concerning psychiatric care used in this study were retrieved from the regional Psychiatric Information System (PIS). As a psychiatric case register, the system gathers information from all public DMHs and from private day treatment and residential facilities. The register has covered the Lombardy region since 1999, giving a full description of the mental health activities and monitoring the treatment provided to patients. The information system collects demographic information and the *ICD-10* diagnoses (15) of patients in contact with mental health services and records all patient care episodes in any treatment setting (outpatient and home contacts, day treatment attendance, and admissions to general hospital and residential facilities).

All demographic and administrative data (including death or emigration dates) and information pertaining to the use of other health services, including hospitalization in public and private hospitals in Lombardy and outpatient drug prescriptions reimbursed by the National Health Service, were retrieved from the health service database of Lombardy.

Through a patient's identification code it was possible to join the PIS database and the National Health Service database to reconstruct the clinical history of each patient. At the time of this study, the formal approval of a study protocol by an ethics committee or institutional review board was not required in Italy: however, to preserve patient privacy, the identification codes from all the databases were converted to anonymous codes, and the conversion table was then destroyed.

Study design and population

The target population was the residents of Lombardy who were at least 18 years old and who were in contact with mental health services between January 1 and December 31, 2007, and received a diagnosis of a schizophrenia spectrum disorder or an affective disorder.

The *ICD-10* diagnostic codes (15) included in the PIS were used to assess mental health diagnoses. Depressive disorder included *ICD-10* codes 32.XX, 33.XX, 34.9X, 43.20, and 43.21; bipolar disorder included codes 30.XX, 31.XX, 34.0X, and 38.0X; and schizophrenia spectrum disorders included codes 2X.XX.

For each patient, the date of the first contact with DMH during 2007 was considered the index date. Treatment adequacy was then assessed for the 12 months starting from this index date. Patients who did not reach one year of follow-up (about 2% of those treated as of baseline died or emigrated from Lombardy by follow-up) were excluded from the study. Patients with incomplete data (about 8% of the remaining patients) were also excluded. The final cohort included 44,462 patients with a diagnosis of a schizophrenia spectrum disorder or an affective disorder: 16,281 with depressive disorder, 5,711 with bipolar disorder, and 22,470 with a schizophrenia spectrum disorder.

The patients were divided into three subgroups by the frequency of mental health contacts with DMH before 2007, the year of evaluation: "new patients" had no previous contact with DMH; "former patients" had received care in the period 2003–2005 but concluded their treatment and had no further contact up to 2007; and "continuous-care patients" received continuous care and were in contact with DMH in 2006.

Assessment of minimally adequate treatment

Quality of treatment during the follow-up period was defined in line with the recommendations of the American Psychiatric Association and with other studies on quality of mental health care (3,9,16–18). Minimally adequate psychotherapy was defined for this study as receiving at least eight psychotherapy sessions; minimally adequate pharmacotherapy was defined as receiving at least two months' supply of appropriate medication (antidepressants for depression, antipsychotics or mood stabilizers or both for bipolar disorder, and antipsychotics for schizophrenia spectrum disorders) plus at least four visits with a psychiatrist. Finally, minimally adequate treatment was defined for depressive disorders as receiving minimally adequate psychotherapy, pharmacotherapy, or a combination, and it was defined for schizophrenia and bipolar disorders as receiving minimally adequate pharmacotherapy.

The mental health service database of the PIS recorded the psychotherapy sessions and visits with a psychiatrist, whereas the pharmaceutical prescription database of the National Health Service showed the prescriptions administered. Drugs

were selected according to the Anatomical Therapeutic Chemical Classification (ATC) system (19): antidepressants, such as those with ATC code N06A; antipsychotics, such as those coded N05A (excluding N05AL); and mood stabilizers, such as those coded N03AF, N03AG, N03AX, and N05AN. To calculate the 12-months' daily supply of pharmacological treatment, we used the defined daily dose system provided by the WHO Collaborating Centre for Drug Statistics Methodology (19). In this approach it is assumed that the patients consumed all the drugs prescribed by National Health System providers and available through outpatient pharmacies. Any period spent as a psychiatric inpatient, whether it be in a general hospital or residential setting, was considered as being under appropriate pharmacological treatment, and the relative information about days spent there was taken from the psychiatric databases.

Patient characteristics

In line with other studies of quality of care for mental illness (4,8,9,20), we included sociodemographic and clinical variables in the analysis of the predictors of minimally adequate treatment. These were age at the index date (categorized as 18–29, 30–44, 45–59, and ≥60 years); gender; completed years of education (one to five, six to eight, nine to 13, and ≥14); employment status (employed or unemployed); marital status (married, never married, divorced, and widowed); urbanicity, defined according to Eurostat (21), as low, medium, and high urbanization; and the Charlson Comorbidity Index, a score summarizing the overall burden of comorbidity and using diagnostic information from hospitalization one year before and one year after the index date (categorized as 0, 1, and ≥2) (22,23). The variables relating to DMHs, expressed in terms of rates per 10,000 inhabitants >14 years old, were beds in general hospital psychiatric units and residential facilities and working hours spent by health care professionals in community mental health centers and community day treatment facilities during the year. Both variables were categorized with the use of quartiles, the statistical criterion required to ensure that each group is of comparable size.

Statistical analysis

The proportion of patients who received minimally adequate treatment was calculated for the entire cohort and among the predictor levels. To evaluate the determinants of minimally adequate treatment, a hierarchical (also called multilevel or mixed) regression model was used for a dichotomous outcome. Because it has been reported that an odds ratio can overestimate the effect of association when the outcomes are not common (incidence of 10% or more), we instead used a log-binomial regression to estimate risk ratios (RR) and to directly evaluate adjusted RRs (24). Also, because the observations (that is, the patients) were nested in units (DMHs in this case), the log-binomial regression model was fitted with the use of a hierarchical approach (25). The risk of receiving minimally adequate treatment was evaluated, and RRs were adjusted with relative 95% confidence intervals (CIs), which were estimated according to level of the exposure variables. The final model included all the independent variables, so that the assessment of each covariate's effect took into account the effects of all the other measured covariates. The results were considered significant at $p<.05$. The SAS statistical package (SAS Institute Inc., Cary, NC), version 9.1, was used for data management and statistical analysis; the hierarchical log-binomial model was fitted with the use of the NLMIXED procedure.

Results

We identified 44,462 residents in Lombardy with diagnoses of schizophrenia spectrum or affective disorder who were treated during 2007 in a DMH (Table 1). The mean±SD age was 49.9±15.0, and 43.7% were male. Only 12.5% were new patients, 28.3% were former patients, and the other 59.3% were continuous-care patients. Most patients (50.5%) were treated for a schizophrenia spectrum disorder, 36.6% were treated for depression, and the other 12.8% were treated for bipolar disorder. Only 9.0% had one or more somatic comorbidities.

Overall, by 12-month follow-up, 48.7% of the patients received minimally adequate treatment (N=21,658 of 44,462). In terms of diagnosis, this quality criterion was met by 45.5% of the patients with depressive disorder, 55.7% of those with bipolar disorder and 49.3% of those with a schizophrenia spectrum disorder. Patients treated for bipolar disorder or a schizophrenia spectrum disorder were more likely to receive minimally adequate treatment (RR=1.14 and RR=1.08, respectively) than those treated for depression (Table 1). Male patients (RR=1.03), patients with nine to 13 years of education (RR=1.06), and patients never married (RR=1.03) were also more likely to receive minimally adequate treatment. Patients who were most senior (RR=.86), employed (RR=.94), widowed (RR=.95), and who had a higher burden of illness (Charlson Comorbidity Index ≥2; RR=.95) were less likely than their comparison group to receive minimally adequate treatment. Finally, new patients and former patients were significantly less likely than patients in continuous care to receive minimally adequate treatment (RR=.74 and RR=.50, respectively). Neither urbanicity nor DMH characteristics seemed to be related to quality of treatment.

Discussion

Originally, the minimally adequate treatment indicator was used mainly within large community surveys (such as the World Mental Health Survey), where information was collected through interviews with persons in the community who had mental disorders. In this study we applied the indicator to evaluate the quality of care provided to patients who received mental health services and analyzed retrospective data from mental health and pharmaceutical information systems. Changing the sample and the way of collecting information did not reduce the validity of the indicator, which summarized into a single item two important dimen-

Table 1

Characteristics at baseline of patients with serious mental illness and as predictors of receipt of minimally adequate treatment at 12 months

Characteristic	Baseline (N=44,462) N	%	Minimally adequate treatment at 12 months (N=21,658) N	%[a]	Relative risk	95% CI
Clinical and sociodemographic						
Age						
18–29[b]	3,710	8.3	1,956	52.7	1.00	
30–44	13,859	31.2	7,378	53.2	1.02	.99–1.06
45–59	14,598	32.8	7,281	49.9	1.01	.98–1.04
≥60	12,295	27.7	5,043	41.0	.86*	.83–.90
Gender						
Female[b]	25,016	56.3	11,728	46.9	1.00	
Male	19,446	43.7	9,930	51.1	1.03*	1.01–1.05
Education (years)						
≥14[b]	2,059	4.6	997	48.4	1.00	
9–13	10,853	24.4	5,685	52.4	1.06*	1.02–1.11
6–8	18,879	42.5	9,618	51.0	1.04	1.00–1.09
1–5	12,671	28.5	5,358	42.3	.97	.92–1.02
Employment						
Unemployed[b]	28,963	65.1	14,041	48.5	1.00	
Employed	15,499	34.9	7,617	49.2	.94*	.93–.96
Marital status						
Married[b]	18,190	40.9	8,535	46.9	1.00	
Never married	19,477	43.8	10,116	51.9	1.03*	1.01–1.06
Divorced or separated	3,984	9.0	1,906	47.8	1.02	.99–1.06
Widowed	2,811	6.3	1,101	39.2	.95*	.90–.99
Urbanicity						
Low[b]	3,461	7.8	1,669	48.2	1.00	
Medium	12,296	27.7	5,867	47.7	.99	.95–1.03
High	28,705	64.6	14,122	49.2	1.01	.97–1.06
Charlson Comorbidity Index[c]						
0[b]	40,488	91.1	19,887	49.1	1.00	
1	1,577	3.6	738	46.8	1.01	.97–1.06
≥2	2,397	5.4	1,033	43.1	.95*	.91–.99
Type of disorder						
Major depressive disorder[b]	16,281	36.6	7,408	45.5	1.00	
Bipolar disorder	5,711	12.8	3,179	55.7	1.14*	1.11–1.18
Schizophrenia	22,470	50.5	11,071	49.3	1.08*	1.06–1.10
Type of care						
Continuous[b]	26,349	59.3	15,663	59.4	1.00	
Former	12,563	28.3	3,682	29.3	.50*	.48–.51
New (treatment at index date)	5,550	12.5	2,313	41.7	.74*	.72–.76
Environmental (Department of Mental Health)						
Psychiatric beds (per 10,000 population)						
.93–2.48[b]	11,449	25.8	5,307	46.4	1.00	
2.49–3.22	11,019	24.8	5,218	47.4	.96	.85–1.08
3.23–4.47	11,100	25.0	5,763	51.9	1.09	.96–1.24
4.48–17.58	10,894	24.5	5,370	49.3	1.01	.90–1.14
Hours worked in community mental health facilities (per 10,000 population)						
812–2,180	11,590	26.1	5,611	48.4	1.00	
2,181–2,660	10,525	23.7	5,027	47.8	1.05	.92–1.19
2,661–3,122	11,765	26.5	5,792	49.2	1.04	.92–1.18
3,123–6,791	10,582	23.8	5,228	49.4	1.06	.94–1.20

[a] Percentages are based on the N for each characteristic at baseline (that is, the row percentage).
[b] Reference
[c] Higher scores indicate more comorbidity.
*p<.05

sions of care quality: the continuity of care and the adherence to specific psychotropic treatment. However, this approach did not facilitate the comparison of such data with data from community surveys, mainly because of the small number of people in the community samples with serious mental disorders (particularly schizophrenia).

A question could be raised concerning the capacity of this indicator, which was based essentially on visits with psychiatrists, to capture the complexity of community mental health care. In fact in a well-integrated community mental health system such as Lombardy's, the continuity of care for patients with serious mental disorders is guaranteed not only by psychiatrists but also by other mental health professionals, including nurses, social workers, and rehabilitation therapists. From this point of view this indicator may be inadequate to evaluate integrated community mental health care in depth.

With regard to patients with schizophrenia spectrum disorders, only about half the patients (49.3%) received minimally adequate treatment. This highlights that, although more than half of Lombardy's mental health system resources go mainly toward these patients (13), the quality of care is not as good as it should be and could therefore be improved greatly. The only available comparison was the study performed by Wang and colleagues (4), who found that 55% of patients with nonaffective psychosis received minimally adequate treatment. However, the two sample sizes differ greatly (in the Wang sample there were several dozen patients with nonaffective psychosis), making comparison questionable.

With consideration of bipolar disorders, our results (with 55.7% of bipolar patients receiving minimally adequate treatment) are comparable with those of Simon and colleagues (6) (59%, although in their paper treatment quality was rated only with regard to psychotropic treatment) and Wang and colleagues (9) (54%).

The results for depression in Lombardy (49% with minimally adequate treatment) were lower than those in

Finland (61%) (26), Canada (55%) (27), and the United States (64%) (28) and similar to those from another survey in the United States (46%) (8). The quality of care in the Teh and colleagues paper (7) related to new episodes of depression was notably better (70%) than that assessed in Lombardy (45%). If we consider all the affective disorders jointly, our results (48.1% for depressive and bipolar disorder) were lower than those in a Mexican survey (59%) (29).

Which patients were at major risk of receiving low-quality care? They were older people, those who were employed, and those with serious somatic diseases. Comorbidity with somatic illnesses is an important issue, one that is often not adequately addressed by mental health services and, from our data, one that severely affects quality. Patients with depression received less adequate treatment than patients with schizophrenic and bipolar illnesses. In Italy, after reform of psychiatric care in the 1980s, mental health services focused on patients with psychotic disorders because they were particularly at risk of being left behind after the closure of the psychiatric hospitals, and DMHs probably underestimated the burden of depressive disorders, in terms of both disability and chronicity.

Poorer treatment quality for new patients and former patients is another issue highlighted by the data: these patients received less adequate treatment than patients with continuous care. Indeed, the attitude of mental health professionals should be changed from a "wait and see" policy to a proactive one. Over the past five years the implementation of early treatment for psychosis services has been a major mental health policy issue in Lombardy (30), and such treatment is a major step in the right direction, but as of 2007 this approach had not been fully implemented. Finally, the DMH variables available for analysis may not have been ideal for our analyses and could explain their lack of influence on quality. All were structural variables in terms of Donabedian classification (31) and were apparently unrelated to the processes of care. Indeed more sophisticated process indicators than those used in this article are needed.

The study revealed that in 2007 in Lombardy, about half the patients with serious mental disorders did not receive adequate treatment. This important result indicates that monitoring will be needed in the coming years to evaluate the quality of care provided by the regional mental health system. The role of information systems in this process is crucial: epidemiological data are essential in order to change mental health services and improve quality of care. Thus system-level interventions might include efforts to provide clinicians with information about their performance in comparison with their peers. The data should be used at both the regional and the local levels to implement clinical audits, develop benchmark measures, and define new quality improvement projects tailored to meet specific DMH needs. This promising methodology already has been used in the outcome management area, as outlined by Knaup and colleagues (32).

Which areas need to be improved at the system level to achieve better treatment quality? First of all, continuity of care should be improved at the outpatient level. Recent analyses (14,33) have shown that serious mental illness in the regional mental health system is mainly treated only at the community mental health centers level, without any inpatient care. If these facilities are not able to follow up with patients who have a serious mental illness, a gap in care is created, which breaks continuity of care. To remedy this situation, community mental health center activity requires specific strengthening, mainly by allocating more resources to the sector. Continuity as well as adherence should be targeted. Active clinician-patient partnerships are essential to optimize treatment quality, and the careful selection of drug therapy, with an emphasis on drug tolerability, combined with psychosocial interventions, could decrease the nonadherence of patients with serious mental illness (34).

Conclusions

Our findings suggest that interventions are needed to increase the extent to which mental health care conforms to evidence-based recommendations. Indeed, it is essential that policy makers and professionals use all the information available concerning factors related to quality of care and respond in a manner that ensures high-quality treatment to relieve suffering from serious mental illness.

Acknowledgments and disclosures

The authors report no competing interests.

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