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Contents

The Mental Health paradox, between increased demand and cutback of resources

Italian Mental Health system has so far represented a positive anomaly in the international scenario of community psychiatry. With psychiatric hospitals closed since 1978 and forensic psychiatric hospitals dismissed since 2014, Italy has shown that a community alternative to large institutions is feasible and cost-effective. Strategies to support housing, job placement and social inclusion of people affected by mental illness put into practice the EU Fundamental Rights of citizenship and non-discrimination, contributing to fight stigma and to reduce the risk of hospital admission. As a matter of fact, Italy has one of the lowest number of acute beds among OECD countries and shows rates of compulsory admissions which are significantly lower of other western industrialized countries. However, the ongoing economic crisis and the recent, additional cuts to public health financing, cast considerable doubts over the sustainability of the Italian mental health system. Paradoxically, this happens while the same economic crisis is exerting a heavy toll on community mental health, increasing the need of psychiatric care.

The burden of mental disorder

Actually, the burden of mental health problems on society is still underestimated and the economic costs associated with mental illness are largely overlooked by policy makers. The epidemiological complexity of the problem, the marginalization and stigma attached to mental illness have represented, at least in part, a barrier for an in-depth appreciation of its magnitude.

Epidemiological figures are bewildering: only in the EU, mental illness affects about 165 million people per year and it is estimated that over 50% of people living in developed western countries would suffer from at least one mental health problem at some point in their life. Between 2011 and 2030, the cumulative economic loss due to mental illness is estimated in 16.3 trillion US dollars worldwide, which in other words means that the burden of mental disorders will equate that of cardiovascular diseases and will be higher than cancer, diabetes and respiratory diseases [1].

As regards Italy, mental disorders represent today 10% of the total Disability-Adjusted Life Years (DALY, a measure that combines years of life lost due to premature death along with years of life lived with disability) and 20% of Years Lived with Disability (YLD) [1 2]; mental disorders, as a whole, account for 35% of the causes of lost productivity and about half sick leave from work are caused by mental health problems [3]. According to ISTAT [4], depression affects about 2,6 million people; our analysis on ISTAT database yielded an estimated prevalence of common mental disorders in the adult population of 17.7%. Quite interestingly, in 2005 it was 15.7%, which in absolute numbers indicates that in less than a decade, people with psychiatric problems raised by about one million of individuals, arguably confirming the adverse impact of economic crisis. In the same time span, an excess of suicide and attempted suicides has been linked to the economic effects of the recession [5].

Mental Health spending

Bearing the above in mind, decision makers should carefully reconsider the provision of public health care and the accessibility of community mental health services, promoting a redistributive approach of available resources.

According to the Italian Ministry of Health, mental health sector gets allocated about 5% of national health expenditure. Hower, an analysis carried out by the Italian Society of Psychiatric Epidemiology (SIEP) found that across Italian Regions a mean estimate of mental health spending does not go beyond 3,5%, revealing large regional variability and plausible disparities. In the European context, Italy's investment in mental health sector is far below other countries such as Germany, France, UK which allocate an average 10-12% of their national health expenditure. Moreover, if we consider the theoretical 5% as rate of Gross Domestic Product, Italy comes only a little ahead of Eastern European countries and is far behind North and Western Europe [6].

The treatment gap

Given this picture, it is not surprising that in the last years community mental health services struggled with many difficulties to provide an adequate response to users' needs. Italian Society of Psychiatry survey found that in the past decade staff allocated to community services faced a reduction of about 50%, with a rate of professionals per 1500 inhabitants going down from 0.8 to 0.4. On the other side, people in contact with public mental health services account for about 1.6% of the adult population; 0.7% is the rate of "new" cases per year. Consider-

ing the increased needs, the stability of these figures over the last years allows us to believe that a problem of accessibility exists, causing a "treatment gap" [7]. Unfortunately, this phenomenon does not concern only individuals with common psychiatric disorders, such as anxiety or mild depression, but is relevant in 45% of schizophrenic syndromes, major depression and bipolar disorders. Needless to say, the fact that serious psychiatric disorders do not reach public mental health services represents quite a worrisome data.

Furthermore, the lack of suitable "extra-hospital facilities" and the limited activity of understaffed community services may be the cause of involuntary hospital admissions, rather related to structural deficiencies of the care system than to the severity of underlying psychopathological conditions. The paradox here is that an individual might get deprived of his/her personal freedom due to the underpowered structures of the same care system which in the first place should guarantee his/her well-being.

The choice that lies ahead is therefore to turn the current trend by considering the cost of changes necessary for mental health services as an investment for the whole community.

The road ahead

Data from health economics analyses confirm that desirable changes represent a "cost-effective" opportunity in many areas of psychiatric practice. A good example comes from studies carried out to assess the costs and benefits of parenting programs to prevent conduct disorders; over ten years a return on investment of nearly € 8 for every € 1 spent has been reported, confirming that benefits would interest different public sectors, such as criminal justice, yielding a reduction in the impacts of violent crime on individuals [8]. Additional evidence comes from the estimate of the long term return on investment related to early detection and early intervention services for psychosis [9]. Early intervention services are cost saving after just one year; over ten years, for every € 1 spent there would be a return of nearly € 18, with more than half of all these gains accruing to the health system.

In our opinion, knowledge and dissemination of these data should inform the scaling-up of mental health policies and investments, overcoming the lack of political commitment observed in the last years. For these reasons, the Italian Society of Psychiatric Epidemiology (SIEP) has recently launched a national campaign to appeal for convening regional conferences, where professionals, users and families meet policy makers to discuss and define, on the basis of valid and reliable data, which development lines should be adopted to make our community mental health worthy of its past.

Fabrizio Starace

Direttore, DSMDP AUSL Modena
Presidente, Società Italiana di Epidemiologia Psichiatrica

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One-year changes in capacity and participation in patients with schizophrenia or bipolar I disorder treated in community-based mental health services in Italy

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Summary

Objective

To investigate the capacity and participation restrictions over one-year in patients treated in community mental health services.

Materials and Methods

We recruited 100 consecutive patients with schizophrenia or bipolar I disorder. The assessment instruments included the Mini-ICF-APP, the BPRS and the Clinical Global Impression Scale (CGI).

Results

Capacity/participation restrictions and psychopathology levels improved significantly at one year in each diagnostic group. Moreover, changes in Mini-ICF-APP factors (proficiency, relational capacity, autonomy) were significantly higher in patients who were improved or much improved (CGI-Improvement = 1, 2) compared with those observed in patients who were not improved . A higher baseline functional impairment and a higher decrease in psychopathology predicted a higher improvement in total Mini-ICF-APP. After controlling for the effect of these predictors, no difference between diagnostic groups was found.

Conclusions

When a community-based treatment is effective in reducing symptom severity, a concurrent improvement is obtained in capacity and participation functioning. The Mini-ICF-APP was sensitive to change in psychopathology and therefore can be used in routine clinical assessments.

Key words

Bipolar Disorder • ICF • Mini-ICF • Schizophrenia • Social Functioning

Introduction

The bio-psycho-social model of the International Classification of Functioning, Disability and Health (ICF)[1] predicates that the definition of illness should include 3 key elements: "impairment of functions" (for instance poor concentration), "limitations in activities or capacities" (e.g. inability to perform daily tasks) and "restrictions in participation" (e.g. reduced work productivity).

This broader view of illness has deeply influenced the scientific community and as a result, in the last decade, research on social and occupational consequences of illness has increased [2-5]. In the field of mental health the relationship between functioning, capacities, and restrictions in participation is a challenge for clinicians [6 7]. The capacity domains, which may be impaired especially in people with mental illness, include adherence to regulations, planning and structuring of tasks, flexibility, endurance, assertiveness, self-maintenance, mobility, or competence in making judgements or decisions.

To our knowledge, only one study to date has examined the extent to which mental disorders are characterized by functional impairment and also by limitations in capacities [8], so further research on this topic is still needed.

Answering this question would allow to determine which capacities are impaired in specific mental disorders. This could support the choice of specific compensatory treatments, or social interventions tailored to the affected people.

Limitations in capacities can be assessed using the Mini-ICF-APP ("Mini instrument for describing capacity and participation in mental disorders" according to the ICF-model of impairment), a rating scale that has been initially developed in German [9]. Subsequently, the Mini-ICF-APP has been translated to English in a validated version [10], and its usefulness has been confirmed in a pilot study conducted in a UK community mental health team [11].

This study investigates the capacity and participation restrictions, as measured with the Mini-ICF, over the course

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of one-year community-based treatment in patients with schizophrenia or bipolar disorder.

Materials and Methods

We recruited 100 consecutive patients (50 with schizophrenia and 50 with bipolar I disorder) attending the Community Mental Health Center (CMHC) of North-Udine (Italy). The diagnosis was determined using DSM-V clinical criteria by the psychiatrists working in the CHMC.
The patients were those recruited for a validation study of Mini-ICF-APP, Italian version [12]. All participants were followed up for one year. All patients were on psychotropic drugs, in monotherapy or polypharmacy as appropriate for the diagnostic indications and the severity of illness (data not provided). One half of patients were involved in rehabilitation programs, that were implemented according to Spivak's model of social competence [13].

Instruments

Patients' baseline assessment consisted of a socio-demographic form, including information on gender, age, marital status, working status, duration of illness and duration of untreated illness, previous hospitalizations, alcohol and/or substance abuse, pharmacological treatment, rehabilitation interventions, social network and life events. The Mini-ICF-APP, the Brief Psychiatric Rating Scale (BPRS) and the Clinical Global Impression Scale (CGI) were administered at baseline and one year. All patients were interviewed by 2 psychiatrists with experience in RCTs and mental health research programs, who attended a national training course on the use the ICF classification system and participated in a specific training on the administration of Mini-ICF-APP. The BPRS is part of the routine clinical assessment of patients and study raters were trained by one psychiatrist (EM).
The Mini-ICF-APP is a clinician-rated instrument designed to assess limitations of capacities in patients with mental disorders [6 7 9 14]. This instrument has been developed by preserving the structure and dimensions of ICF[1] and taking also into account the definitions of the Groningen Social Disabilities Schedule II (GSDS II) [15]. Capacity limitations are rated in terms of activity competence limitations. The 13 items of the instrument explore: (1) adherence to regulations, (2) planning and structuring of tasks, (3) flexibility, (4) competency, (5) judgment, (6) endurance, (7) assertiveness, (8) contact with others, (9) integration, (10) intimate relationships, (11) spontaneous activities, (12) self-care, (13) mobility. For each capacity item, the impairment degree was rated 0 = no impairment, 1 = mild impairment, i.e., there are some difficulties for the person to fulfill the demands, but there are no negative consequences, 2 = relevant impairment, i.e., there are visible problems in fulfilling the demands, 3 = severe impairment, i.e., help from others is needed regularly in order to fulfill the demands and activities, 4 = extreme impairment, i.e., no activity is possible, and complete dispensation is necessary. The total score ranges from 0 to 52, with higher scores denoting higher disability and vice versa.
The Mini-ICF-APP rater collects information on the patient's capacity, i.e. what the patient can do, in a "uniform or standard environment" or in a social reference group, whichever applies. Information about the patient and his/her living situation is obtained from different sources including self-reports, information from the family, colleagues, friends, caregivers and mental health professionals involved in treatment, from clinical observations or standardized tests. The Mini-ICF-APP assessment requires at least a sufficient acquaintance with the patient and can be filled out in about 20 minutes, and often quite less. A rating manual is currently available in Italian, German and English [9 10 12]. The reliability of Mini-ICF was assessed in the context of mental health services by Balestrieri et al. [12] In particular, this instrument showed excellent inter-rater (ICC = 0.987, 95% CI 0.981-0.990) and test-retest (ICC = 0.993, 95% CI 0.984-0.997) reliability. Moreover, Mini-ICF proved to have a good convergent validity with two well-known instruments designed to assess social functioning (PSP and SOFAS).
In a previous paper [16], we found that Mini-ICF-APP has a three-factor structure of. The first factor, named "proficiency", represents the cognitive and performance-related skills necessary to begin and maintain a task such as a work or a commitment in general (items 1-7). The second factor was interpreted as "relational capacity" since included the items "contacts with others", "integration", and "intimate relationships" (items 8-10). Lastly, the third factor included the items related with the physical "autonomy" of the individual (items 11-13).
The Brief Psychiatric Rating Scale (BPRS) is a well-known clinician-rated instrument designed to measure the severity of psychopathology in patients with psychosis and mood disorders [17]. For the purpose of the present paper, we used the expanded version of the instrument including 24 items and the 4-factors solution derived by Velligan et al. [18 19]:

- Depression/Anxiety (items 1-6, 13);
- Activation (items 7, 15, 19, 21-24);
- Retardation (items 14, 16-18, 20);
- Psychosis (items 8-12).

Our choice was related to the large sample investigated by Velligan et al. [19], that included 1331 patients with schizophrenia, depression or bipolar disorder, thereby providing a stable factor solution. The Clinical Global Impressions

Scale (CGI) is an overall clinician-rated instrument that takes into account patient's history, psychosocial problems, symptoms, behaviors, and patient's functioning [20]. The CGI consists of two one-item measures. The first item (CGI-S) measures the severity of psychopathology on a 1 to 7 scale: 1 = normal, not at all ill; 2 = borderline mentally ill; 3 = mildly ill; 4 = moderately ill; 5 = markedly ill; 6 = severely ill; 7 = among the most extremely ill patients. The CGI-I measures change from the beginning of treatment on a 7-point scale (1 = very much improved; 2 = much improved; 3 = minimally improved; 4 = no change; 5 = minimally worse; 6 = much worse; 7 = very much worse). In this paper, we dichotomized the CGI-I score into two categories: improved *vs* not improved.

Statistical analysis

Quantitative data were summarized as mean ± standard deviation or median and range, and qualitative data were summarized as percentages. Wilcoxon sum rank test was used to analyze differences in scores between T0 and T1 in the overall sample.

In order to explore the predictors of changes in capacity/participation, the change in Mini-ICF-APP total score from baseline (computed as baseline total score minus one-year score) was regressed on the diagnostic group and on socio-demographic and clinical predictors, including baseline Mini-ICF-APP total score, gender, age, duration of untreated illness (DUI), presence of specific rehabilitation programs, alcohol or substance abuse, presence of a family network, presence of life events and change in BPRS from baseline. In these models, higher changes in Mini-ICF-APP scores denote higher functional improvement. The diagnostic group was included first into the model, and the other predictors were entered using a forward stepwise procedure that selects only those variables which are significant at 5% and substantially improve the fit of the model. This was done to avoid over-parameterization of the models and improve estimator efficiency [21].

χ^2 test was used to compare categorical variables between the study groups; when at least one cell frequency in the contingency table was < 5, Fisher's exact test was used.

The association between changes in three Mini-ICF factors (proficiency, relational capacity, autonomy)[16] and changes in four BPRS factors (depression/anxiety, activation, retardation, psychosis) [19] was analyzed using Spearman's correlation coefficient. For these correlation analyses we set the significance level at $p < 0.01$. Lastly, we compared the mean one-year Mini-ICF factor scores between patients improved/much improved and patients with minimal or no improvement, as defined by the CGI improvement score (CGI-I score = 1, 2 *vs* other). All statistical analyses were carried out using the IBM SPSS Statistics, version 23.

Ethics statement

The authors assert that this study has been approved by the Local Ethics Committee, and that all procedures contributing to this work comply with the ethical standards of the local institutional committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. All patients signed a written consent to participate prior to their inclusion in the study. Data were anonymized before statistical analyses.

Results

The study sample consists of 100 patients consecutively recruited from those presenting to the CMHC of North-Udine (Italy). The demographic and clinical characteristics of the sample, overall and by diagnostic group, are described in Table I.

Compared with schizophrenia patients, patients with bipolar I disorder were significantly older, more likely to be female, married or separated/divorced, and employed. Moreover, they had a longer duration of illness, a lower severity of illness and a better functioning at baseline. In fact, as shown in Figure I, patients with bipolar I disorder exhibited lower baseline impairment in each of the 13 Mini-ICF-APP items.

In the overall sample, a general improvement from baseline was found in all psychopathology and capacity/participation (C/P) measures: Mini-ICF total score (from 23.1 ± 12.3 to 15.6 ± 11.8; $Z = -6.6$, $p < 0.001$), BPRS (from 59.0 ± 22.3 to 38.8 ± 15.0, $Z = -7.4$, $p < 0.001$) and CGI-S (from 5.1 ± 1.2 to 5.0 ± 1.2, $Z = -2.1$, $p = 0.03$). All Mini-ICF-APP and BPRS factor scores improved significantly as well ($p < 0.001$).

Changes in Mini-ICF-APP total score were examined in a stepwise linear regression model as a function of diagnosis, baseline Mini-ICF-APP total score, gender, age, DUI, rehabilitation programs (yes/no), alcohol or substance abuse (yes/no), family network (yes/no), life events (yes/no) and change in BPRS from baseline. Table II shows that, when the diagnostic group was first included in the model, patients with schizophrenia exhibited a higher improvement in C/P at one year compared with patients with bipolar disorder. After completing the stepwise procedure, the only predictors of C/P improvement entered and retained in the final model were change in psychopathology and baseline C/P. In particular, patients with a higher decrease in psychopathology levels and higher C/P limitations at baseline exhibited a higher C/P improvement at one year. After controlling for the effect of these two variables, C/P improvement did not differ significantly among diagnostic groups. This model proved to have a good fit to the data and accounted for 58.0% of variance of change in C/P.

TABLE I.
Characteristics of the sample (n = 100). Data are reported as percentages, or as mean ± standard deviation (SD).

Characteristics	Schizophrenia	Bipolar I disorder	Total	Test, p
Gender				7.1, p = 0.008
Males	74	48	61	
Females	26	52	39	
Age (mean ± SD)	41.1 ± 10.5	58.3 ± 13.1	49.7 ± 14.7	7.2, p < 0.001
Marital status				25.3, p < 0.001
Single	80	30	55	
Married	12	38	25	
Separated/divorced	8	32	20	
Education				11.5, p < 0.05
Less than primary school	0	4.3	2.1	
Primary school	8	13.1	10.4	
Secondary school	40	5.2	28.1	
High school diploma	46	47.8	46.9	
University degree	6	19.6	12.5	
Living situation				1.1, p = 0.29
Self-sufficient/with relatives	88	94	91	
Clinic/Residential facility	12	6	9	
Occupation				8.0, p < 0.05
Employed	22	32	27	
Unemployed	44	18	31	
Housewife/student	10	12	11	
Retired	24	38	31	
Alcohol/substance abuse				0.23, p = 0.63
No	76	80	78	
Yes	24	20	22	
Rehabilitation program at T0				31.3, p < 0.001
No	36	91.3	62.5	
Yes	64	8.7	37.5	
Rehabilitation program between T0 and T1				26.0, p < 0.001
No	26	79.1	50.5	
Yes	74	20.9	49.5	
Duration of illness (mean ± SD)	17.4 ± 10.0	22.0 ± 11.8	19.7 ± 11.1	-2.1, p < 0.05
Duration of untreated illness (mean ± SD)	4.3 ± 6.7	6.9 ± 9.1	5.6 ± 8.0	-1.66, p = 0.101
Mini-ICF-APP total score (mean ± SD)	28.9 ± 9.9	17.3 ±11.7	23.1 ± 12.3	5.3, p < 0.001
F1: proficiency	17.2 ± 6.0	10.4 ± 7.6	13.8 ± 7.6	4.9, p < 0.001
F2: relational capacity	7.7 ± 2.9	4.5 ± 3.3	6.1 ± 3.5	5.3, p < 0.001
F3: autonomy	3.8 ± 2.2	2.5 ± 2.5	3.1 ± 2.5	2.8, p < 0.01
CGI severity score (mean ± SD)	5.6 ± 1.0	4.6 ± 1.2	5.1 ± 1.2	4.4, p < 0.01
BPRS total score (mean ± SD)	68.9 ± 20.4	50.0 ± 19.6	59.0 ± 22.3	5.0, p < 0.001

Mini-ICF-APP: Mini instrument for the observer rating according to ICF of Activities and Participation in Psychological disorders; CGI: Clinical Global Impression Scale; BPRS: Brief Psychiatric Rating Scale.

TABLE II
Predictors of change in Mini-ICF-APP total score in patients with schizophrenia and bipolar disorder. Results from stepwise linear regression.

Model	Variables	Unstandardized coefficients (b)	Standardized coefficients (β)	95% Confidence Interval for b	p
1	(Constant)	7.427	7.427	5.605, 9.249	< 0.001
	Schizophrenia *vs* bipolar disorder	3.985	0.219	0.341, 7.629	0.032
2	(Constant)	7.682	7.682	6.426, 8.937	< 0.001
	Schizophrenia *vs* bipolar disorder	0.869	0.048	-1.711, 3.449	0.505
	ΔBPRS	6.672	0.731	5.381, 7.962	< 0.001
3	(Constant)	7.654	7. 654	6.429, 8.879	< 0.001
	Schizophrenia *vs* bipolar disorder	-0.565	-0.031	-3.350, 2.220	0.688
	ΔBPRS	6.256	0.686	4.950, 7.561	< 0.001
	Baseline Mini-ICF	1.759	0.190	0.298, 3.220	0.019

Standardization of the regression coefficients was done to allow comparison of variables which are measured on different scales, thus answering the question of which of these independent variables have a greater effect on the dependent variable (i.e., change in Mini-ICF-APP).
ΔBPRS: change in BPRS from baseline to one year.

TABLE III
Correlations between % changes from baseline in Mini-ICF-APP factors and BPRS factors, as measured by Spearman's ρ.

Schizophrenia				
Mini-ICF-APP factors	BPRS factors			
	Depression/Anxiety	Activation	Retardation	Psychosis
Proficiency	0.702**	0.778**	0.685**	0.527**
Relational capacity	0.728**	0.715**	0.618**	0.596**
Autonomy	0.569**	0.615**	0.579**	0.523**
Bipolar disorder				
Mini-ICF-APP factors	BPRS factors			
	Depression/Anxiety	Activation	Retardation	Psychosis
Proficiency	0.586**	0.515**	0.474**	0.460**
Relational capacity	0.462**	0.316*	0.310*	0.211
Autonomy	0.472**	0.528**	0.494**	0.388**

* Correlation is significant at the 0.05 level (2-tailed). ** Correlation is significant at the 0.01 level (2-tailed).

We then examined in deeper detail, separately for schizophrenia and bipolar I disorder, the relationship between % changes in Mini-ICF factors and % changes in BPRS factors (Table III). In each patient group, correlations between psychopathology and C/P limitations were all substantive and significant, except for the ICF factor relational capacity and the BPRS factor psychosis in patients with bipolar disorder. In general, correlations were stronger for patients with schizophrenia than for patients with bipolar disorder.

In order to examine the sensitivity to change of Mini-ICF-APP factors, we compared the mean factor scores at one year between patients who were improved or much improved (N = 59) and those who exhibited minimal or no improvement (N = 37). Patients whose severity of illness was improved or much improved had on average lower factors scores than the rest of the sample (proficiency: 1.2 ± 1.9 *vs* 3.9 ± 2.6, Z = 5.9; p < 0.001; relational capacity: 2.5 ± 2.2 *vs* 6.6 ± 2.9, Z = 7.7; p < 0.001; autonomy: 6.2 ± 5.1 *vs* 14.6 ± 6.7, Z = 7.0; p < 0.001).

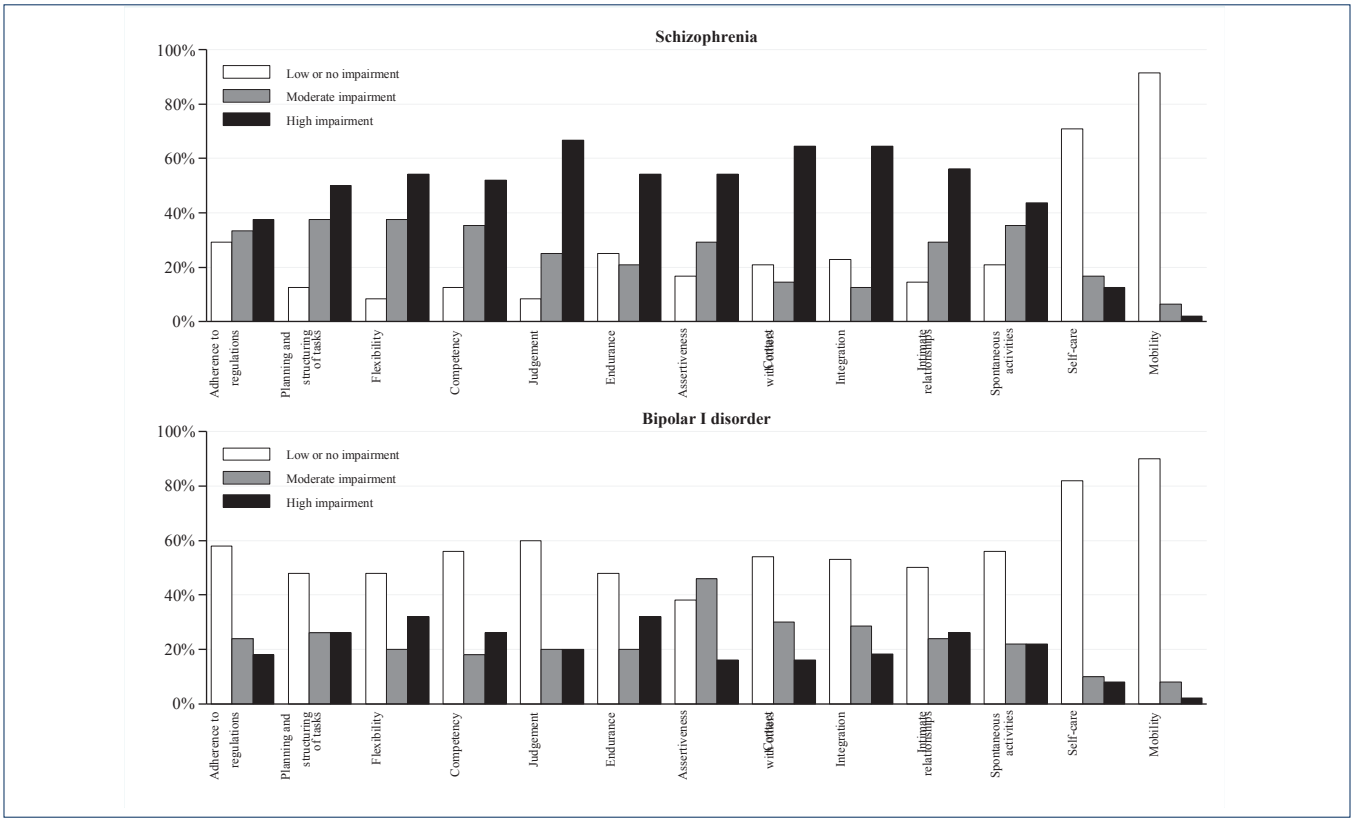

FIGURE 1.
Capacity impairment at baseline in patients with schizophrenia and with bipolar I disorder.
Notes: Low or no impairment (Mini-ICF-Ratings 0, 1), moderate impairment (Mini-ICF-Ratings 2), high impairment (Mini-ICF-Ratings 3, 4).

Discussion

To our knowledge, this is the first study to evaluate one-year changes in psychosocial C/P in a sample of patients treated within a community-based service, using an instruments built up according to ICF classification.

In this classification, participation is defined as involvement in a life situation, and participation restrictions are impaired capacities that do not allow context or role requirements to be fulfilled [7].

The emphasis on social functioning has been stressed also by the GBD 2015 study, which underlined that many populations are spending more time with functional health loss, an absolute expansion of morbidity [22]. The relevance of assessing participation as one of the treatment outcomes derives from the shift from to the traditional focus of mental health services on deficit amelioration to the promotion of a recovery, defined as "a growing sense of agency and autonomy, as well as greater participation in normative activities, such as employment, education, and community life" [23 24]. It is also worth of mention the original definition of recovery by Anthony [25], that is "the developing of new meaning and purpose in life as one grows beyond the catastrophic effects of psychiatric disability". The World Health Organization underscored the importance of enhancing recovery in the management of psychiatric disorders [26] and this concept has become a core feature of mental health reforms in western Countries, including community psychiatry in Italy [27]. Our community psychiatric centre is strongly committed towards promoting psychosocial recovery, so that the search for a handy instrument to measure the improvements in the C/P has been pursued for a long time.

The choice of Mini-ICF-APP was driven by its usefulness in everyday clinical practice to monitor in an operazionalized way patients' variations over time in the C/P domains. Other instruments measuring psychosocial dimensions are available. The WHO has published the WHODAS 2.0 [28],which consists of six domains: cognition, mobility, self-care, getting along, life activities and participation. However, the WHODAS 2.0 does not discriminate well between capacities and participation: most items refer to participation, while only few and very specific capacities are mentioned, which are not very relevant for mental disorders. For a more detailed discussion on the pros and

cons of WHODAS and other instruments, as compared with Mini-ICF-APP, refer to Balestrieri et al. [12].

A major advantage of Mini-ICF-APP is that it can be administered after an in-deep assessment of the patients or after a reasonable time lapse (for example few months) from the first examination, when a sufficient number of mental-health operators remember the characteristics of the patients at a specific point in time. Thus, it is suitable for sharing information among the multidisciplinary team of carers, such as those working in mental health community-based services, who know the degree of restrictions of the subject in different capacities or participation. Another advantage of Mini-ICF-APP over other existing instruments such as the Personal and Social Performance (PSP) or the Global Assessment of Functioning (GAF) is the possibility to detail the restrictions that can hinder the full accomplishment of daily life duties. Thus, the Mini-ICF-APP fulfils the need of an accurate description of the specific restrictions of the person, which is a consolidated principle of rehabilitation programs. Moreover, in this study the Mini-ICF-APP proved to be sensitive to changes in psychopathology.

Our results indicate a general improvement in psychopathology and C/P limitations in both bipolar and schizophrenic patients. This is particularly remarkable, given that the health care staff of the North-Udine CMHC is 0.61 per 1,500 inhabitants, well below the standard of 1 per 1,500 inhabitants recommended by the Italian Ministry of Health. Since the instruments and the diagnostic distribution of other Italian studies focusing on mental health outcomes in the community are different from those of the present study [29 30], only limited comparisons are possible. However, our results are similar to those obtained by a better staffed (0.7 and over per 1,500 inhabitants) CMHC in Sardinia [30], and our 100% retention rate is consistent with the 97% rate reported in the large Italian sample of patients treated in CMHCs [29]. Among the number of socio-demographic and clinical baseline characteristics we considered as potential predictors of changes in C/P at one year, only the existing limitations in C/P at baseline proved to be relevant. Patients with most severe limitations were in fact those who benefited most from community treatment.

The implementation of rehabilitation programs was unrelated with the outcome. A possible reason for this result is that, after adjusting for changes in psychopathology over one year and baseline functioning, the presence of rehabilitation programs did not further contribute significantly to the outcome prediction. Moreover, improvement in Mini-ICF-APP factors was highly correlated with the four areas of BPRS psychopathology, except for relational capacities in bipolar I disorder. It seems that the decrease of psychotic symptoms in bipolar disorder did not affect the relational capacities, which on the other hand were influenced by variation in BPRS factor of mood/anxiety symptoms. This confirms the higher relevance of mood disregulation as compared with the cognitive domain in bipolar disorder in the process of building and maintaining interpersonal relationships.

The results of the present study should be interpreted keeping in mind some limitations. First, the diagnoses were not made with a standardized clinical interview and, given that non-prototypical cases of schizophrenia and affective psychosis can show similar clinical features, some degree of disease misclassification may have occurred. Second, the lack of a control group did not allow to evaluate the clinical effectiveness of one-year community-based treatment on psychosocial capacities, and the fact that higher Mini-ICF-APP scores at baseline were associated with greater improvement suggests the presence of a "regression toward the mean" effect. Third, we evaluated only the relationship between C/P and impairment due to psychopathology, but we are aware that C/P levels can be influenced also (and sometimes exclusively) by context changes in the patient's life; this issue needs to be addressed in further studies.

Conclusions

Our results corroborate the observation that in community-based mental health treatment, when treatment is effective in reducing symptom severity, a concurrent improvement is obtained in capacity and participation functioning, and this association is present not only in patients with schizophrenia but also in those with bipolar I disorder. Of note, even (and particularly) patients with the most severe limitations proved to benefit from treatments. The Mini-ICF-APP proved to be sensitive to changes in psychopathology and therefore it is a useful tool to be used in routine clinical assessments.

Conflict of interest

Prof. M. Balestrieri and Drs. J. Lenzi, A. Lestani, F. Taboga, R. Bonn, P. Rucci, E. Maso declare that they have no conflict of interest in relation to the present work and that they did not receive any grant.

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Postmodernity: clinical and social reflections about new forms of psychopathology

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Summary

This article proposes a reflection on the impact that some postmodern features can have on the sense of identity and on mental functioning to propose possible explanations for identity changes and new forms of psychopathology. After revisiting the most recent literature on the theme, this study proposes a clinical consideration for a possible link between new forms of psychopathology and mental suffering. It particularly suggests that the changes observed in affectivity (including increase in dysphoria, irritability, restlessness, boredom, feeling of emptiness) and behaviour (reduction in impulse control ability, in interpersonal skills and reflective function, etc.) are important indices of a bigger change that involves the entire personality and indicates a shifting towards a borderline level of personality functioning. Finally, the article offers a possible explanation for this shift and advances therapeutic questions.

Key words

Postmodernity • Identity changes • New forms of psychopathology

1. Introduction: the literature on effects of postmodernity on identity and new forms of psychopathology

From the group-analytic perspective, "The individual is not only dependent on the conditions [...] of the community and the group in which he lives [...], but literally he is permeated with them" [1]. Therefore, to understand the personological and psychopathological contemporary profiles, we must look for the habits [2] and the rooted conditions of our psyche (if it has changed and how), and recognize in this change the new addresses of the psychic suffering and the psychopathology. Adopting this theoretical perspective and revisiting the literature on this theme, this article proposes a reflection on the impact that some features of postmodernity can have on mental functioning to propose possible explanations for identity changes and new forms of psychopathology.

Over the last ten years, several studies have investigated the effects of postmodernity on the construction of identity [3-19] and have subsequently focused on the effects of postmodernism on new forms of psychopathology and mental suffering [20-31].

Despite the different perspectives, all studies agree with the opinion that mental stress and disorders are strictly related to context and environmental changes. Multiple results show that from the modern to postmodern epoch, social changes have caused increasing stress levels in both individual and collective terms, with a risk to mental health.

In particular, some studies suggest a significant reduction of impulse control ability, an increase in behaviours linked to obsessive-compulsive spectrum and a general deterioration of interpersonal skills with negative impacts on family, school and work performances [21]. Similarly, other studies highlight an increase in the crisis of human reflexivity with repercussions to the relational functioning [6 7].

Different studies consider the increase of dysphoria and uncomfortable mental states (irritability, restlessness, boredom, feeling of emptiness, shame, etc.) as specific examples of postmodernity psychopathology, and underline the link between these affective states with borderline personality disorder (BPD) and functioning [3 4 8 9 22 26 32 33-35].

Other studies highlight a progressive loss of body language as the original anchor for the sense of self [3] (such as, for example, in eating disorders) and an increase of communication problems with alterity [9 22 36].

Additional studies show an increase in multiple weak identifications, a collision between localization and globalization and a change in social bonds [8 27 37].

Finally, some studies discuss the increase of impasse in life projects caused by an excess of "present time" and this negative impact on the continuous sense of identity [4-6].

To understand these changes, it is necessary to think

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about the changes in collective demands (in psychoanalytic terms, the super-ego requests) for the integration in the social world as suggested by many authors such as Kohut [38-40] and Lash [41]. These demands are dramatically and radically changed from a social experience based on avoiding guilt to a social experience based on avoiding feelings of shame.

Overall, as evidenced by the literature, the reflection on these social and clinical changes is still in progress, and because of this, more theoretical, epidemiological and empirical studies are necessary. Placed within the context of the literature, this study suggests a possible common thread that binds the new forms of mental and psychopathological suffering.

2. Three steps to understand a possible link between postmodernity and new forms of psychopathology

From our point view the socio-cultural changes are reflected not only in the singular aspects of psychopathology, but in the whole personality functioning.

We particularly believe that the indicated current changes in affectivity and behaviour are important indices of a larger change involving personality functioning in its entirety. Indeed, we believe that the changes in affectiveness (increase in dysphoria, shame, irritability, restlessness, boredom, feelings of emptiness, etc.) and in behaviour (reduction in impulse control ability, in interpersonal skills and reflective function, etc.) indicate a shifting towards a borderline level of personality functioning.

But, how can we explain this shifting? And what are the effects of this shifting? In our studies, we propose some social and clinical reflections to answer these questions.

In particular, starting by the group-analytic perspective, we assume that:

1. postmodernity has partially corroded and modified our constituent matrices;
2. this corrosion has created favourable conditions for the birth of a sense of discontinuity in one's self experience
3. this sense of discontinuity has empowered the pole diffusion, in the index: "identity integration *versus* identity diffusion" used for assess of the level of personality functioning.

But let us try to better define the proposed assumptions.

About the first point: postmodernity has partially corroded and modified our constituent matrices. On his concept of mental matrix, Foulkes [1] argued that there is no difference between internal psychic reality and external social reality, because what is inside is outside. From the group-analytic perspective, indeed, the social is not only external but also internal, and it penetrates the more intimate essence of the individual. Starting from this concept, the Italian group analysis, and namely the *Subjectual* [a] group analysis, has made explicit the idea of the correspondences between the internal and external through studies on the *Transpersonal* levels, which we can metaphorically consider as the "places" where all the aspects composing our identity have consolidated [b], and of which the anthropological and social conditions represent a specific aspect [42 43]. In group-analytic theory, the constituent matrix concept corresponds to the "sameness" concept [44], and it is the presence of the constituent matrix precisely allows the dialogue between identity and alterity. This presence guarantees the dynamic balance between identification and originality, self-fidelity and adaptability to different social contexts, continuity and discontinuity, permanence and change. But, in the absence or given a lack of elements of sameness (metaphorically fixed into the constituent matrix), each biography risks getting lost in small, disconnected pieces that would make it difficult to integrate the sense of identity. Constituent matrices, indeed, offer the possibility to identify oneself (both consciously and unconsciously) with unconscious expectations, behavioural codes, relational modalities, internal or social prohibitions, etc., starting from which each individual can work to develop his own identity (for adhesion or differentiation). Therefore, the corrosion of constituent matrices generates uncertainty in "self-construction". More precisely, we believe that the contemporary corrosion of the constituent matrices impairs the continuous dialogue between the sameness and the alterity. From our point of view, postmodernity is responsible for the lack of established codes, or for the deficient support of sameness for identity building [26 36 45].

Adopting group-analytic language, we would say that the anthropological and social changes have involved the dialogue between identification (with the constituent ma-

[a] "Subjectual" is a new term with a broader meaning than "object relations". It emphasizes the importance of the relationship between bios and real relational experience with other subjects life [42].

[b] From the most biological to the most cultural, from the most aware to the most unconscious, in the interweaving of different levels of articulation: the biologic-genetic, ethnic-anthropological, familiar, institutional, socio-communicative five levels of transpersonal matrices. From this perspective, the human psyche is founded on the transpersonal mental/bodily/relational configurations of anthropological organizations of all subjects, e.g., family, reference community, institutional groups and new forms of social communication, such as media and the internet. These sum up the main collective experiences that originate and connect individual psychic life and offer useful reading tools to understand the psyche in therapeutic and non-therapeutic groups [42 43 45].

trices) and originality, or between Idem and Autòs [44], determining the loosening of some social and internal structures that constitute the boundaries of meaning-making. The consequence of this phenomenon is an "epiphany" of signs and symptoms that are completely different from those that characterized the previous modern epoch.

Starting from these considerations, we have proposed the concept of "dis-identity" [26 36 45] initially to describe "the health status of our constituent matrices" and subsequently to understand the new forms of psychopathology, particularly the common thread of the new forms of psychopathology.

About the second and third points: we started from the concept of the sense of discontinuity described by Kernberg [46], particularly from the index "identity integration *vs* identity diffusion" involved in the assessment of personality functioning. As emphasized in the psychopathologic literature, the dialectic between identity integration and identity diffusion is very important in order to preserve a sense of self. In particular, the sense of identity integration is linked to the feeling of temporal and affective continuity that the patient has of himself or herself and of significant others. The sense of identity diffusion, instead, is linked to the difficulty of integrating, temporally and emotionally, images, experiences, and representations of self and others in complex and non-contradictory pictures. Hence, the sense of identity integration allows the patient to preserve stable and deep relationships with significant others, of which the patient can feel multifaceted representations, including both positive and negative (as about the self). Instead, the sense of identity diffusion is characterized by the presence of the split representations of the self and significant other. Representations appear to be, in fact, poor, rapidly changing, two-dimensional, extreme and unmodulated. Furthermore, as a result of the discontinuity in the experience of self, the sense of identity diffusion is associated with a sense of inner emptiness and a strong aggressiveness. Kernberg suggests that other aspects characterizing the sense of identity diffusion are: the so-called "not specific manifestations of ego weakness" (namely the lack of control of the anguish and the impulses), the lack of mature sublimator channels and sometimes the inability to differentiate the image of self from the object.

As we have seen, many of these aspects are highlighted by the most recent literature.

Now, we more closely explore our hypotheses and consequently wonder: did postmodernism really corrode our constituent matrices? Did this really create favourable conditions to the birth of the sense of discontinuity in the self-experience? And finally, does this sense of discontinuity really involve one of the indices for the assessment of personality functioning?

3. On the corrosion of constituent matrices, the discontinuity sense of identity and the index "integration *vs* diffusion" identity

In order to catch the sign of social changes in the individual and proceed towards a review of theories on psychotherapy, we now go into the details of our social and clinical reflections by highlighting some key points. We begin by exploring our first questions: Did postmodernism really corrode our constituent matrices? Did social life really change so much as to require an adjustment of psychodynamic and psychopathological readings? If so, exactly which aspects of postmodernity corrode our constituent matrices? Below, we underline only some postmodern changes which can have a strong corrosive power on constituent matrices. Later, we will try to understand the effects of these corrosions.

Among postmodern characteristics with a hypothetical corrosive impact, we have:

1. the loss of the "big frameworks" (metaphysical, ideological, religious, political, etc.), which makes it difficult to understand the world starting from universal principles and promotes a context in which everyone is returned to himself [8 47]. Until the previous epoch, in fact, big frameworks and constituent matrices have inspired (consciously and unconsciously) the attitudes, behaviours, etc. guiding the previous generations;
2. the eradication of social relations from their local contexts and the transfer of them to indefinite and global space-time dimensions [21 48]. This process is exacerbated by psychic retreats and virtualization of relations" in terms of change in psychic and neurologic architecture[50], but also in terms of failure of "real relationships" and in new forms of web related psychopathology like internet addiction [51-54];
3. the multiplication of the "non-places", as defined by Augé [55], that increase the loss of the sense of continuity in the self and also the sense of strangeness from the community. From a clinical perspective, the loss of references regarding oneself and the community recalls the psychotic and pre-psychotic experiences [56]. From the sociological perspective, Lasch [57] offers an analysis of the dominant cultural patterns in American society since the 1970s, highlighting the exaggerated individualism and its effects as the widespread fall of moral and political tension, expansion of the cult of the body, the obsession for old age and death, etc. These are all aspects that we would say are dominated by the death instinct;
4. hypertrophy of the present [4-6], as described by Minkowski [58], can corrode élan vital (that is, the impulse that allows humans to create the future in front of him). The possibility of reuniting past and future to

the present time, indeed, gives everyone the feeling of being on a the road towards the realisation of one›s existence. Disconnected instead, past and future make the present moment excessive and overflowing, but without a developmental perspective and stagnant. Therefore, inclined to depressive psychopathological feelings;

5. the so-called "liquidity" [59 60], namely the fact that human action is lost even before being consolidated and transmitted. With the concept of liquidity, we are not referring to normal liquidity in the self, as suggested by Bromberg [61], but to the impact that the new lifestyles (also geared to the satisfaction of pleasure and consumption from the relational point of view) may have on some psychopathological aspects reported as an increase from psychopathological contemporary literature: narcissism [12 57], dissociation [29 30], addictive behaviours, etc. Especially together with the absence of reference frameworks and the resulting self-reference increase as we said above.

But, above all, through these aspects, the triumph of the sense of fleeting, of the ephemeral, and of the fragmentary, as expressions of the contingent, creates favourable conditions to the birth of a sense of discontinuity in the experience of the self. Besides, these aspects put to the test the "integration *vs* diffusion" index of identity.

If we accept the idea that these postmodern features tend to corrode constituent matrices, we should analyse subsequent questions and wonder what the effects of this corrosion are. Indeed, in our explanation, we said that the corrosion of constituent matrices creates favourable conditions to the birth of the sense of discontinuity, and that this sense elicits/reinforces an important index which is involved in the assessment of the level of personality functioning.

As we said, the psychopathological literature teaches that the "sense of identity diffusion" is the result of the discontinuity in the experience of self, and that it appears also through those behavioural aspects that contemporary literature defines as increasing (dysphoria, irritability, restlessness, boredom, emptiness and "non-specific manifestations of ego weakness", that is, lack of impulse control and of mature channels of sublimation, etc.) [3, 6 7 9 21 22 26]. Therefore, if we consider them all together, it is possible that these aspects show an increase of borderline personality functioning (regardless of any specific diagnosable disorder).

In more detail, the traditional literature underlines that borderline personality functioning reflects difficulty in integrating (both emotionally and temporally) images, experiences, representations of self and other people in complex frameworks; in having poor, two-dimensional, rapidly changing representations; and finally, in having painful feelings of inconsistency due to unstable beliefs. Therefore, the general shift of the younger population to a borderline level of personality functioning could lead to loss of important psychic experiences such as the feeling of invariance and personal integrity (even in a process of continuous change); the commitment toward some representations of oneself and toward social roles that can help to define it; a commitment toward a set of values and rules that can guide behaviours; and the experience of internal solidarity toward a social group [62-64].

Now, in our opinion, this shift is more likely and frequent than before because it finds its reason not only in the individual biographies but, together with them, in the changed social and anthropological conditions that accompany these individual stories.

Certainly, the social and anthropological conditions are the frames of the individual biographies, but the absence of good social references can increase certain forms of discomfort and, particularly, the difficulty to mentalise, that is a fundamental function for monitoring our experiences, affect and behaviour [65-70].

But returning to our reflection: what we called "the process of corrosion of constituent matrices" is a transversal phenomenon which precedes the birth of our youngest patients (indeed, postmodernity started fifty years ago). This process is not strictly linked to personal experiences but to general loss of frameworks and constituent matrices that we talked about (particularly in family, ethic-anthropological and institutional aspects [42 43]).

To consider that the reason for what patients – increasingly – complain about in treatment no longer (or not only) resides in their personal stories but in socio-anthropological changes introduces a series of important clinical and therapeutic consequences.

4. Therapeutic considerations

So far, on the basis of signs and symptoms reported in literature, we have discussed new forms of psychopathology proposing the general shifting from the neurotic level to the borderline personality functioning as main effect of postmodernism. Now, it is useful to reflect on the therapeutic consequences of this shift.

Generally, the therapy for borderline personality functioning is a very difficult matter for mental health professionals [71-73]. The reason is that, together with "the sense of identity diffusion", patients with borderline functioning often show other indices which directly intervene in therapeutic process (making it more complex). These indices are:

- the ability to observe their own pathology or to have the so-called "observing Ego" (patients with borderline functioning do not have these abilities and not

develop this capacity quickly within the therapeutic process);
- implications of transference and countertransference (that with these patients are frequently intense and disturbing independently from the fact that they are positive or negative); and
- the main "near *vs* distance" conflict (that makes it more difficult to involve these patients in treatment) [74].

Besides, if it is true that this shifting finds its justification not (only) in individual stories but more generally in social-anthropological changes, this makes therapeutic work more difficult, because unlike historical and biographical reasons, social and anthropological ones are more difficult to recognise and rework in therapy.

Regarding this, in a previous publication we referred to a study by Winnicott [75], who highlighted the need to "remember" but also the inability for psychotic patients to do so because their psyche broke up before their minds were formed [c]. Therefore, according to the author, despite their need to "remember", they are not able to do it because it is not possible to remember something that happened while they would not (mentally) present.

We believe that something similar happens with the corrosion of the constituent matrices. For this reason, thinking about all of this, we insist that the psychic functioning plan may be inclined towards the most archaic functioning levels.

There are many examples of this. The so-called "new depressive affectiviness" [28], for example, does not find any longer its epicentre in the Superego internal-scolding voice because, differently from "classical depression", patients who refer to "depressed affectivity" today do not feel guilty (both consciously or unconsciously) for something they lived, but for interchangeable opportunities and for dictates of postmodernity [10 31] because they frequently do not feel themselves to be at the height of society's demands.

This does not mean that the classical depressions no longer exist, but that the younger population is more exposed to different depressive experiences that involve borderline and narcissistic vulnerabilities. In particular, as we have seen, while borderline vulnerability reveals itself through dysphoria, chronic widespread feeling of inner emptiness, irritation, a tendency to complain and to act out, experiences of depersonalization and sometimes even the expression of violent rage, the narcissistic area is more latent and keeps patients in check. They are continuously busy in activities of hyper-compensation of self-esteem to exorcise that inner emptiness that is a real precipice on their identity and value (in this case as in the first).

[c] During the failure of maternal containment capacity.

Kohut's pioneering work on narcissism [38-40] theorized that personality disorders ("disorders of the self") concern primarily the poorly differentiated self-its cohesiveness, stability, and affective colouring. The anxiety of a narcissistic personality is a result of a realistic appraisal of the vulnerability of the self to fragmentation ("disintegration anxiety") and/or intrusion of archaic forms of grandiosity. The theory places unusual emphasis on cohesion, or coherence, of the self and on creativity and self-actualization; this differentiation, albeit with different gradients, will be taken up by the theorists of group analysis and become central in our perspective.

Other examples we can find in the psychotic functioning, as in cases of libidinal disinvestment and social withdrawal.

In any case, what seems to be stronger is a kind of psychopathology no longer based on the removal of desire but on the defence of anguish.

All this calls us to new responsibilities in clinical practice which are useful to discuss together. For example, as we know, there is a continuum of appropriate interventions at different levels of functioning [76], so we ask: is it a task of psychotherapy to move toward a more supportive side? Naturally, we know that good psychotherapy has always included a mix of supportive and expressive interventions, but in which measure? And, in order to take patients to more mature levels of functioning, which kind of abilities does the therapist have to sharpen? In which way should we promote the formation of therapeutic alliance with patients who are so "culturally" accustomed to untie from relations, tasks and objectives? [d].

About all this, we believe that it would be useful to confer with colleagues, on a theoretical and clinical level, to better understand both the meaning of new forms of psychopathology and the suitability of new therapeutic interventions.

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[d] More generally, considered not only as three specific aspects of the therapeutic alliance.

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Anxiety and depression

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Summary

Objectives

The DSM-5 classifies depressive and anxiety disorders according to clinical symptoms and assesses possible correlations with a medical condition, use of psychoactive or pharmacological drugs, or substance abuse. The objective of the present review is to overview the main depressive and anxiety disorders according to the classification of the DSM-5 and to present the primary pharmacological and non-pharmacological treatments, with particular emphasis on the problem of compliance.

Methods

Literature review of recent years on depressive disorders and anxiety disorders was carried out following publication of the DSM-5 (2013).

Results

In the DSM-5, depressive disorders include disruptive mood dysregulation, major depressive disorder, persistent depressive disorder, premenstrual dysphoric disorder, depressive disorder induced by substances/drugs, and depressive disorder due to other medical conditions. The common characteristic of these conditions is the presence of sad, empty, or irritable mood, which together with specific cognitive and somatic symptoms leads to significant distress or impairment in functioning. The anxiety disorders recognised in the DSM-5 include separation anxiety disorder, selective mutism, specific phobia, social anxiety disorder, panic disorder, agoraphobia, generalised anxiety disorder, anxiety disorder induced by substances/drugs and anxiety disorder due to another medical condition. All the disorders share characteristics of excessive fear and anxiety correlated with behavioural alterations. In anxiety disorders, the stimulus, external or internal, produces a disproportionate anxious reaction that is a source of intense distress or significant impairment of functioning. Pharmacological therapy alone, psychotherapy alone, or the combination of both are efficacious in the treatment of depression, generalised anxiety disorder, panic attacks and insomnia. It is important to involve the patient in the therapeutic course through adequate communication and information about time to therapeutic response and possible side effects. SSRIs (selective serotonin reuptake inhibitors) and SNRIs (serotonin-norepinephrine reuptake inhibitors) are first-choice agents in the treatment of depression, with demonstrated efficacy and safety. A benzodiazepine can be used in the first 4 weeks of therapy for depression in the presence of significant symptoms of anxiety, in panic disorder and insomnia to obtain rapid improvement in symptoms. In the treatment of depressive disorders, compliance is important to achieve the objectives of antidepressant therapy. In recent years, significant progress has been made in identification of risk factors for poor compliance and development of a variety of strategies aimed at increasing adherence to therapy, especially in improving communication, patient education, dose optimisation and scheduled follow-up.

Conclusions

In treatment of depressive and anxiety disorders, therapeutic choice should consider patient preferences and must be decided together with the patient. Compliance is an important aspect that determines the success of treatment.

Key words

Depression • Anxiety • Compliance • DSM-5

The DSM-5 and clinical utility

G. Maina, V. Salvi

Introduction: the DSM-5 in clinical practice

The Diagnostic and Statistical Manual of Mental Disorders (DSM-5) is likely the most well-known and used diagnostic reference in psychiatry. Its descriptive and nontheoretical nature make it easy to use, and no specific theoretical training is needed to use it. In the DSM-5, psychiatric disorders are grouped into broad categories (such as psychotic disorders, depressive disorders, anxiety disorders, etc.) within which the individual disorders are described. Each disorder is diagnosed on the basis of grouping of symptoms. To allow a diagnosis of mental disorder, a particular group of symptoms must be present, which are related to impairment of functioning and/or to significant discomfort. For many disorders, such as depressive disorders and anxiety disorders, 'essential' clinical features are distinguished from those caused by a concomitant medical condition or use of drugs or psychoactive substances.

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The diagnostic course in clinical practice

When applied to depressive disorders and anxiety disorders, two phases are primarily used for diagnosis in the DSM-5:

1. classify the disorder based on objective psychological examination and patient-reported signs and symptoms;
2. evaluate if the symptoms may be correlated with a medical condition, use of psychoactive or pharmacological drugs, or substance abuse.

The first phase involves listening to subjective experiences of the patient together with psychological examination. By grouping symptoms, the disorder can be defined. The second phase involves assessing for potential somatic or exogenous causes of the psychic disorder. A variety of physical diseases can give rise to depression and anxiety. In some cases, depressive and anxious symptoms are characteristic of an underlying medical disease and present as the first manifestations of somatic disease. For example, loss of appetite, weight loss, fatigue and depressed mood in older patients can be symptomatic of pancreatic cancer. In other cases, anxiety and restlessness associated with vegetative symptoms may be caused by onset of hyperthyroidism. In some cases, depression or anxiety may be related to a previously diagnosed disease, as in certain neurological and endocrine disorders. Lastly, depression and anxiety may be caused by pharmacological treatment, a psychoactive drug, or by their discontinuation. Interactions between susceptibility and stressful events may generate diverse symptoms that are accurately classified in the DSM-5. The main clinical pictures of depressive and anxiety disorders according to the DSM-5 are detailed below.

Depressive disorders in the DSM-5

Depressive disorders in the DSM-5 include disruptive mood dysregulation, major depressive disorder, persistent depressive disorder, premenstrual dysphoric disorder, depressive disorder induced by substances/drugs and depressive disorder due to other medical conditions. The common characteristic of these conditions is the presence of sad, empty, or irritable mood, which together with specific cognitive and somatic symptoms, leads to significant distress or impairment in functioning. Disruptive mood dysregulation disorder is diagnosed in children who show severe and frequent outbursts of anger, which are grossly disproportionate to the triggering event, and associated with persistent irritated or sad mood that occurs in different contexts, for example at home and at school. Diagnosis requires that the onset is before the age of 10 years. It is believed that this set of symptoms can constitute the expression of major depressive disorders in early childhood, also considering the strong association with later development of these disorders in adulthood. Major depressive disorder is characterised by the presence of episodes of persistently depressed mood and/or a diminished ability to experience pleasure, associated with at least five of the following symptoms: significant changes in appetite or weight, insomnia or hypersomnia, psychomotor agitation or retardation, weakness and easy fatigue, feelings of worthlessness or guilt, decreased concentration and memory impairment, thoughts of death. Symptoms must be present daily for at least 2 weeks, and depressed mood must be present for most of the time. Major depressive disorder is often recurrent and characterised by episodes throughout life. Onset is usually between the ages of 20 and 30 years and is up to 3 times more frequent in women. It Italy, about 8-10% of the general population is affected.

Persistent depressive disorder is defined by its chronic course, characterised by the presence of persistently low mood for at least 2 years and associated with two or more of the following symptoms: poor or increased appetite, insomnia or hypersomnia, low energy and fatigue, low self-esteem, difficulty in concentrating and feelings and beliefs of hopelessness. Persistent depressive disorder has a prevalence of 2-3%, is more frequent in late adolescence or early adulthood and often associated with personality disorders and substance abuse. Premenstrual dysphoric disorder has phasic fluctuations and appears in the week prior to the menstrual cycle. It tends to resolve during the first days of menstruation. The disorder is characterised by marked affective lability, associated with deflected and irritable mood, increased sensitivity to rejection and tendency to interpersonal conflicts. It is associated with changes in appetite and sleep, lethargy and fatigue, and physical symptoms such as bloating or tension, muscle and joint pain. Its prevalence is about 1.3-1.8%.

Depressive disorder due to substances/drugs is characterised by the presence of low mood and loss of interests that appear during or shortly after intoxication or discontinuation of the responsible agent, or during exposure to a drug. It cannot be diagnosed in cases of depressive symptoms lasting more than 1 month after the discontinuation of the substance/drug. Various abused substances, such as alcohol, opioids, sedative drugs, cocaine or other stimulants, and hallucinogens, can induce depressive symptoms. Regarding the association between drugs and depression, depressive symptoms are associated with treatment with interferon-α, corticosteroids, interleukin-2, GnRH, mefloquine, contraceptive implants that release progesterone and cardiovascular drugs such as methyldopa, clonidine, propranolol and sotalol. A recent study on the reporting of drug-related adverse events

in the UK from 1998-2011 found an association between depression and use of isotretinoin, rimonabant and varenicline. In Italy, there are no data on the prevalence of depressive disorders induced by substances/drugs, while in the US it has been estimated that the prevalence is 0.26%.

Lastly, depressive disorder due to other medical conditions can be diagnosed when depressive symptoms are the direct pathophysiological consequence of another medical condition. In some cases, the association between an underlying disease and depression is very strong, and common pathophysiological links have been demonstrated in the two conditions. This is the case with neurological conditions such as stroke, Parkinson's and Huntington's diseases, cranial trauma and multiple sclerosis as well as with endocrinopathies such as Cushing's disease and hypothyroidism. In other cases, if the onset of depression is a response to stress related to an underlying disease, it is more correct to diagnose adjustment disorder with depressed mood.

Anxiety disorders in the DSM-5

Anxiety disorders share the characteristics of excessive fear and anxiety and related behavioural alterations. In anxiety disorder, the stimulus, external or internal, produces a disproportionate anxiety that is the source of intense distress or significant impairment of functioning. Another characteristic of anxiety disorders is anxious anticipation, or rising levels of concern and tension at the approach of a feared situation, and avoidance of stimuli or situations that trigger anxiety, with further limitations in functioning. The anxiety disorders recognised in the DSM-5 include separation anxiety disorder, selective mutism, specific phobia, social anxiety disorder, panic disorder, agoraphobia, generalised anxiety disorder, anxiety disorder induced by substances/drugs and anxiety disorder due to another medical condition. Separation anxiety disorder is diagnosed in children who have disproportionate anxious reactions to separation, even temporary, to attachment figures, especially parents. The disorder can even last into an adult age. Children with separation anxiety manifest the fear of losing their parents, refusal or reluctance to be alone, unwillingness to go outside for fear that an external event might separate them from their parents, or to sleep away from home. Affected children may also report nightmares and somatic complaints. Separation anxiety disorder is diagnosed if three or more of the following symptoms are present for at least 4 weeks, or for 6 months in adults. In Italy, 2% of children suffer from separation anxiety disorder, with frequent onset at preschool age.

Selective mutism is diagnosed in children who do not speak in certain social situations, for example at school, which is related to high levels of social anxiety or excessive shyness, and not to linguistic or intellectual deficits. Selective mutism is a rare disorder, with a prevalence of 0.03-1%.

Specific phobias are characterised by excessive or unreasonable fear of an object or situation, disproportionate to the actual danger, to which exposure leads to intense anxiety. The object or situation feared is actively avoided. Diagnosis of a specific phobia can be considered when the duration is at least 6 months. The most frequent phobias are those of animals (spiders, insects, dogs, etc.), natural (heights, storms, etc.), needles/blood and situations (aeroplanes, elevators, etc.). In Italy, about 6% of the population suffers from a specific phobia over their lifetime, with onset normally around the age of 10 years. Social anxiety disorder is characterised by fear of finding oneself in certain social situations. Some examples are speaking in a group of people, eating or drinking in public, or carrying out specific tasks. An individual with social anxiety is afraid of failing in certain situations and then be judged, ridiculed, or criticised by others. For this reason, the person frequently avoids contact in the feared social situation. Even in this case, symptoms must be present for at least 6 months. In Italy, about 2% of the population suffers from

TABLE I.
Depressive and anxiety disorders in the DSM-5.

Depressive disorders	Anxiety disorders
Disruptive mood dysregulation disorder	Separation anxiety disorder
Major depressive disorder	Selective mutism
Persistent depressive disorder	Specific phobia
Premenstrual dysphoric disorder	Social anxiety disorder
Depressive disorder induced by substances/drugs	Panic disorder
Depressive disorder due to another medical condition	Agoraphobia
	Generalised anxiety disorder
	Anxiety disorder induced by substances/drugs
	Anxiety disorder due to another medical condition

TABLE II.
Drugs that can induce depressive and anxiety disorders.

Depressive disorders	Anxiety disorders
Interferon α-β Corticosteroids Interleukin-2 GnRH Contraceptive implants that release progesterone Cardiovascular (methyldopa, clonidine, propranolol, sotalol) Mefloquine Isotretinoin Rimonabant Varenicline	Corticosteroids Salbutamol Sympathomimetics Insulin Thyroid hormones L-Dopa

TABLE III.
Medical conditions that can cause depression and anxiety disorders.

Depressive disorders	Anxiety disorders
Stroke Parkinson's disease Huntington's disease Head injuries Multiple sclerosis Cushing's disease Hypothyroidism	Hyperthyroidism Hypoglycaemia Pheochromocytoma Cushing's disease Vitamin B12 deficiency Porphyria Cardiovascular disease (heart failure, atrial fibrillation) Pulmonary diseases (pulmonary embolism, asthma)

social anxiety disorder over the course of a lifetime, with onset generally at the start of adolescence at around 13 years.

Panic disorder is diagnosed in cases of recurrent or unexpected manic. Panic attack is a sudden episode of intense anxiety and discomfort, which reaches a peak in a few minutes and is associated with somatic symptoms such as palpitations, sweating, trembling, shortness of breath, choking sensation, chest pain, nausea, dizziness, numbness, fear of going crazy, or dying. In panic disorder, attacks are usually followed by the constant worry that they can recur or by concern about the consequences of attacks. Patients often actively avoid situations that can trigger the attacks, for example driving or visiting crowded places. Panic disorder is frequently associated with agoraphobia, or the fear of being in situations where it is difficult or embarrassing to escape in case of a panic attack: classically feared situations are being in crowded places (public transport, cinemas, supermarkets), open spaces, being in a queue of cars or people, or being outside the home alone. Finding oneself in the feared situation frequently triggers a panic attack, which is the reason for which such situations are avoided in individuals with agoraphobia. Panic disorder usually appears in a young adult age and is more frequent in young women, with a frequency that is about twice that in men. In Italy, the lifetime prevalence of panic disorder is 1.6%, and 1.2% for agoraphobia.

Generalised anxiety disorder is diagnosed in cases of excessive anxiety and worry related to a large number of daily activities. The worry of having to carry out such activities, controlled with difficulty, is associated with at least three of the following symptoms: constant restlessness, easy fatigue, difficulty in concentrating, muscle tension, interrupted or unsatisfactory sleep. On average, the disorder begins around the age of 30 years, although it frequently has onset in adolescence or older age. In Italy, the lifetime prevalence of generalised anxiety disorder is 1.9%.

Anxiety disorder due to substances/drugs is defined by the presence of anxiety or panic attacks that occur during or shortly after intoxication or withdrawal from a substance, or during exposure to a drug. It cannot be diagnosed if the anxiety symptoms persist more than one month after discontinuation of the substance/drug. Several substances cause symptoms of anxiety: caffeine, cannabis, cocaine, amphetamines and other stimulants. Even exposure to drugs, such as salbutamol, sympathomimetics, insulin, thyroid hormones, L-Dopa and corticosteroids, can trigger anxiety symptoms. In addition, abstinence from alcohol, opioids, anxiolytics and especially benzodiazepines is frequently related to anxiety symptoms.

Depressive disorder due to other medical conditions can be diagnosed when depressive symptoms are the direct pathophysiological consequence of another medical condition. Pathologies of the endocrine system and metabolic conditions can cause anxiety and panic attacks, for example hyperthyroidism, hypoglycaemia, pheochromocytoma, Cushing's disease, vitamin B12 deficiency and porphyria. Even cardiopulmonary conditions, such as heart failure, pulmonary oedema, asthma and some arrhythmias can cause anxiety disorder.

Conclusions

The use of a diagnostic manual to define mental disorders in defined categories has many advantages, such as simple classification of patient experiences in well-defined clinical pictures and ease of communication with col leagues. Finally, the availability of validated treatments for individual disorders allows, not only for the specialist but for the general practitioner, to establish an effective treatment, which in some cases can fully resolve referred symptoms.

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Pharmacological and non-pharmacological treatment

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Data from the international literature have shown that the majority of patients with major depression are treated by a general practitioner (GP) [1]. GPs more frequently prescribe SSRIs and SNRIs than tricyclic antidepressants and monoamine oxidase inhibitors (MAO-I) [2]; moreover, it has been demonstrated that the use of antidepressants is effective in improving symptoms in primary care settings [3]. The OsMed report from 2013 documented that SSRIs represent a first choice in terms of costs among drugs that act on the CNS in reimbursed treatment regimens, and are the most widely prescribed; however, data from HealthSearch 2011 reported that only 35.4% of patients in whom a problem with depression has been identified are prescribed an antidepressant.

The use of drugs that act through multiple pathways seems to be even more valid in borderline pathologies and in pathologies within the spectrum of comorbidity. Thus, given the documented efficacy of many drugs classified as 'antidepressants' on anxiety symptoms, when dealing with an anxious-depressive condition, these drugs may be useful for 'anti-depressive' pharmacological treatment. Clinical experience has shown that many depressed patients do not respond or show only partial response to antidepressants, with complete remission of symptoms seen in 30% to 65% of cases. In other words, considering the entire population treated for major depression, it is possible to affirm that:

- 20-30% achieve remission;
- 20-30% show a reduction of 50% in depressive symptoms without achieving complete remission (HAM-D > 7);
- 10-15% have a partial response, with 25-50% reduction in symptoms;
- 20-30% are non-responsive to therapy, with < 25% reduction in symptoms;
- in addition, 10-30% of the entire population does not respond to multiple pharmacotherapies and psychotherapies, and these subjects are at high risk of morbidity and mortality.

Scientific evidence suggests that depression is much more disabling and resistant to treatment the longer it continues over time, and that a chronic course and/or highly recurrent disorder is associated with an increased risk of substance abuse, physical illness, suicide risk and social difficulties [4]. Despite these considerations, to date clear and definitive criteria have not been identified for choice of optimal initial therapy or to substitute or modify ineffective or partially effective therapy. Research is hindered by the wide variability of clinical presentations of depression, which is in part also responsible for incorrect or delayed recognition of the disease.

The main goals of treatment are:

- eliminate depressive symptoms;
- reduce or eliminate associated impairment;
- improve the quality of life and psychosocial functioning;
- prevent relapses and recurrences.

The objectives of initial treatment of major depression is remission of symptoms and improvement of the quality of life and psychosocial functioning. For initial treatment of a patient with mild-moderate depression there are several therapeutic strategies that involve the use of antidepressants alone, psychotherapy alone or combined antidepressant/psychotherapy. Randomised trials have shown that combined antidepressant/psychotherapy is more effective than either of the individual approaches alone [5]. Notwithstanding, additional studies have indicated that pharmacological therapy or psychotherapy alone are also valid choices; moreover, the efficacy of the two therapies is comparable. It is important to decide on the therapeutic course together with the patient, whose preferences can influence choice of therapy. In addition, complete evaluation of the patient must also include all aspects that could interfere with the therapeutic objective (previous therapies, comorbidities and psychosocial stressors). For patients with mild-moderate depression, treatment with SSRIs is recommended as first-line; these recommendations are based on the

TABLE I.
Antidepressant drugs, initial dose and therapeutic dose.

Drug	Initial dose (mg)	Therapeutic dose (mg)
SSRI		
Citalopram	20	20-40
Escitalopram	10	10-20
Fluoxetine	20	20-60
Fluvoxamine	50	50-200
Paroxetine	20	20-40
Sertraline	50	50-200
SNRI		
Duloxetine	30-60	30-120
Venlafaxine	37,5-75	75-375
Atypical antidepressants		
Buproprion	150	300
Mirtazapine	15	15-45
Serotonin modulators		
Trazodone	100	200-500

demonstrated efficacy and better tolerability of SSRIs [6]. SNRIs (e.g. venlafaxine, duloxetine), atypical antidepressants (e.g. bupropion, mirtazapine) and serotonin modulators (e.g. trazodone) can be used as alternatives to an SSRI.

Tricyclics and MAO-Is are not recommended as first-line treatment due to their poorer safety profile and increased incidence of adverse events. A meta-analysis in 2011 showed that there is no evidence in the choice of a second-generation SSRI in terms of improvement of symptoms (Tables I, II) [7].

Pharmacological treatment of depression should consider critical aspects. First, the severity of depression, for which antidepressants show significant benefits over placebo, has not been clearly defined. In general, the more severe the symptoms the greater the benefits of treatment. Antidepressants are nonetheless normally recommended as first-choice treatment in patients in whom depression is at least of moderate intensity. Secondly, there is large variability in tolerability, for which an individualised approach is useful in the attempt to find the best drug at the best dose, combining adequate clinical response with the lowest number of adverse effects. In the choice of an antidepressant, it is thus necessary to consider factors related to treatment (efficacy, tolerability, safety, formula-

TABLE II.
Adverse effects of the main antidepressants (adapted from http://tmedweb.tulane.edu/pharmwiki/doku.php/antidepressant_side_effects).

Drug	Anticholinergic	Drowsiness	Insomnia/ agitation	Orthostatic hypotension	QTC	Gastrointestinal toxicity	Weight gain	Sexual dysfunction
SSRI								
Citalopram	0	0	1+	1+	1+	1+	1+	3+
Escitalopram	0	0	1+	1+	1+	1+	1+	3+
Fluoxetine	0	0	2+	1+	1+	1+	1+	3+
Fluvoxamine	0	1+	1+	1+	0-1+	1+	1+	3+
Paroxetine	1+	1+	1+	2+	0-1+	1+	2+	4+
Sertraline	0	0	2+	1+	0-1+	2+	1+	3+
SNRI								
Duloxetine	0	0	2+	0	0	2+	0	3+
Venlafaxine	0	1+	2+	0	1+	2+	0	3+
Atypical antidepressants								
Bupropion	0	0	2+	0	1+	1+	0	0
Mirtazapine	1+	4+	0	0	1+	0	4+	1+
Serotonin modulators								
Trazodone	0	4+	0	3+	2+	3+	1+	1+

Other strategies to treat depression, especially treatment-resistant depression, include electroconvulsive therapy (ECT), transcranial magnetic stimulation (TMS), vagal nerve stimulation (VNS) and deep brain stimulation (DBS).

tion, costs, availability) and the patient (clinical picture, somatic comorbidities, individual response and tolerability, previous response to therapy).

For initial treatment, a drug must be chosen that can be tolerated by the patient and that allows achieving a therapeutic dose with good adherence to therapy; the role of the GP is important in informing the patient about possible adverse effects and adequately communication with patients so that therapy will not be interrupted. It also minimises patient distrust of pharmacological treatment. Initial improvement of symptoms can be observed at 2-4 weeks after therapy is initiated; the patient must understand that effects are not immediate. Before considering a treatment inefficacious, a trial period of 6-12 weeks should be used.

While behaviour towards the use of drugs is measurable, since data is available (number of prescriptions, consumption, costs), it is more difficult to analyse the "prescribing" behaviour of psychotherapeutic treatment. As outlined in the following paragraphs, guidelines emphasise the use of psychotherapy in treatment of patients with depression and anxiety disorders; both specialists and GPs need to keep several considerations in mind:

- accessibility to psychotherapy within the healthcare system is limited and therefore the patient's willingness to bear costs will affects its use;
- "psychotherapy" does not exist, but rather a series of psychotherapeutic approaches that are specific for treatment of various disorders; the wide range available creates confusion for GPs about the correct approach;
- from the above considerations, such approaches may be underutilised and/or used incorrectly, exposing the patient to failure to achieve therapeutic goals, in addition to sustaining economic costs.

It is therefore desirable that in the future a more codified and collaborative care model can be adopted where the GP, psychiatric specialist and psychotherapist share the information needed to establish the correct course of treatment to reduce 'split care', which reduces the efficacy of treatment.

The psychotherapies that can be used for treatment of depression include:

- cognitive behavioural therapy (CBT);
- interpersonal psychotherapy;
- family and couple therapy;
- psychodynamic psychotherapy;
- supportive psychotherapy.

Although scientific studies have shown small differences in the effectiveness of different approaches for treatment of unipolar depression [8], CBT and interpersonal psychotherapy are most frequently used in the initial therapy of mild to moderate depression, as they represent the most widely studied and effective. Compared to pharmacological therapy, psychotherapy has been shown to be comparable in reducing the symptoms of depression [9]. CBT aims to help patients identify recurring thoughts and dysfunctional patterns of reasoning and interpretation of reality in order to replace and/or supplement them with more functional beliefs.

In cases of severe depression at significant risk of suicide, self-harm, or self-neglect, the therapeutic course should consider referral by the GP to a psychiatric specialist; such cases may require hospitalisation. Concern-

FIGURE 1.
Considerations in patients who do not respond to antidepressant therapy (from Nemeroff, 2007, mod.) [10].

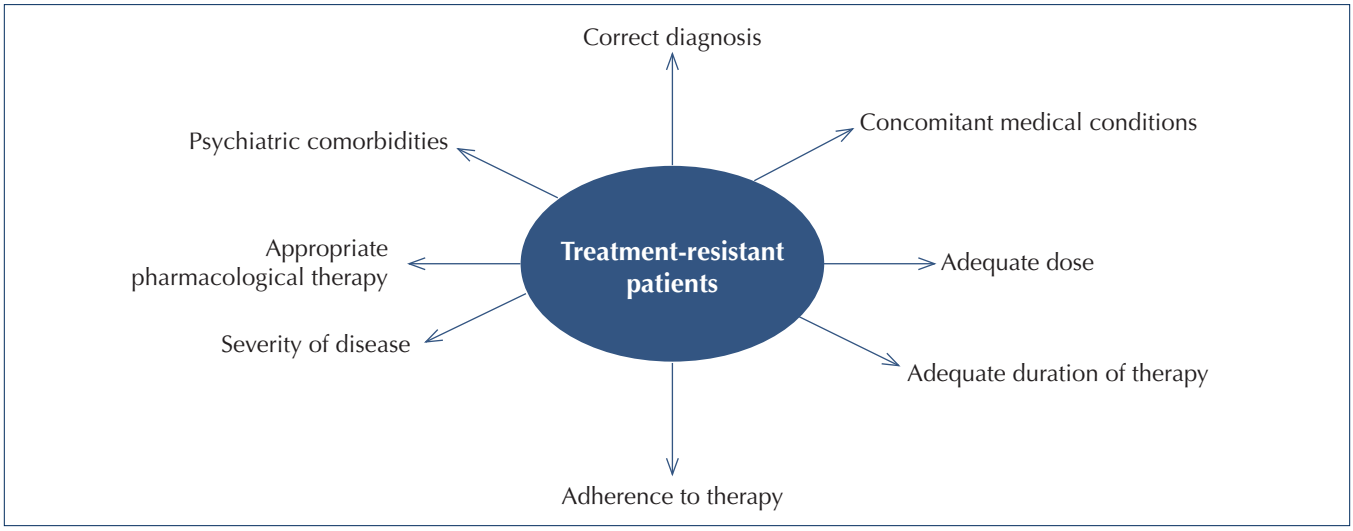


TABLE III.
Potential advantages and disadvantages of the main drug classes in clinical use.

	Advantages	Disadvantages
Tricyclic antidepressants	High clinical efficacy (reuptake of serotonin and/or norepinephrine)	Increased incidence of side effects (interaction with β-adrenergic, muscarinic and histamine H1 receptors)
Antidepressant SSRI	Particularly effective on psychic symptoms; reduce any anxious concomitant depressive symptoms; low potential for abuse	Less effective on somatic symptoms; variability in patient response; delay in onset of action; sexual dysfunction; weight gain; withdrawal symptoms; drug interactions (CYP 2D6)
Antidepressant SNRI	Broad spectrum of therapeutic activity Safety: reduced risk of toxicity in overdose Tolerability: less incidence of discontinuation for side effects	Related to activity of serotonin receptors: • gastrointestinal disturbances (nausea, vomiting, weight loss) • headache • sexual dysfunction (anorgasmia, decreased libido) • anxiety, tremor, nervousness, agitation • physical dependence "discontinuation syndrome" Related to noradrenergic receptor activity: • hypertension (at high dose
Trazodone	Anxiolytic and antidepressant efficacy with sedative effects (improved sleep); few anticholinergic effects; minimal sexual side effects	Orthostatic hypotension; sedation (sleepiness); cardiovascular problems: interaction with antihypertensives (may facilitate onset of hypotension and CNS depressant effects, e.g. clonidine); ventricular arrhythmias and torsades de pointes
Bupropion	Effective on lethargy, fatigue, apathy, drowsiness, reduction of interest and anhedonia Minimal effects on body weight and sexual function	Initial increase in anxiety levels; lowers threshold seizure
Mirtazapine	Improved sleep; no agitation, no sexual side effects, no nausea, no headaches	Increased weight gain
Agomelatine	Increases release of dopamine and norepinephrine but not 5-HT in the frontal cortex, with favourable effects on restoration of correct circadian rhythm	Possible worsening of liver function tests
Benzodiazepine	Especially effective for somatic symptoms; rapid onset of action; reproducible response and good tolerability	Less effective in psychological symptoms; possible addiction with the use of high long-term dosages; cognitive and psychomotor impairment; drug interactions (CYP 3A4)

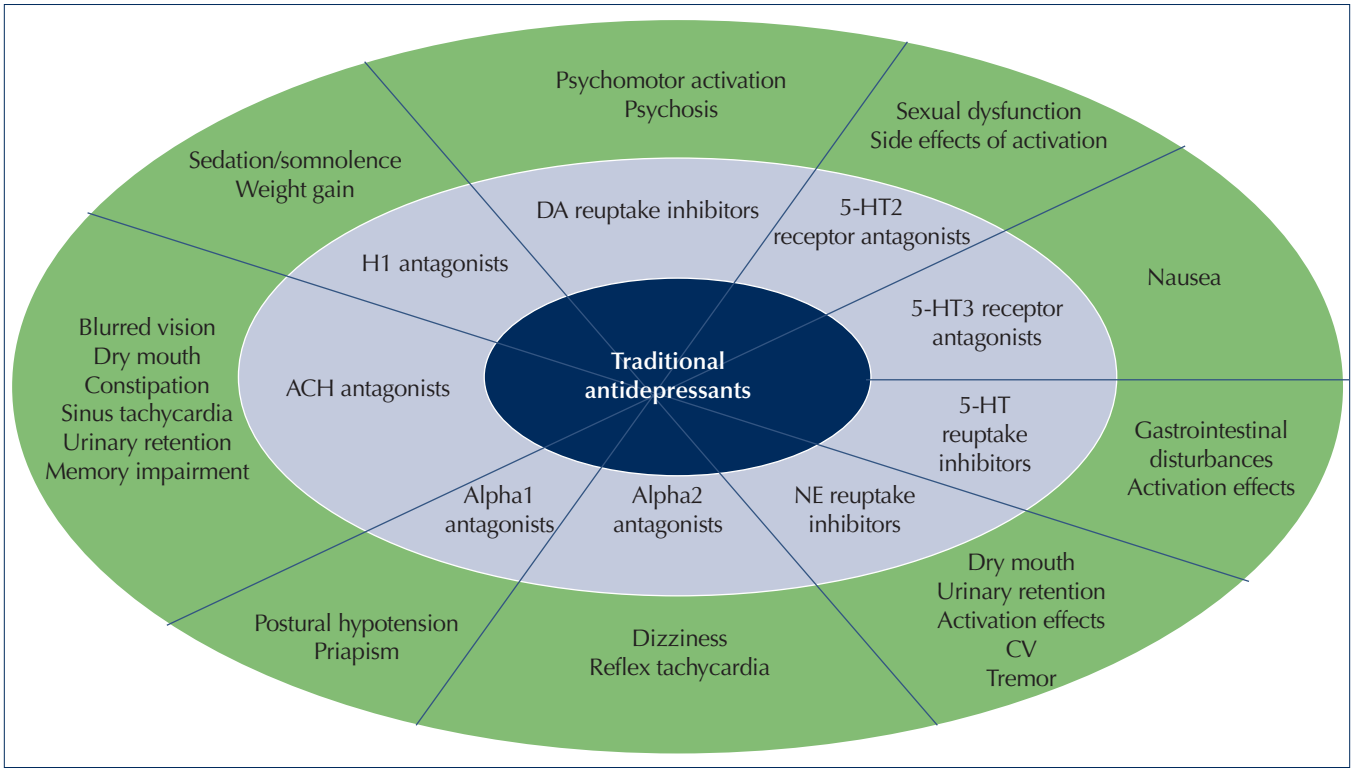
ing long-term treatment, the following should always be considered:

- a single episode of depression should be treated for at least 6-9 months after remission;
- the risk of recurrence of depression increases after each episode;
- patients suffering from several episodes require maintenance treatment for many years.

Patients with depression who present with significant anxiety symptoms are common in clinical practice; some studies have reported the co-presence of anxiety and depression in > 50% of patients. Treatment of patients with comorbid anxiety and depression includes the use of anxiolytics to control symptoms; in the acute phase of depression with significant anxiety symptoms, antidepressants have been shown to be less efficacious in this subgroup and, in some cases, anxiety symptoms can worsen during the first few weeks of treatment with antidepressants. Concomitant administration of anxiolytics and antidepressants should not continue for more than 4 weeks; after this initial phase of treatment, the anxiolytic should be tapered gradually and slowly for at least 2-4 weeks before discontinuation.

The use of combined therapies with a BDZ can rapidly improve anxiety symptoms, and also reduces the possible effects related to initiation of antidepressant therapy. Nonetheless, it is important to remember that the use of BDZs is associated with possible risks such as loss of efficacy over time (tolerance), sedation, psychomotor impairment and increased risk of falling (especially in elderly). BDZs should also be used with extreme caution in patients with a history of addiction (alcohol and/or sub-

FIGURE 2.
Side effects (adapted from Racagni G, Popoli M. Int Clin Psychopharmacol 2010;25:117-31).



stance abuse) and a history of difficult adherence to antidepressant therapy: both categories of patients are at risk of discontinuing the antidepressant and only continuing treatment with the BDZ, since it has a faster onset of action. The use of on-demand BDZs is not recommended: such an approach does not appear to be effective from a therapeutic standpoint; repeated access to a rescue dose can reinforce psychological dependence on the drug.

Several aspects should be considered in patients with panic disorder:

- the initial dose of an SSRI corresponds to half of the initial dose used for major depression and gradual titration is highly recommended to reduce the possibility of exacerbation of symptoms in the first days of therapy, in consideration of the greater sensitivity of these patients to the stimulating effects of SSRIs [11];
- the use of a BDZ should be considered in the first weeks of therapy to achieve rapid improvement of symptoms (the clinical benefits of an SSRI alone are obtained in 4-6 weeks), and to minimise possible side effects of initiation of therapy with an SSRI.

In patients who complain of insomnia, drug treatment is an effective and economical approach to treat a large number of patients. BDZs have demonstrated efficacy on insomnia, reducing latency and increasing the total sleep time. BDZs are not all equal as they have different affinities for the different subpopulations of receptors and different half-lives; all have the same dose-dependent effects (anxiolytic action, hypnotic-sedative, muscle relaxant, anticonvulsant). The choice between various BDZs depends primarily on the type of insomnia to be treated (initial, middle, end). When indicated, it is preferable to use a short or intermediate half-life BDZ to reduce the possibility of adverse events and complications, such psychomotor functions and daytime sedation.

In insomnia associated with depression, therapeutic intervention may include the use of antidepressants associated with hypnotic drugs, with varying effectiveness depending on the severity of depression and type of insomnia. Antidepressants can have a positive effect on insomnia during the course of depression or may have an "activating" effect that disturbs sleep. Some SSRI and SNRI antidepressants can disrupt sleep; in order to minimise effects on sleep the dose should be taken in the morning and at an antidepressant dosage.

Take-home messages

- Pharmacological therapy with antidepressants alone, psychotherapy alone, or a combination of both treat-

ments are efficacious in treatment of depression, generalised anxiety disorder, panic attacks and insomnia.
- The choice of treatment should take into account patient preferences and should be decided together with the patient.
- It is important to involve the patient in the therapeutic process through adequate communication that informs the patient, especially regarding the time to therapeutic response after the start of treatment (pharmacological and/or psychotherapeutic) and possible onset of common adverse effects when an antidepressant is used.
- SSRIs and SNRIs are the first choice for treatment of depression and have demonstrated efficacy and safety even when used in the setting of general medicine.
- It is recommended to use the lowest effective therapeutic dose of an SSRI or SNRI at the beginning of therapy for depression. Initial improvement begins at 4 weeks after the initiation of therapy.
- In panic attack disorder, the starting dose of an SSRI or SNRI is one-half that normally used in treatment of depression, and should be gradually titrated over 2-4 weeks.
- A BDZ can be used in the first 4 weeks of therapy for depression in the presence of significant anxiety symptoms, in panic attack disorder and insomnia in order to achieve rapid improvement in symptoms.

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Antidepressants and compliance

A. Rossi

Introduction

Compliance is defined as the extent to which the behaviour of a person, in terms of taking medication or lifestyle changes, corresponds to a medical prescription [1]. Therefore, compliance should not be understood simply as "lack of taking a medication", since it involves a wide range of behavioural and lifestyles changes, each of which plays an important role in the overall success of treatment. As a result, unsatisfactory compliance can be related to failure to comply with outpatient visits, not performing monitoring tests, early treatment discontinuation, or rejection or modification of the prescribed treatment [2].

For a more interactive, collaborative and proactive approach, many researchers and clinicians have suggested the use of the term 'adherence' or 'alliance', rather than 'compliance' [3]. However, at present, the terms adherence and compliance are used interchangeably. Traditionally, rates of discontinuation during treatment are considered the best index of non-adherence.

In the field of psychiatry, Cramer and Rosenheck [4] reported that adherence to pharmacological therapy in patients with psychiatric disorders is less than patients with physical diseases, with a rate of non-adherence in the former that varies from 24 to 90% with a mean level of non-adherence of around 60%. In particular, in treatment of depressive disorders compliance is important to achieve all the objectives of antidepressant therapy, which include resolution of symptoms, restore normal functioning and prevent relapses and recurrent episodes [5]. If therapy is adhered to, about 70% of patients with depression can be successfully treated by pharmacotherapy [6], but in spite of the availability of efficacious antidepressants, the rates of recurrence for depression

approaches 80% [7], and therapeutic failure is frequent, from 40 to 60% [8].
Moreover, guidelines for treatment of depression are not always followed and non-adherence rates are high, with 28% of patients discontinuing treatment with antidepressants within the first month and 44% discontinuing within three months after initiation of therapy. Bull et al. [9] have reported that up to 68% of patients with depression stop taking antidepressants after only three months of treatment.
In randomised clinical trials, discontinuation rates are between 20 and 40%, with the most frequent reason for discontinuation represented by "side effects", while in naturalistic studies the rates are higher, usually 50-60% within 10 weeks, with the category 'feel better' cited as the most frequent reason [10]. In addition, the overall rate of adherence decreases by 2.5% for each month of treatment with antidepressants, as reported Demyttenaere et al. (2008) [11].
In recent years, considerable progress has been made in the identification of risk factors of non-compliance to therapy with antidepressants and in developing strategies to assess and improve adherence, which can lead to better therapeutic results and decrease the morbidity of depressive disorders

How to assess compliance

Compliance to pharmacological therapy is usually classified as "good" (75-100% of doses), "average" (25-75% of doses), "poor" (0-25% of doses). "Hyper-compliance" is defined as the intake of >100% of doses. Such behaviour is often established by the patient in the belief that this will accelerate the onset of action or increase its effectiveness [12]. Leite et al. [13] stated that adherence to treatment should be defined as use of the prescribed medication for at least 80% of the time, taking into account time of day, dosage and total duration of treatment.
Quantifying non-compliance and its consequences is not straightforward. Demyttenaere [12] identified two methodological problems: the first is inherent to the reliability of study results, while the second involves the instruments used. The author holds that compliance is greater in clinical studies than in clinical practice, and that it is even greater in clinical studies that investigate adhesion to therapy. It was also stated that, in the field of adherence to therapy, simple measurement tools are not accurate, and accurate ones are not easy to use.
According to Farmer, tools to measure adherence to pharmacological therapy can be divided into direct and indirect [14]. The first provide evidence that the patient has taken the drug and include: detection of the drug or its metabolite in a biological fluid (usually blood or urine), detection of a biological marker co-administered with the drug (or placebo) and direct patient observation. The presence of a drug or its metabolite in a biological fluid provides confirmation that the patient has received a dose of medication within a certain period before testing. The presence of the drug in a test, however, does not ensure good compliance, and its absence does not always correspond to non-compliance. Most patients may have similar serum levels of the target drug, but may have taken the drug in a different way; serum or urine levels cannot quantify the mode in which the patient has taken the drug or detect fluctuations of compliance over time. Finally, inter-individual variations in metabolism and in the volume of distribution influence the level of medication regardless of adherence, making it hard to measure. Biological markers are non-toxic, stable compounds that are easily identifiable, which can be added to the drug to be monitored; they provide qualitative evidence that the patient has recently received a dose of drug. Lastly, in closely monitored clinical trials patients can be observed directly while taking the drug. This method is not always applicable or infallible as patients can deliberately pretend to swallow the medication.
The majority of the assessment methods used, however, are indirect and include self-reporting by the patient, counting of tablets, revision of the prescription registers and electronic monitoring devices.
Accounts given by patients on how they take medication is the easiest means of evaluating compliance. Patient interviews are generally considered to be a reliable method, even if the method of self-report used and the way in which it is used must be considered, given that patient responses may be influenced by both communication with the physician and the specific wording of questions. Several researchers have tried to correct such shortcomings by developing standardised self-report questionnaires to measure adherence to a treatment regimen, including the Morisky-Green test (MGT) [15] and Brief Medication Questionnaire (BMQ) [16].
For patients with depressive disorder, Demyttenaere et al. [17] developed the Antidepressant Compliance Questionnaire (ADCQ), which evaluates attitudes and beliefs of patients about depression and treatment with antidepressants. Finally, Gabriel and Violato [18] developed the Antidepressant Adherence Scale (AAS), which queries the patient's knowledge and attitudes towards depressive disorder as determinants of compliance.
Counting tablets involves simple counting of the number of doses that the patient has not taken, and comparing the doses given to those prescribed. In recent years, the use of computerised prescription records has increased utilisation of prescription adjustments, which allow researchers to investigate early discon-

tinuation of therapy and taking medicines in ways that it was not prescribed.
Finally, electronic monitoring devices, including the Medication Event Monitoring System (MEMS), contain a microprocessor that records the time and date on which the patient receives a dose of the drug. They are useful as they allow one to identify the voluntary deviations from the prescribed regimen and the effect of daily distribution of doses.
George et al. [19] compared four different methods for evaluation of compliance to determine the advantages and disadvantages. The following were used: patient self-report, counting tablets, MEMS and plasma assays of dothiepin and nordothiepin. The techniques were evaluated in 88 patients who initiated treatment with a tricyclic antidepressant in a GP setting. MEMS was the most informative technique and was considered to be the 'gold standard'. The Morisky questionnaire was found to be a useful screening technique with a sensitivity between 72 and 84% for identification of low compliance and a specificity of 74.1% for good compliance (> 80%). As in previous studies, pill count was difficult and of questionable validity. Of the four methods, the least satisfactory was measurement of blood concentration.

Factors that influence compliance

Adherence to antidepressant treatment is influenced by multidimensional factors. In agreement with most literature data, the aforementioned study by Demyttenaere et al. [10] showed that the most frequently reported reasons for discontinuation of therapy by patients are "feel better" (55%, average time of discontinuation 11 weeks) and appearance of side effects (23%, average time 6.5 weeks). However, several reasons were responsible for the discontinuation at different times over the course of the study.
The main factors influencing adherence are related to the characteristics of the disease, the patient, treatment and the doctor-patient relationship. Chronic, asymptomatic diseases that require long-term treatment, such as depressive disorder, are associated with lower compliance: the longer the remission phase, the lower compliance to therapy [20]. In addition, diseases in which the relationship between non-compliance and relapse is clear (e.g. diabetes) are associated with better compliance than those in which the relationship is less clear (e.g. depressive disorder) [21]. Demyttenaere [11] highlighted that depression in itself can passively reduce adherence. In fact, patients often have memory problems, and may feel hopeless and have less motivation. Ayalon et al. [22], in a study of elderly patients, noted that interruption of treatment, and in particular unintentional interruption, is associated mainly with the presence of more pronounced cognitive deficits. Furthermore, cognitive impairment can also affect patient insight. Lee et al. [23] examined the role of insight and adherence and showed that patients with more severe depression tend to have a greater insight, but that the latter is not associated with better adherence. Many studies have investigated the correlation between patient demographics and compliance. Despite the general assumption that older patients are less compliant than younger individuals, this relationship is not yet firmly established [24], and it seems that other related features, such as old age, social isolation and polypharmacy, are predictive of lower compliance. The notion that older patients are less compliant is supported by a study by van Geffen et al. [25] in which interruption of treatment was twice as high in patients 60 years and older.
In contrast, Brown et al. [26] reported that older patients are more adherent to therapy than younger patients. Looking in detail at the results of van Geffen et al. [25] and Brown et al. [26], it would seem, however, that older patients were more likely to question the use of drug therapy before trying it, whereas they may be more motivated to stay on therapy once it is initiated. Demyttenaere [11] found that non-compliance is higher in women than in men [11] and, similarly, Brown et al. [26] observed that men are more compliant women.
Kessing et al. [27] investigated the attitudes and beliefs of depressed bipolar patients and towards antidepressants. They reported that a large number of patients, especially those over 40 years, generally had a negative view of antidepressants, unclear ideas regarding their influence and a critical vision of the doctor-patient relationship.
Even personality-related aspects are important predictors of compliance, and their identification can help in developing individualised treatment regimens. In 2004, Cohen et al. [28] investigated the relationship between personality characteristics, according to a 5-factor model, and compliance to antidepressant treatment in 65 outpatients with major depressive disorder. They reported that extroversion was a significant negative predictor of compliance, while the subdomain modesty was a positive predictor. In the same study, the authors showed that none of the socio-demographic or disease-related characteristics such as age, sex, or number of previous depressive episodes, correlated with compliance.
Another interesting aspect is the type of pharmacological treatment that the patient receives and, above all, its dosage. Shigemura et al. [29], in a study on 1151 subjects with major depressive disorder, observed that patients with daily monotherapy had greater adherence compared with bid or tid dosing, suggesting that a reduction in the frequency of administration improves

adherence. The class of antidepressants had no significant effect on adherence.
Even the formulation may affect compliance. The currently available antidepressants are typically formulated as tablets or capsules for oral administration; in some cases they are also available as an oral suspension and intravenous formulation. However, extended release formulations of fluoxetine, venlafaxine, bupropion and paroxetine are under development, which offer greater ease of use and improved adherence [30-32]. Regarding the visual characteristics of the drug (e.g. form, size and colour), de Craen et al. [33] found that red, orange and yellow tablets are most appropriate for stimulant drugs, and that blue and green are better suited for sedatives. Buckalew et al. [34] reported that capsules are perceived as being more powerful than tablets and that the size of the capsule corresponds to perception of efficacy. In many studies, the appearance of side effects was a key cause of treatment discontinuation.
In an investigation by Bull et al. [35], 43% of patients who discontinued treatment within 3 months did so because of side effects. This proportion decreased to 27% in the second quarter of treatment, suggesting that patients who interrupt for side effects are more likely to do so at an early stage of therapy. Ashton et al. [36], even if they found that lack of efficacy was the most common reason for interruption, also stressed the central role of side effects, including loss of sexual interest, fatigue and lethargy, and significant weight gain.
Regarding the influence of the drug class on compliance, data in the literature have given as much consideration to effectiveness as to side effects of the two major classes of antidepressants currently in use (SSRIs and TCA). A meta-analysis [37] of 102 randomised controlled clinical trials of SSRIs and TCAs found no significant differences in efficacy between the two classes. However, although significant differences were seen in discontinuation rates, the clinical relevance of such differences is unclear. Discontinuation rates between the two classes are similar, although SSRIs have a better tolerability profile.
Bull et al. [35] studied doctor-patient communication. Considering the availability of many well-tolerated antidepressants, the authors found that the rate of treatment interruption cannot be explained solely by the appearance of side effects. Both physicians and patients compiled a questionnaire about the information that had been given to the patient on the antidepressant and duration of treatment. Interestingly, 72% of doctors referred that they had advised the patient to continue treatment for at least 6 months. In contrast, only 34% of patients remembered receiving such advice. The percentage of non-compliance was three times greater for patients who thought they were not informed. Moreover, if the possible side effects of the drug had been discussed, patients were more likely to continue therapy. These results clearly highlight the importance of the doctor-patient relationship in adherence to therapy.
More recently, Tamburrino et al. [38] found that patients who are not satisfied with their physician tend to be less compliant, and especially among those who have felt that they had not been adequately informed about the side effects of treatment. Similar results were found in the study by Brown et al. [26], who reported that it is beneficial for physicians to discuss the possible side effects with patients and inform them about how to take their therapy. In general, patients who are very satisfied with their physician are more compliant [29].

How to improve compliance

Adequate education and active participation are fundamental to improve adherence during treatment in patients with depressive disorder. Interventions that target the patient, the physician and the structural aspects of care can potentially improve adherence and treatment outcomes. If the patient is well informed about the course of the disease, symptoms and prognosis, adherence is better.
Several strategies have been developed to improve compliance, including: improving communication, patient education, dose optimisation and scheduling of follow-up visits. To improve doctor-patient communication, Cramer [39] proposed that the physician should discuss diagnosis and treatment with the patient, as well as the therapeutic plan chosen and timing of follow-up. Education should include information about treatment and healthcare providers should offer supportive interventions to patients and family members, while the treatment regimen should include reduction in the number of daily doses and number of drugs taken.
Even the problem of generic prescriptions may interfere with adhesion and should be discussed with the patient [40]. As early as 1997, Demyttenaere 12 highlighted the importance of the doctor-patient relationship in this regard, stating that patients who perceive the physician as empathetic and disposed to diminish their worries are more compliant. In the previously-mentioned study by Ashton et al. [36], the authors concluded that compliance can be promoted through better understanding of the expectations and desires of patients to therapy and by prescription of antidepressants associated with a low incidence of side effects.
Finally, in a systematic review assessing the effectiveness of interventions to improve compliance, Vergouwen et al. [41] noted that collaborative care interventions, tested in primary care settings, have shown significant improve-

ments in adherence during the acute and maintenance phases of treatment, and were associated with clinical benefit, especially in patients with major depression who were prescribed suboptimal doses of drugs. In the same meta-analysis, however, the evidence did not confirm the utility of educational interventions.

Conflict of interest
None.

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Validation of the Italian version of the Devaluation Consumers' Scale and the Devaluation Consumers Families Scale

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Summary

Objectives

This study aimed to assess the psychometric properties of the Italian versions of the Devaluation of Consumers Scale (DCS) and the Devaluation of Consumer Families Scale (DCFS), two short-scales examining public stigma towards people with mental disorders and their relatives.

Methods

The scales were administered to 117 individuals with a clinical diagnosis of affective or non-affective psychoses (ICD 10 criteria F20-29, F30-33). Translation procedures were carried out according to accepted standards. Internal reliability was assessed using Cronbach's alpha coefficient. Convergent validity was evaluated in terms of correlation with the Global Functioning Scale (GAF) and with the Questionnaire on Users' Opinions (QUO). Known-group validity was assessed comparing patients at first-episode of psychosis and patients with a history of psychosis of at least 3 years (long-term psychosis).

Results

The overall Cronbach's alpha value was 0.85 for DCS and 0.81 for DCFS; subscales' alpha values ranged from 0.80 to 0.55 for DCS, and from 0.68 to 0.55 for DCFS. Negative correlations were found between the Italian DCS and the DCFS total score and the QUO affective problems (DCS -0.33; DCFS -0.235) and social distance subscales (DCS -0.290; DCFS -0.356). Moreover, the GAF positively correlated with some of the DCS and DCFS subscales. Patients with long-term psychosis had higher scores in most DCS and DCFS subscales.

Conclusion

The Italian translation of DCF and DCFS showed good internal consistency, known-group validity, and convergent validity. These psychometric properties support their application in routine clinical practice in Italy as well as their use in international studies.

Keywords

Perceived stigma • Stereotype awareness • Devaluation of Consumers Scale • Devaluation of Consumer Families Scale • Questionnaire on Users' Opinions

Introduction

Stigma is a factor associated with negative outcomes in severe mental disorders, especially in schizophrenia [1]. Stigma negatively affects the quality of life of people with mental disorders and their caregivers, as well as the short and long-term clinical course of psychotic disorders. Examples of the negative impact of stigma are delays in care seeking and treatment [2], poor therapeutic adherence [3], low social integration [4], and difficulties in finding or keeping a job [5]. These negative effects, taken together, result in an increased risk for clinical relapse and poor functional recovery.

Stigma may be expressed through three different levels: stereotyping (cognitions, beliefs), prejudice (emotions, feelings), and discrimination (behaviors). Furthermore, stigma is classified in three main types: public stigma, self-stigma, and experienced stigma. Public stigma refers to what the society or the majority of lay people believe about the person with mental health problems; self-stigma expresses the degree of internalization of the stigma by the victim; experienced stigma corresponds to objective discriminations [6]. According to the "modified labeling theory" [7], receiving a diagnostic label of schizophrenia increases the perception of public negative attitudes towards individuals affected with mental disorders (public stigma). In people with mental disorders, this "stereotype awareness" may lead to internalize such negative attitudes and to anticipate possible acts of discrimination [8]. In other words, stereotype awareness may significantly affect users' self-esteem and self-efficacy, further influencing quality of life and treatment-seeking behaviors. Indeed, it was demonstrated that insight, and therefore

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stigma, are associated with poor therapeutic alliance in patients with psychotic spectrum disorders [9].
Compared to stigma towards people with common and socially accepted mental disorders, such as depression [10 11], public attitudes are particularly negative towards People With Schizophrenia (PWS). A large number of studies confirmed that PWS are often viewed as dangerous, unpredictable, and socially impaired. These attitudes have been found associated with desire for social distance and prognostic pessimism [12-14].
Stigma not only invests people diagnosed with mental disorders, but also those around them, primarily their caregivers. The so-called "affiliate stigma" or "courtesy stigma" [6 15] refers to the process of being stigmatized because of an association with a stigmatized person. Affiliate stigma is associated with increased family burden, as well as with stereotype awareness and increased symptoms in patients [16 17], suggesting pervasive effects of the stigmatization process both on PWS and caregivers' quality of life.

Given the relevance of stigma in many domains of the life of people with severe mental disorders, it is worthwhile measuring stigma – by means of valid and reliable assessment tools – as a first step to promote sensitization and educational programs for the public. Some international assessment scales on stigma have been recently validated in Italian, such as the Attribution Questionnaire-27/AQ-27 [18], whereas other instruments, as the Questionnaire on Users' Opinions/QUO [19] and the Questionnaire on Families' Opinions/QFO [20] have been originally developed in Italy and subsequently used in different populations [21-23].
Within the EUGEI project, the most recent epidemiological European survey on psychotic disorders [24], stereotype awareness towards PWS and their family members were assessed using the Devaluation of Consumers Scale (DCS) and the Devaluation of Consumer Families Scale (DCFS)[25]. These short-scales stand out for their convenience of administration – since they require few minutes to be completed – the possibility of evaluating public stigma towards family members – not covered by other scales – and the ability to evaluate various features of public stigma towards mental disorders, such as social status reduction, friendship refusal, or community rejection. In this study, we report data on the assessment of the psychometric properties of the Italian versions of the DCS and the DCFS, both administered to a sample of 117 PWS.

Method

Participants and procedure

The scales were administered to individuals with a clinical diagnosis of schizophrenia (ICD 10 criteria F20), other non-affective psychoses (ICD 10 F21-29), or affective psychoses (F30-33) [26], attending mental health services of Palermo (Southern Italy) in the period 2010-2015. Inclusion criteria were: 1. age between 18 and 65 years; 2. being resident in Palermo; 3. diagnosis of psychotic disorders according to ICD-10 F20-29 or F30-33 criteria. Exclusion criteria were: 1. psychosis due to organic causes; 2. presence of severe learning disability.
Ethical approval was obtained for the EUGEI study by the ethical committee of the University Hospital "P. Giaccone" of Palermo. Potential participants were informed about the study aims and procedures, data anonymization (carried out by assigning to each participants a unique number key), and the possibility to withdraw from the study in any moment. Participants that agreed to participate in the study signed an informed consent and then completed the Devaluation of Consumers scale (DCS), the Devaluation of Consumer Families scale (DCFS), and the Questionnaire on Users' Opinions (QUO) about schizophrenia. Main socio-demographic characteristics were also collected by an ad hoc schedule. Symptom and disability severity were registered using the Global Assessment of Functioning (GAF) on the basis of clinical records and information provided by care coordinators.

Measures

The Devaluation of Consumers Scale (DCS)

The Devaluation of Consumers Scale (DCS) is an eight-item scale assessing stereotype awareness by patients with severe mental disorders [24-27]. Factorial analysis led to the identification of the following three-factor solution (total explained percentage: 68.6%): factor 1 "status reduction", describes the altered patients' status in society (five items, 28.7% of variance); factor 2 "role restriction", concerns a pessimistic view related to the possibility of finding a job or getting married (two items, 23.5%); and factor 3 "friendship refusal", accounts for difficulties in establishing friendships (one item, 16.4%). Internal consistence of the DCS was estimated as 0.82 [25].

The Devaluation of Consumers Families Scale (DCFS)

The Devaluation of Consumers Families Scale (DCFS) complements the DCS by assessing the perceived devaluation or discrimination towards family members of patients with severe mental disorders [24-26]. The seven items of the DCFS were grouped in three factors, explaining 71% of the variance. The factors were: factor 1 "community rejection", describes the tendency to avoid friendships and other forms of social contact

with caregivers of patients with psychiatric disorders (four items, 32.9% of variance); factor 2 "causal attribution", is related to the tendency to treat some people in a different way because of the disease of their family member, and to blame parents for the mental illness of their children (two items, 20.9%); and factor 3 "uncaring parents" expresses the view that children affected by mental disorders had received inadequate parental care (one item, 17.2%). The internal consistence of DCFS was estimated 0.77.

The DCS and the DCFS were forward-translated by an Italian psychiatrist and an Italian clinical psychologist, who agreed on the Italian translations of the two scales. Subsequently, the two translations were reviewed and approved by a committee of the EU-GEI research project coordination, including an Italian mother tongue researcher with expertise in psychosis. This was consistent with established methods for translating health status instruments [28].

The Questionnaire on Users' Opinions

The Questionnaire on Users' Opinions (QUO) assesses users' view of their own mental disorder. QUO includes 24 items on the psychosocial impact of severe mental disorders, grouped in the following six subscales: "affective problems" (7 items, Cronbach's alpha 0.73) referring to patients' difficulties in establishing relationships, friendships, and set up their own family; "social distance" (5 items, alpha 0.74), concerning perceived distance, lack of understanding, and fear of "the others" towards PWS; "usefulness of drug and psychosocial treatments" (3 items, alpha 0.56), accounting for benefits and side effects of psychiatric interventions; "right to be informed" (3 items, alpha 0.58) referring to users' right to be informed about own mental problem and treatments; "recognizability" (2 items, alpha 0.56) examining the belief that PWS are easily identifiable because of their symptoms and drugs' side effects; and "social equality" (4 items, alpha 0.55), exploring respondent's views of discriminations in social and work opportunities. Factor analysis identified two factors, the former accounting for social and affective impact of severe mental disorders (33.3%) and the latter being related to clinical outcome and usefulness of treatments for schizophrenia (19.5%) [19].

Global Assessment of Functioning

The DSM-IV Axis V Global Assessment of Functioning (GAF) scale is an established tool for the assessment of symptom severity and psychosocial functioning in clinical and research settings. GAF scales are rated on 1-100 level, where higher scores correspond to better functioning/absent or minor psychiatric symptoms, and lower scores indicate greater disability/more severe symptoms [29].

Data Analysis

Internal reliability was assessed using Cronbach's alpha coefficient on total scales and related subscales. Convergent validity was evaluated in terms of correlation with the GAF and, only for the subgroup of patients with long-term psychosis (n = 72), with the QUO; correlations were calculated using Pearson's r coefficient. Known-group validity was assessed by comparing patients with first-episode of psychosis (FEP) with patients affected by long-term psychosis (LTP). Differences between groups were tested by performing Student's t test. Statistical significance was set at $p < 0.05$. Analyses were performed using SPSS version 21.

Results

Sample

A total of 117 people with psychosis were assessed. Participants had a mean age of 36.32 (sd 12.33) and were mostly males (75, 64.1%), with high level of education (high school degree 53 (45.3%), middle school degree 45 (38.5%), primary school degree 19 (16.2%), and single (99, 84.6%).

Seventy-two out of 117 participants had a clinical history of at least 3 years of psychosis (mean illness duration 16.64 years, sd 9.93), while 45 participants were at their first-episode of psychosis (i.e. presenting for the first time to psychiatric services for psychotic symptoms). In both groups, most participants were males (patients with FEP 25 [55.6%] *vs* patients with long-term psychosis 50 [69.4%], $\chi^2 = 2.321$, p= 0.128), and with high level of education (middle school degree 20 [44.4%] *vs* 25 [34.7%] or high school degree 20 [44.4%] *vs* 33 [45.8%], $\chi^2 = 1.877$, p = 0.391). The two groups were different in their mean age (mean 29.98 [sd 11.38] *vs* 40.28 [11.26], t = -4.795, $p < 0.001$) and marital status (single 32 [71.1%] *vs* 67 [93.1%], $\chi^2 = 10.244$, p = 0.001).

Internal reliability

As reported in Table I, Italian DCS had moderate-high internal reliability both for the total scale (alpha 0.85) and the subscales (status reduction alpha 0.80; role restriction alpha 0.57). Similar level of internal reliability was found for the Italian DCFS (Table I).

Validity

Analysis of convergent validity showed that the GAF functioning subscale positively correlated with the DCS

TABLE I.
Reliability of the Italian Devaluation Consumers' Scale and the Italian Devaluation Consumers' Family Scale

	Items	Cronbach's alpha
DCS		
Total Score	8	0.851
Status reduction	5	0.806
Role restriction	2	0.558
DCFS		
Total Score	7	0.808
Community refusal	4	0.685
Causal attribution	2	0.558

DCS: Devaluation Consumers' Scale; DCFS: Devaluation Consumers' Families Scale.

role restriction subscale, while the GAF symptom subscale positively correlated with the DCFS community refusal subscale.

Negative correlations were found between the DCS and the DCFS total score and the QUO affective problems and social distance subscales. Moreover, the DCS status reduction and the DCS role restriction subscales negatively correlated with the QUO affective difficulties and social distance subscales, while the DCS friendship refusal correlated with the QUO usefulness of treatments and recognizability subscales. Finally, the DCFS community refusal and causal attribution subscales negatively correlated with the QUO social distance subscale, whereas the DFCS neglecting parents correlated with the QUO affective problems and social distance subscales (Table II).

Comparisons between the two groups (patients with FEP *vs* patients with LTP) revealed that participants with long-term psychosis had higher scores than participants at early stage of psychosis in all DCS and DCFS subscales, except for DCS status reduction and friendship refusal and the DCFS causal attribution subscales (Table III).

Discussion

The results of this study confirm that the Italian version of the DCS and DCFS are valid and reliable assessment tools to explore public stigma towards PWS and their relatives. The Italian DCS had an acceptable to good internal reliability for total scale (Cronbach's alpha 0.85), and subscales (status reduction: alpha 0.80; role restriction: alpha 0.57). Similarly, adequate level of internal reliability was found for the Italian DCFS, whose Cronbach's alphas were respectively 0.81 for total scale and 0.68 and 0.56 for subscales. These values are consistent with those reported in the original version [25], where internal consistency of the DCS and the DCFS were, respectively, 0.82 and 0.71.

The validity of the Italian DCS and DCFS was investi-

TABLE II.
Convergent validity of Italian Devaluation Consumers' Scale and the Italian Devaluation Consumers' Families Scale.

	QUO n = 72						GAF N = 117	
	Affective problems	Social distance	Usefulness of treatments	Recognizability	Social equality	Right to be informed	Symptoms	Functioning
DCS								
Overall score	-0.331**	-0.290*	0.042	-0.127	-0.053	0.156	0.112	0.135
Status reduction	-0.315**	-0.235*	0.004	-0.087	-0.057	0.157	0.067	0.095
Role restriction	-0.300**	-0.305**	0.001	-0.049	-0.058	0.119	0.152	0.192*
Friendship refusal	-0.177	-0.230	0.247*	-0.298*	0.014	0.089	0.126	0.081
DCFS								
Overall score	-0.235*	-0.356**	-0.004	-0.116	-0.087	0.014	0.157	-0.024
Community refusal	-0.185	-0.241*	0.023	0.129	-0.031	-0.002	0.205*	0.017
Causal attribution	-0.118	-0.318**	-0.077	-0.032	-0.169	0.085	0.016	-0.064
Neglecting_parents	-0.370**	-0.406**	-0.039	-0.107	-0.024	-0.079	0.138	-0.042

Pearson r correlations. ** Correlations statistically significant at p < 0.01 ; * Correlations statistically significant at p <. 0.05.
DCS: Devaluation Consumers' Scale; DCFS: Devaluation Consumers' Families Scale; QUO: Questionnaire on Users' Opinions; GAF: Global Functioning Scale.

TABLE III.
Known group validity of Italian Devaluation Consumers' Scale and the Italian Devaluation Consumers' Families Scale.

	Patients at their FEP n = 45	Patients with LTP n = 72	Students' t	p value
DCS	Mean (SD)	Mean (SD)		
Overall score	2.35 (0.62)	2.65 (0.62)	-2.539	0.012
Status reduction	2.42 (0.70)	2.66 (0.66)	-1.865	0.065
Role restriction	2.24 (0.67)	2.72 (0.76)	-3.429	0.001
Friendship refusal	2.18 (0.89)	2.44 (0.90)	-1.559	0.122
DCFS				
Overall score	1.98 (0.62)	2.37 (0.58)	-3.375	0.001
Community refusal	1.97 (0.60)	2.43 (0.60)	-3.863	<0.001
Causal attribution	2.10 (0.78)	2.31 (0.75)	-1.415	0.160
Neglecting_parents	1.75 (0.90)	2.24 (0.93)	-2.688	0.008

DCS: Devaluation Consumers' Scale; DCFS: Devaluation Consumers' Families Scale; FEP: first-episode psychosis; LTP: long-term psychosis; sd: standard deviation.

gated as known-group validity and as convergent validity. The higher mean scores of DCS and DCFS found in patients with long-term disease compared to those at their first-episode of psychosis (see Table 3) could be related to the greater experience of public stigma in the former. This is partially in line with a previous study reporting association between the DCS score and age [16]. It is likely that the higher mean score found among long-term psychosis participants is attributable to a deeper internalization of negative stereotype, as well as to participants' higher insight about their own condition, and to a greater likelihood of having experienced discrimination and marginalization [30 31]. Nevertheless, the lack of significant differences in the DCS status reduction and friendship refusal and the DCFS causal attribution suggests that these dimensions of public stigma might be perceived by PWS since the onset of the disease and do not vary substantially over time.

Both DCS and DCFS showed significant correlations with the QUO. In particular, the DCS status reduction and the DCS role restriction subscales positively correlated with affective difficulties and social distance as measured by QUO, while the DCS friendship refusal subscale negatively correlated with the QUO social recognizability subscale. This is consistent with previous studies on clinical samples of people with severe mental disorders showing that public stigma was strongly related to alienation, social withdrawal, and stereotypes endorsement [32 33]. Moreover, we found that the DCS friendship refusal subscale positively correlated with the QUO usefulness of treatments subscale, suggesting that perceived public attitude towards mental disorders is related with treatment-seeking behaviors. This association corroborates findings reported by Jennings et al. [34] on a large sample of college students. A further result concerns the negative correlations of all DCFS subscales with the QUO social distance subscale, pointing out at the effects of courtesy stigma on social relationships.

DCS and DCFS showed few correlations with the GAF subscales. Specifically, the DCS role restriction negatively correlated with the GAF functioning scale. This result is in line with previous studies showing a relationship between public stigma and functional outcome [35-37]. It is likely that psychosocial functioning and stereotype awareness are part of a vicious circle, in which worst functioning leads to greater discrimination in employment and social contexts, while perceived devaluation prevents PWS from looking for a job and intimate relationship, even in absence of experience of discrimination [24 38]. This study also found a positive relationship between symptoms severity (GAF symptoms scale) and perceived marginalization of the families (DCFS community refusal), which replicates the findings of previous research on the link between courtesy stigma and psychopathology [15 16]. These findings suggest that the course of severe mental disorders is related not only to perceived patient's devaluation but also to family devaluation, a condition further contributing to self-defeat and isolation of people with psychosis [39 40].

According to a cognitive model of psychosis, discrimination and stigma, along with other psychosocial stressors (i.e. childhood adversities, see [41 42]), might increase the risk for psychotic symptoms by promoting negative representations of the self and the others, favoring reasoning biases, and increasing the sensitivity of the biologi-

cal stress-response system (the so called "sensitization process"). Sensitization determines an impaired response to life events and social stress (including minor daily life hassles) that, in turn, may trigger delusion and hallucinations, increasing the risk for the onset of psychotic disorders or their relapse. Furthermore, anticipated and experienced discrimination may affect the course of the disease as a maintenance factor, by increasing negative affect and social isolation, lowering self-esteem, and fostering ineffective coping strategies[1 43-45]. Therefore, assessing public stigma in individuals with severe mental disorders might contribute to identify a relevant factor for the course and outcome of psychiatric diseases. Strategies to reduce discrimination should include both anti-stigma interventions, providing the public with information and contact with people with psychosis, and provision of psychosocial treatment to people with psychosis to reinforce their coping strategies and self-esteem[1 46-48].

The findings of this study should be interpreted with caution in light of several limitations, such as: the small sample size that might have affected the statistical power, the cross-sectional study design preventing inferences on causal relations, and the effect of potential, unmeasured confounders (i.e., self-esteem, depression, or perceived social support) on the association between DCS/DCFS, duration of illness, and QUO. Nevertheless, the Italian version of DCS and DCFS showed high internal consistency, relevant association with the stage of the disease, and mild-to moderate correlations with the QUO and the GAF. These encouraging results support the use of these scales in clinical and community settings in Italy. Moreover, because of their convenience of administration and the possibility to assess various dimensions of public stigma (including affiliate stigma towards family members of PWS), DCS and DCFS seem particularly suitable to assess public stigma in the community and how it is modified in response to anti-stigma campaigns [16 25 41].

Conflict of interest
None.

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