



# Effects of Local Guidelines on Prescribing Practice and Treatment Outcomes in a Long-Stay Psychiatric Facility

Ivana M. Iličković<sup>1</sup>, Aleksandar B. Tomčuk<sup>2</sup>, Jovo M. Djedović<sup>2</sup>,  
Kristina B. Bećir<sup>2</sup>, Slobodan M. Janković<sup>3</sup>

<sup>1</sup> Farmegra Ltd., Podgorica, Montenegro

<sup>2</sup> Specialized Hospital for Psychiatric Diseases, Dobrota, Kotor, Montenegro

<sup>3</sup> Faculty of Medical Sciences, University of Kragujevac, Kragujevac, Serbia

## SUMMARY

**Introduction:** A gap between evidence-based recommendations for prescribing antipsychotics and its implementation in practice could be overcome by local guidelines.

**Aim:** The aim of our study was to locally adapt the national guideline for schizophrenia and evaluate its impact on prescribing practice as well as on clinical and humanistic outcomes in a long-stay psychiatric hospital Dobrota in Kotor, Montenegro.

**Subjects and Methods:** This was academic, prospective, IV phase interventional study, which measured outcome before and after investigators intervention within healthcare system. The study was conducted in two six-months phases separated by implementation of the local guidelines. Prescribing practices and treatment outcomes were monitored in both phases of the study.

**Results:** Study included 111 patients. Although the guidelines did not influence total volume of prescribed antipsychotics, social functioning and environmental aspects of quality of life were improved.

**Conclusions:** Writing and adopting the guidelines for local use might be associated with some benefit in humanistic outcomes, but multi-faceted intervention should be considered in order to achieve more substantial impact on prescribing practices and clinical outcomes.

**Keywords:** guidelines, schizophrenia, antipsychotic polypharmacy, inpatients, outcomes

## INTRODUCTION

Main focus of the multidisciplinary treatment of mental illnesses, especially schizophrenia, is still on the pharmacological therapy in majority of settings [1]. It might be, partly, justified, by the increasing availability of newly identified drugs with improved efficacy, safety, and tolerability profiles (e.g., atypical antipsychotics, selective serotonin reuptake inhibitors, al-

ternative mood-stabilizing agents).

Nevertheless, relative cost and complexity of the neuropsychopharmacology advancements have also been emphasised [1,2]. This rendered publication of numerous treatment guidelines and practice recommendation, aiming at best scientific evidence being translated into practice, for improving clini-

Corresponding author:

Professor, Primarius Slobodan M. Janković, MD, PhD

Specialist in Clinical Pharmacology

Faculty of Medical Sciences, University of Kragujevac, Svetozara Markovica Street, 69

34000 Kragujevac, Serbia

E-mail: slobnera@gmail.com

cal, humanistic and economic outcomes of treatment for patients with mental disorders. [1,3-10]. Although it is recognized that appropriate prescribing could improve patient outcomes and cut the expenses [1,11], there is a gap between evidence based recommendations and their implementation in local practices, especially in developing countries [1,12-15]. Several barriers were identified in developing countries that adversely affect implementation of evidence-based guidelines in clinical practice (lack of evidence-based healthcare system [16], lack of political support [16], lack of knowledge and appropriate training of physicians [17] , etc.), but still we are far from complete insight into the problem, partially due to social and cultural differences across the countries.

In 2012, the Ministry of Health of Montenegro issued the first National guideline for the treatment of Schizophrenia [7]. Consistent with other guidelines and research findings [2,13,18] antipsychotic polypharmacy (APP) was not supported; advantages of efficacy/tolerability profiles of second-generation antipsychotics (SGA) and effectiveness of clozapine augmentation for treatment resistant patients were elaborated. However, national guidelines did not cover issues such as treatment of chronic schizophrenia patients resistant even to clozapine, treatment of adverse effects of antipsychotics, or optimal dosing regimens.

## AIM

The aim of our study was to locally adapt the national guideline for schizophrenia and evaluate its impact on prescribing practice as well as on clinical and humanistic outcomes in hospital patients with severe mental illnesses in Montenegro.

## SUBJECTS AND METHODS

### Subjects with ethical considerations and informed consent

This academic, prospective, IV phase, interventional study, which measured outcome before and after intervention - adaptation and application the national guideline for schizophrenia, was conducted at specialized psychiatric hospital Dobrota in Kotor, Montenegro. The Ethics approval for the study was ob-

tained from the Ethics Committee of Clinical Center of Montenegro, Podgorica (No 03/01-11941/1), and from the Ethics Committee of Dobrota hospital (No 24-12-09).

This is a 241-bed, non-research facility for patients with severe mental illnesses, with 141 beds for long term patients. The study was conducted during the period from June the 15<sup>th</sup>, 2012, to June the 15<sup>th</sup>, 2013. All chronic patients of this facility (hospitalized for more than 6 months) with the diagnosis of schizophrenia (F20.0-F20.9) were included in the study, except for the patients with concomitant mental retardation or impairment of consciousness.

### Methods

The intervention consisted of development, adoption and implementation of local guideline for pharmacological treatment of schizophrenia in Dobrota hospital. The study had two phases separated by adoption and implementation of the local guideline: the first, six-month phase, when baseline prescribing practice in the hospital was monitored, and the second six-months phase, after the guideline were adopted and implemented, when effects of the guidelines to prescribing practice were observed. The guideline was developed initially by an independent expert, and then further refined and adopted by the Expert Board of the Dobrota hospital (composed of psychiatrists), after discussion with all other employed psychiatrists and taking into account their feedback.

All study variables were measured at the end of the respective study phase. The demographic data collected included: age, sex, duration of illness, duration of current hospitalization, type of hospitalization (continuous or interrupted during weekends), psychiatric and other diagnosis. Data about medications, laboratory monitoring and adverse reactions were also collected.

Clinical and humanistic outcomes of the intervention (implementation of local treatment guidelines) - were assessed using standardized rating scales: (1)18-item Brief Psychiatric Rating Scale-BPRS to evaluate clinical status [19]; (2)The Abnormal Involuntary Movement Scale-AIMS was used for assessing occurrence and severity of dyskinesias [20]; (3)Humanistic outcomes were assessed using Euroqol (Serbia (Serbian) EQ-5D-5L)

**Table 1.** Demographic characteristics of the study patients

Gender	female	27
	male	84
Age/ years $\pm$ SD (range)	54.8 $\pm$ 10.7 (30-89)	
Hospitalization	weekends	29
	continuous	82
Mean duration/years $\pm$ SD (range)	disease	20.3 $\pm$ 11.0 (1-53)
	hospitalization	11.5 $\pm$ 9.1 (1-45)
Main diagnosis	Schizophrenia	107
	Bipolar Disorder	2
	Depression	2

and WHOQOL (WHOQOL BREF\_Serb\_Croat\_Bosnian). The BPRS and AIMS are scales in the public domain, while permissions for use of EQ-5D-5L and WHOQOL BREF were obtained from copyright holders.

### Statistical analysis

The study data were statistically described by means and standard deviations (for continuous variables) or percentages (for categorical variables). The differences between values of continuous study variables before and after the intervention were tested by Student's T-test for large, dependent groups, when the values were normally distributed (as tested by Kolmogorov-Smirnov test), and by Wilcoxon's test, when the values were not normally distributed. The differences between values of categorical variables before and after the intervention were tested by Chi-square test. The differences were considered significant if probability of null hypothesis was less than 0.05.

## RESULTS

Study included 111 subjects. Demographic characteristics and diagnosis are presented in the Table 1. Mean BPRS score of 25.7 ( $\pm$  12.13) demonstrated clinical status of moderately severe illness.

### Phase 1

No adverse event was noted in the first phase of the study. Presence of dyskinesia, as rated by

the Assessing involuntary movements (AIMS) scale, was 13.34  $\pm$  4.89.

Patient-perceived quality of life on EUROQOL 5D 5L visual analogue scale was 53.6% ( $\pm$  26.2), and WHOQOL BREF scores in the first phase of the study for the four domains: physical health, psychological, social relationships and environment are presented in the Table 2.

Antipsychotics were prescribed to 108 of 111 patients, at the median daily dose expressed as chlorpromazine equivalent of 546 mg, ranging from 50 to 2600 mg. The first generation antipsychotics (FGA) were prescribed to 85 and the second generation to 74 patients. Most of the patients (69.4%) received combinations of antipsychotics. Antidepressants were co-prescribed to 6 and lithium to 9 patients. Percentages of patients taking anticonvulsants, antiparkinsonian medications and benzodiazepines were: 38.7%, 45% and 58.6%, respectively.

### The intervention

The local guidelines for pharmacological treatment of schizophrenia were developed by an independent expert in clinical pharmacology (from Faculty of Medical Sciences, University of Kragujevac, Serbia), and then discussed and finally adopted by the Professional Board of Dobrota hospital at the session held on December 21<sup>st</sup>, 2012. The local guidelines for treatment of schizophrenia were based on the National guidelines of Montenegro, and then developed further in following areas: treat-

**Table 2.** WHOQOL BREF scores in the first phase of the study

Domains	WHOQOL-BREF			
	Physical health	Psychological	Social relationships	Environment
Mean scores %	61.26	50.89	39.99	53.98
SD	16.21	18.59	12.70	0.79

	Phase 1	Phase 2	p value
FIRST GENERATION ANTIPSYCHOTICS	85	88	0.837
SECOND GENERATION ANTIPSYCHOTICS	74	75	0.986
BENZODIAZEPINES	65	68	0.916
ANTIEPILEPTICS	43	44	0.986
ANTIDEPRESSANTS	6	8	0.859
ANTIPARKINSONIAN DRUGS	50	50	0.988
LITHIUM	9	9	1.000
COMBINATION OF ANTIPSYCHOTICS	75	79	0.783

**Table 3.** Therapeutic choices before and after the implementation of local guidelines

ment of chronic schizophrenia patients resistant to clozapine, treatment of adverse effects of antipsychotics, and optimal dosing regimens of antipsychotics.

### Phase 2

The post hoc therapeutic choices did not demonstrate guideline adherence (Table 3). Treatment with combinations of antipsychotics increased (75 to 79), but not significantly. However, the median daily dose of antipsychotics expressed as chlorpromazine equivalent increased from 546 mg in the first phase to 572 mg (range from 50 to 2600 mg) in the second study phase ( $p = 0.016$ ,  $Z = -2.398$ ).

Mean scores on the rating scales, before and after the implementation of guidelines, are presented in the Table 4. Involuntary

movements worsened in the second phase of the study, with higher AIMS scores recorded for 63 of 107 patients assessed (Table 4).

Laboratory analyses revealed increase of the blood glucose level ( $4.94 \pm 0.93$  (2.71-8.52) in the phase 1, and  $5.86 \pm 2.25$  (4.04-16.71) in the phase 2,  $p = 0.005$ ) and cholesterol regulation ( $5.046 \pm 1.06$  (1.99-7.7) in the phase 1, and  $5.59 \pm 1.31$  (3.15-8.61) in the phase 2,  $p = 0.023$ ) after the adoption of local guidelines, but not that of triglycerides ( $2.01 \pm 1.28$  (0.54-7.7) in the phase 1, and  $2.41 \pm 1.31$  (3.15-8.61) in the phase 2,  $p = 0.805$ ).

There were no significant differences in mean BPRS scores, as well as estimated severity of illness (Table 4).

Patient-perception of quality of life assessed by EUROQOL 5D 5L visual analog scale, as well as physical health or psychical

Scale	AIMS		BPRS					
Phase	phase 1	phase 2	phase 1	phase 2				
Domain								
Mean	13.34	16.14	25.70	27.56				
SD	4.89	7.83	12.13	13.13				
p value*	0.000		0.200					
Scale	EURQOL VAS							
Phase	phase 1	phase 2						
Domain								
Mean	53.65	55.95						
SD	26.20	26.38						
p value*	0.371	9						
Scale	WHOQOL BREF DOMAINS							
Phase	phase 1	phase 2	phase 1	phase 2	phase 1	phase 2	phase 1	phase 2
Domain	I	I	II	II	III	III	IV	IV
Mean	61.26	59.60	50.89	48.84	39.99	48.53	53.98	58.48
SD	16.21	16.52	18.59	15.75	12.71	15.35	0.79	14.13
p value*	0.375		0.158		0.000		0.000	

**Table 4.** Scores of the psychiatric and quality of life scales

\* Wilcoxon signed rank test

condition assessed by WHOQOL BREF questionnaire did not significantly change from baseline after adoption of the local guideline. However, quality of life of the patients concerning social and environmental domains significantly improved after adoption of the guideline (Table 4).

## DISCUSSION

Overall, the study showed that adoption of local guideline did not significantly alter prescribing patterns. Antipsychotic polypharmacy remained routinely used with FGAs as prevailing treatment choice and the daily dose in CPZ equivalents has significantly increased. Such result is not surprising, since differing adherence to psychiatric guidelines is documented worldwide [13,15]. Broekema [13] in European pharmaco-epidemiological study, carried out at 45 hospitals in six western European countries, implied that “more than half (52.9%) of the patients are not being treated according to the psychiatric handbooks and guidelines”. In Canadian schizophrenia treatment services [21] conformance with pharmacological guideline recommendations ranged between 58% and 90%.

This finding of our study could have been anticipated, since it is recognized that well-designed multifaceted interventions are needed for improving adherence to guideline recommendations [12,22,23]. In Montenegro the first National schizophrenia guideline was published shortly before the study onset (in June 2012), with, to our knowledge, no evidence based supporting interventions for augmenting implementation. Observed guideline non-adherence could be further elaborated within the Cabana's [24] conceptual framework, explaining that before external research evidences (i.e. guidelines) can affect patient outcomes, it first affect physician knowledge, then attitudes, and finally behavior.

Antipsychotic polypharmacy did not decrease after the guideline adoption comparing with baseline. Several other studies have shown that patients receiving APP before the intervention were more likely to receive it at the study end point as well [25-27]. This phenomenon is not characteristic only for the developing countries, and the trend of not decreasing APP is commonly observed in long term studies from North America and Europe, both in national and local settings [28]. APP

prevalence in North America increased from 12.7% in the 1980s to 17.0% in the 2000s. In Europe an increase from the 1980s (17.6%) to the 1990s (26.3%) was observed, followed by a plateau in the 2000s (25.0%) [28].

The extent of APP observed in our study (69.4% to 73.1%), was not frequent in the recent literature. Although acknowledging geographical variations (Asia: median = 32%, Europe: median = 23%, North America: median = 16%, and Oceania: median = 16.4%), a systematic review Gallego [26] found global median of 19.5% of patients receiving APP. It is also reported that combination treatment occurs between 3% and 71%, with mostly recorded prevalence rates of between 10% and 30% [28]. There are some distinctive features of our study settings that have been described in the literature as correlated with the high extent of APP prescribing. Variables such as: non-teaching hospital settings, less research involvement [29], FGA prescribing, duration of the disease, in patient treatment [30-32], longer inpatient stay [25,27], are found to be associated with higher rates of APP prescribing. Although its efficacy/safety profile is not evidence based, APP is often advocated in the literature with greater illness severity, complexity, chronicity, and refractoriness [27], which are all characteristics of patients in our study.

Median daily dose of antipsychotics significantly increased during the study: from 546 to 572 mg of CPZ equivalent. Although close to the upper limit, the median dose remained within the recommended range (300-600 mg of CPZ equivalent), but the prescribed daily doses showed considerably large amplitude from 50 to 2600 mg of CPZ equivalent. Previously published studies consistently showed relation between APP and greater total antipsychotic dose [27,29,34-36]. In addition, it was recorded that patients treated in the specialized psychiatric facilities were frequently overdosed in comparison with recommendations [37]. Increasing the dose may not necessarily indicate poor quality care, and may be appropriate for non-responders to lower doses. The reasoning is mostly based on the differences between patients who fulfill stringent criteria for inclusion in pivotal randomized controlled trials (RCTs) on which dosing recommendations are usually based, and real life settings [37,38].

There is lack of reported psychopa-

thology ratings or adverse effects in APP studies, and our study adds value to this, “under-researched area” [28]. The results of BPRS scale consistently revealed no improvement in clinical outcomes. Bearing in mind lack of significant changes in prescribing habits after adoption of the guidelines, these findings were expected. The observed increase in daily dose did not have positive impact on clinical outcomes, and it could be associated with significantly higher score on the AIMS scale. Higher total daily antipsychotic dosing together with extensive FGA prescribing and APP could predispose worsening of involuntary movements. However, there were some positive effects of the intervention on the humanistic outcomes, as shown by WHOQOL scale in social and environmental domains.

The limitation of our study is its single-center character resulting from the fact that Dobrota hospital is the only long-stay psychiatric facility in Montenegro. Besides, the study was conducted shortly after introduction of concept of national evidence-based guidelines in Montenegro, so culture of using guidelines in general was not developed enough among the physicians. The naturalistic setting and sample characteristics obtained using broad inclusion and minimal exclusion criteria, and assessing outcomes using validated scales adds new knowledge about treatment of schizophrenia. Patients with wide age range, extensive period of permanent hospitalization and disease duration, presence of coexisting conditions and co-medications provide context, which is not often presented in the literature due to stringent criteria for sampling in randomized controlled trials.

## CONCLUSION

From the results of our study it could be concluded that mere writing and adopting the guidelines is not sufficient to change established prescribing practice in treatment of schizophrenia, or clinical and humanistic outcomes in developing countries with short-lived culture of evidence-based healthcare; much more has to be done on promotion of the guidelines, including research of effectiveness of various healthcare interventions.

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## CONFLICTS OF INTEREST

All authors report no conflicts of interest relevant to this article.

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## Uticaj lokalnih vodiča na propisivačku praksu i ishode lečenja kod dugotrajno hospitalizovanih psihijatrijskih pacijenata

Ivana M. Iličković<sup>1</sup>, Aleksandar B. Tomčuk<sup>2</sup>, Jovo M. Djedović<sup>2</sup>, Kristina B. Bećir<sup>2</sup>, Slobodan M. Janković<sup>3</sup>

<sup>1</sup> Farmegra Ltd., Podgorica, Crna Gora

<sup>2</sup> Specijalna psihijatrijska bolnica, Dobrota, Kotor, Crna Gora

<sup>3</sup> Fakultet Medicinskih nauka, Univerzitet u Kragujevcu, Kragujevac, Srbija

### KRATAK SADRŽAJ

**Uvod:** Odstupanja između preporuka za propisivanje antipsihotika u vodičima dobre prakse i njihove primene u praksi se mogu prevazići usvajanjem lokalnih vodiča.

**Cilj:** Cilj ove studije je bio da ispitamo uticaj lokalno prilagođenih nacionalnih vodiča za lečenje šizofrenije na propisivanje antipsihotika i ishode lečenja u Specijalnoj psihijatrijskoj bolnici Dobrota u Kotoru, Crna Gora.

**Metodologija:** Studija je bila akademska, IV faza, prospektivna, intervencijska u preporukama zdravstvenog sistema, sa merenjem ishoda pre i posle intervencije. Studija je sprovedena u dva šestomesečna perioda koji su bili razdvojeni usvajanjem i primenom lokalnih vodiča. Propisivanje antipsihotika i ishodi lečenja su bili praćeni u oba studijska perioda.

**Rezultati:** Ukupno je 111 pacijenata učestvovalo u studiji. Vodiči nisu uticali na (ukupan volumen) ukupnu potrošnju propisivanja antipsihotika, ali je došlo do poboljšanja socijalnog funkcionisanja i komunikacije pacijenata sa okolinom.

**Zaključak:** Izrada i usvajanje lokalnih vodiča dobre prakse može dovesti do izvesnih poboljšanja u pogledu humanističkih ishoda lečenja, ali za postizanje značajnijeg uticaja na propisivanje i ishode lečenja neophodno je sprovesti složenu intervenciju, u kojoj će lokalni vodiči biti samo jedan od aspekata.

**Ključne reči:** vodiči, šizofrenija, polifarmacija, bolnički pacijenti, ishodi lečenja

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