

# Standard medical care of patients with systemic lupus erythematosus (SLE) in large specialised centres: data from the Russian Federation, Ukraine and Republic of Kazakhstan (ESSENCE)

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## ABSTRACT

**Objectives:** To describe disease characteristics and treatment regimens for adult patients with systemic lupus erythematosus (SLE) with autoantibody positive disease in three countries (the Russian Federation, Ukraine and Republic of Kazakhstan).

**Methods:** The ESSENCE study was a 1-year, retrospective, multicentre, observational study. Data included patients' characteristics, disease activity and severity, and healthcare resource use in 2010.

**Results:** Twelve centres enrolled 436 eligible patients: 232 in Russia, 110 in Kazakhstan and 94 in Ukraine. Mean age ranged from 36 to 42 years and median SLE duration from 3 to 6.8 years. According to study definitions, 69.2% of patients in Russia, 72.7% in Kazakhstan and 55.4% in Ukraine had severe disease at diagnosis. SLE activity (Nasonova classification, 1972) decreased from diagnosis to the last visit in 2010 in all countries. At the last visit, mean (SD) Safety of Estrogens in Lupus Erythematosus National Assessment–Systemic Lupus Erythematosus Disease Activity Index score was 13.8 (10.5) in Russia, 19.4 (16.9) in Kazakhstan and 7.2 (6.8) in Ukraine, and Systemic Lupus International Collaborative Clinics/American College of Rheumatology damage index was 2.0 (2.2), 3.3 (3.2) and 2.2 (2.0), respectively. Treatment regimens included predominantly glucocorticoids (96.7–99.1%), immunosuppressants or cytotoxic drugs, for example, azathioprine and cyclophosphamide (20.7–53.2%), and antimalarial drugs (18.3–40.8%).

**Conclusions:** The study provides reliable insight into the SLE clinical profiles in the referenced countries. Patients were 4–10 years younger in the study and had 3–7 years shorter SLE duration than in Western European countries and both SLE activity and severity were higher with higher rate of hospitalisations, but decreased during treatment. Local and international scales demonstrated correlation in SLE activity and organ damage evaluation. There were differences in clinical characteristics and healthcare features across the countries.

## INTRODUCTION

Systemic lupus erythematosus (SLE) is a complex disease that may affect numerous organs leading to a wide possible combination of clinical manifestations.<sup>1 2</sup> Previously described prognostic factors include demographic characteristics, number of involved and damaged organs, and degree of inflammatory disease activity.<sup>3</sup> Standard treatment regimens include glucocorticoids, non-steroidal anti-inflammatory drugs (NSAIDs), antimalarials and immunosuppressive/cytotoxic drugs.<sup>4 5</sup> Biological drugs have been developed more recently and showed interesting beneficial effects in lupus.<sup>6</sup>

As SLE is a serious disease with potentially severe outcomes, it is important to understand how SLE presents and is managed across different geographical regions and settings. There are several recent studies describing SLE epidemiology, clinical features and healthcare use in different populations: Asians,<sup>7</sup> Europeans,<sup>2 8</sup> Americans<sup>9</sup> and African Caribbean.<sup>10</sup> A large retrospective study evaluating patients' characteristics, disease activity and severity, flare assessments and health resource use was conducted in five European countries recently.<sup>11</sup>

To date, there have been no publications that present a real-life picture of SLE features and management in post-Soviet countries and no current SLE disease registers or patient cohorts have been created. The ESSENCE study was to describe the presentation of SLE and disease management practices for adult patients with SLE with active, autoantibody-positive disease in selected cities from three countries (the Russian Federation, Ukraine and the Republic of Kazakhstan). Data from



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the part of the study addressing the gap in SLE prevalence and incidence are available elsewhere.<sup>12</sup>

## PATIENTS AND METHODS

### Study design

ESSENCE was a retrospective, multinational, multicentre, epidemiological study carried out across three countries (Russia, Kazakhstan and Ukraine) in 12 specialised rheumatological centres. Six centres in Russia (Moscow, St-Petersburg, Voronezh, Yekaterinburg, Kursk, Yaroslavl), three centres in Ukraine (Kyiv, Donetsk, Vinnitsa) and three centres in Kazakhstan (Almaty, Semey, Shymkent) participated. The design of this study was described previously.<sup>12</sup>

Trained medical staff hand-searched clinical records to identify all patients  $\geq 18$  years old with an established SLE diagnosis according to the American College of Rheumatology (ACR) criteria (presence of four or more criteria)<sup>13</sup> or clinical judgement before 31 December 2010 according to medical records. Patients were required to have evidence of autoantibody-positive disease and to have made at least one clinic visit in 2010. Autoantibody-positive disease was defined as antinuclear antibody (ANA) and/or antibodies to double-stranded DNA (anti-dsDNA)-positive test at or prior to the last clinic visit in 2010. Patients with miscoded diagnoses and drug-induced lupus as well as patients diagnosed with SLE after 2010 or deceased before 2010 were excluded.

Investigators captured data from patient medical records using a standardised case report form, including demographic and baseline characteristics, SLE activity profile, investigations, SLE treatment and healthcare use.

### Inflammatory disease activity

Inflammatory disease activity related to SLE was defined according to Nasonova's criteria<sup>14 15</sup> and based on medical records. This classification is widely used in participating countries. Nasonova classification is defined as low (I), moderate (II) and high (III), and based on major SLE signs and symptoms (body temperature/weight loss/skin impairment/pericarditis/myocarditis/pleuritis/glomerulonephritis; haemoglobin/ $\gamma$ -globulins/LE cells/ANA). Investigators captured the activity grade directly from medical documentation.

Involved organs and systems were defined as biologically active (eg, proteinuria or blood abnormalities that do not cause symptoms) or symptomatic. Organs were assessed as damaged in the case of non-reversible change.

### Laboratory markers of SLE activity

SLE was considered active in the presence of at least one biomarker (positive test for anti-dsDNA antibodies and/or C3 or C4 below normal ranges) and one clinical and/or haematological feature of SLE.

### SELENA/SLEDAI activity

The original Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) is a weighted, cumulative index

of lupus disease activity, and the Safety of Estrogens in Lupus Erythematosus National Assessment–SLEDAI (SELENA-SLEDAI) represents a further refinement.<sup>16</sup> The total score falls between 0 and 105, with higher scores representing increased disease activity. SLEDAI has been shown to be a valid and reliable disease activity measure in multiple patient groups.<sup>16</sup>

### SLICC/ACR damage

Systemic Lupus International Collaborative Clinics/ACR (SLICC/ACR) Damage Index (SDI)<sup>17</sup> was developed and validated to measure accumulated organ damage from either the disease process or its sequelae, in 12 organ systems; the maximum possible score is 47. It is an important predictor of long-term mortality and is an independent outcome measure.<sup>18</sup>

### Organ involvement/damage

Active involvement or organ damage was established by the investigator retrospectively, based on clinical judgement. 'General symptoms' included at least one of the following: pyrexia, weight loss, lymphadenopathy/splenomegaly, fatigue/malaise/lethargy, anorexia/nausea/vomiting.

### SLE severity

The definition for severe SLE was created for the purpose of this study and was defined as the presence of any of the following condition(s): low complement (C3 or C4) and/or high-dose glucocorticoid ( $\geq 30$  mg per day) and/or immunosuppressant and/or immunomodulator and/or biological treatment for SLE (rituximab or intravenous immunoglobulin). Other cases were established as non-severe.

### SLE profile

SLE profiles were defined according to Barr *et al*<sup>19</sup>: relapsing-remitting profile was defined if episodes of activity (eg, SLEDAI $>0$  score) alternated with periods of precise remission (eg, SLEDAI=0); not less than one remission and one flare during last year. Chronic active profile was defined if the disease was persistent in a varying degree (eg, SLEDAI $>0$ ) and did not attenuate during at least last year.

### Healthcare resource use

Use of healthcare resource (planned visits and visits due to flare, emergency room and hospitalisations, visits to specialists) was collected and will be reported separately.

### Statistical analysis

Statistical analysis was performed using IBMSPSS Statistics V.18.0.<sup>1</sup> Descriptive analyses (proportions, mean, SD, median, ranges) were performed on all

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variables independently for each country. The mean SELENA-SLEDAI score and SDI at diagnosis were presented stratified by grade of activity by Nasonova; correlation between these variables was evaluated with Spearman's correlation coefficients.

## RESULTS

A total of 436 consecutive, eligible patients (232 in Russia, 110 in Kazakhstan and 94 in Ukraine) were included in the analysis. A full description of demographic, clinical and laboratory SLE characteristics is presented in [table 1](#).

### Activity based on Nasonova criteria

The proportion of patients with high grade of SLE activity according to Nasonova decreased from SLE diagnosis to the last visit in 2010, and the proportion of patients with low and moderate activity increased correspondingly. It was noted that Kazakhstan had the highest number of patients with high grade of disease activity (see [figure 1](#)).

### Organ damage based on SLICC/ACR criteria

According to SLICC/ACR criteria, most patients had some degree of organ damage at baseline (SDI>1) and organ damage increased over time ([figure 2](#)) from diagnosis until the last visit in 2010.

### Activity based on SELENA-SLEDAI criteria

With the exception of Kazakhstan, a decrease in the mean level of activity based on SELENA-SLEDAI score was observed overtime ([figure 3](#)).

The correlation between the Nasonova classification of SLE activity and the total SELENA-SLEDAI score was calculated for each country ( $p=0.013$ , correlation coefficient ( $r$ )=0.180 in Russia;  $p=0.002$ ,  $r=0.327$  in Kazakhstan; and  $p=0.044$ ,  $r=0.257$  in Ukraine). See [figure 4](#) for score distributions.

At SLE diagnosis, the most common symptom manifestations and actively involved organs/systems were general symptoms (73.4% of patients in Russia, 85.4% in Kazakhstan and 77.7% in Ukraine), mucous/cutaneous (66.8%, 73.0% and 74.5%), musculoskeletal system (74.7%, 80.9% and 79.8%) and blood (51.8%, 88.8% and 54.3%). The most commonly damaged organs/systems at the diagnosis were mucous/cutaneous (4.0%, 22.5% and 1.1%), cardiovascular and/or respiratory systems (3.5%, 21.3% and 17.0%), vessels as vasculitis (2.0%, 21.6% and 0.0%) and the renal system (1.5%, 22.5% and 2.1%).

At the last visit in 2010, frequencies for the most common manifestations and actively involved organs/systems (in Russia, Kazakhstan and Ukraine, correspondingly) were 41.3%, 79.1% and 66.0% for general symptoms; 45.8%, 60.9% and 69.1% for mucous/cutaneous system; 54.5%, 79.1% and 73.4% for musculoskeletal system; and 27.0%, 84.5% and 33.0% for blood. Also,

4.5%, 22.7% and 1.1% of patients had experienced mucous/cutaneous damage; 10.0%, 29.1% and 21.3% cardiovascular and/or respiratory damage; 3.0%, 9.3% and 0.0% damage to vessels; and 6.5%, 25.5% and 2.1% had renal damage. It was noted that the lowest rate of actively involved or damaged organs was observed in Russia and the highest was observed in Kazakhstan.

### Laboratory tests

The main immunological parameter of SLE activity, the test for anti-dsDNA, was positive at diagnosis in 92.6% ( $n=87/94$ ) of patients in Russia, 94.3% ( $n=33/35$ ) in Kazakhstan and 88.4% ( $n=38/43$ ) in Ukraine. At the last visit in 2010, the rate of positive anti-dsDNA test was slightly lower in Russia and Kazakhstan: 84.8% ( $n=139/164$ ) and 74.0% ( $n=54/73$ ) of patients, respectively. ANA test was positive at diagnosis in 89.0% ( $n=73/82$ ) of patients in Russia, 15.4% ( $n=2/13$ ) in Kazakhstan and 100.0% ( $n=39/39$ ) in Ukraine. By the last visit in 2010, percentages of this value remained high: 88.9% ( $n=128/144$ ), 71.7% ( $n=38/53$ ) and 98.6% ( $n=73/74$ ) of patients, correspondingly.

Many other secondary immunological parameters such as anti-Sm antibodies, anti-RNP, anti-Ro, anti-La and antiphospholipid antibodies were assessed in <20% of patients, therefore are not described.

### Treatment regimens

SLE treatment regimens during 2010 are displayed in [table 2](#).

#### In-patient hospitalisations, emergency room visits and specialist visits

During 2010, 96.5% (Russia), 98.2% (Kazakhstan) and 90.1% of patients (Ukraine) were hospitalised at least once or attended the emergency room. At least one planned visit to a rheumatologist was made by 56.5% of patients in Russia, 59.1% in Kazakhstan and 37.2% in Ukraine. At least one unscheduled visit to a rheumatologist due to flare was made by 39.2%, 75.5% and 74.5% of patients, respectively. Information on healthcare resource use (including length of hospitalisation, medication use, laboratory tests and imaging) and associated costs will be fully explored in a different publication.

## DISCUSSION

To our knowledge, this is the first time that data on the presentation of SLE and on standard of care have been made available for these post-Soviet countries. The demographic characteristics of patients with SLE in the current study were generally similar to those reported in the other international studies,<sup>20–25</sup> but it was noted that our patients were 4–10 years younger in the study and had 3–7 years shorter SLE duration than those from a recent European retrospective study, The LUPus erythematosus Cost of Illness in Europe study (LUCIE).<sup>11</sup>

**Table 1** Demographic, clinical and laboratory SLE characteristics, by country

	<b>Russia (n=232)</b>	<b>Kazakhstan (n=110)</b>	<b>Ukraine (n=94)</b>
Gender, n (%)			
Male	14 (6.0%)	5 (4.5%)	10 (10.6%)
Female	218 (94.0%)	105 (95.5%)	84 (89.4%)
Race/ethnicity, n (%)			
Caucasians	224 (96.6%)	8 (7.3%)	94 (100.0%)
Asian	1 (0.4%)	102 (92.7%)	0 (0.0%)
Black	0 (0.0%)	0 (0.0%)	0 (0.0%)
Unknown	7 (3.0%)	0 (0.0%)	0 (0.0%)
Age at SLE diagnosis, years			
Mean (SD)	30.3 (12.2)	31.6 (11.4)	33.0 (13.3)
Median (min–max)	29.0 (7–68)	30.5 (12–59)	32.0 (4–74)
Age at the last visit in 2010, years			
Mean (SD)	36.1 (12.3)	36.9 (11.4)	41.7 (21.1)
Median (min–max)	33.0 (18–74)	36.5 (19–67)	41 (20–74)
SLE duration at the last visit in 2010, years			
Median	4.5	3.0	6.8
25–75% quartile	0.6–9.1	0.0–6.8	3.2–12.2
Severe SLE, n (%)			
At the SLE diagnosis	137/198 (69.2%)	64/88 (72.7%)	51/92 (55.4%)
At the last visit in 2010	108/200 (54.0%)	69/109 (63.3%)	53/94 (56.4%)
SLE profile at the last visit in 2010			
Relapsing-remitting	85 (36.6%)	39 (35.5%)	1 (1.1%)
Chronic active	74 (31.9%)	55 (50.0%)	90 (95.7%)
Unknown, n (%)	73 (31.5%)	16 (14.5%)	3 (3.2%)
Laboratory markers of activity (positive test for anti-dsDNA antibodies and/or C3 or C4 below normal ranges)			
At diagnosis	88/98 (89.8%)	33/37 (89.2%)	38/44 (86.4%)
At the last visit in 2010	143/174 (82.2%)	54/74 (73.0%)	52/58 (89.7%)
SLE activity by Nasonova, n (%) at the diagnosis			
High	107/192 (55.7%)	57/89 (64.0%)	18/63 (28.6%)
Moderate	71/192 (37.0%)	29/89 (32.6%)	19/63 (30.2%)
Low	14/192 (7.3%)	3/89 (3.4%)	26/63 (41.3%)
SLE activity by Nasonova, n (%) at the last visit in 2010			
High	57/201 (28.4%)	54/110 (49.1%)	8/93 (8.6%)
Moderate	93/201 (46.3%)	50/110 (45.5%)	16/93 (17.2%)
Low	51/201 (25.4%)	6/110 (5.5%)	69/93 (74.2%)
SELENA-SLEDAI score, mean (SD)			
At SLE diagnosis	16.6 (10.1)	18.6 (17.4)	9.4 (7.8)
N	198	89	93
At the last visit in 2010	13.8 (10.5)	19.4 (16.9)	7.2 (6.8)
N	201	110	94
SDI score, mean (SD)			
At SLE diagnosis	1.2 (1.9)	2.0 (2.3)	1.1 (1.7)
N	198	89	93
At the last visit in 2010	2.0 (2.2)	3.3 (3.2)	2.2 (2.0)
N	200	109	91

Percentages were calculated from the valid data.

If SLE profile was impossible to establish retrospectively, it was considered as 'unknown'.

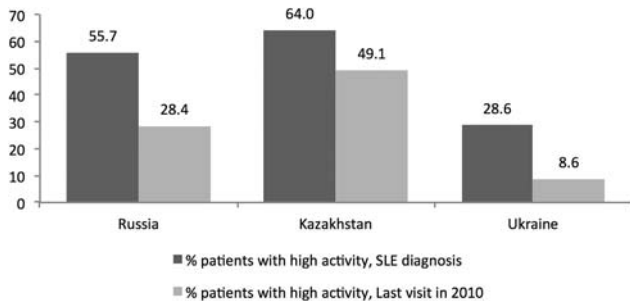
Patients could have no autoantibody-positive disease at the date of SLE diagnosis but could be autoantibody-positive between the diagnosis and before the last visit in 2010.

SDI, SLE Damage Index; SLE, systemic lupus erythematosus; SELENA-SLEDAI, Safety of Estrogens in Lupus Erythematosus National Assessment–Systemic Lupus Erythematosus Disease Activity Index.

Across the three countries, the majority of patients had severe disease, according to our study definitions. SELENA-SLEDAI and SDI scores were reconstructed based on retrospective medical records and/or investigator's judgement. In Russia and Ukraine, the mean total SELENA-SLEDAI score decreased between diagnosis

and last study visit in 2010, although this change was less than three points. SLE activity, measured by classification of Nasonova, decreased across all countries from the time of diagnosis to the last visit in 2010. These results could reflect either a natural change in the disease pathophysiology over time with an actual reduction in

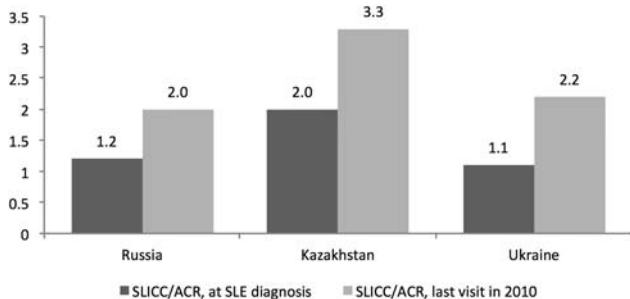




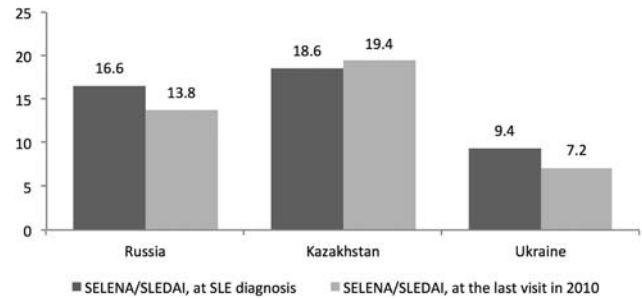
**Figure 1** Proportion of patients with high grade of activity according to Nasonova at systemic lupus erythematosus (SLE) diagnosis and the last visit in 2010.

inflammatory activity later in the disease course or they could be the result of successful disease management strategies that stabilised patients who presented in an acute disease state. The mean total SELENA-SLEDAI score correlated with Nasonova's scale assessment, suggesting that these two systems could be capturing similar information. SDI scores increased over time as expected,<sup>18</sup> as patients accrued new organ damage over time. The country with the highest organ damage scores does reported the highest glucocorticoid use.

The levels of disease activity observed in our study were higher than those detected in SLE cohort studies from Western Europe and North America.<sup>26</sup> In the LUCIE study,<sup>11</sup> the mean SELENA-SLEDAI score at the inclusion in the study was 11.2 (SD 7.7) in patients with severe disease (vs 5.3 (SD 3.9) in those without severe disease). The mean SDI score was 1.0 in those with severe disease vs 0.7 in those with non-severe disease. In the SLICC inception cohort, the mean SLEDAI-2K score (another variation of the SLEDAI score<sup>27</sup>) reported was 4.0 (SD 5.3).<sup>28</sup> Levels of organ damage were also elevated relative to other international settings. Mean SDI scores were >1 at diagnosis across all study countries, indicating that most patients had suffered some organ damage prior to diagnosis. By comparison, the mean SDI score reported in the SLICC inception cohort was 0.32 (SD 0.76).<sup>28</sup> One of the reasons for such difference may be the fact that in our study countries patients visit specialised clinics predominantly due to active disease.



**Figure 2** Mean SLE Damage Index score at the last visit in 2010 and systemic lupus erythematosus (SLE) diagnosis. SLICC/ACR, Systemic Lupus International Collaborative Clinics/American College of Rheumatology.



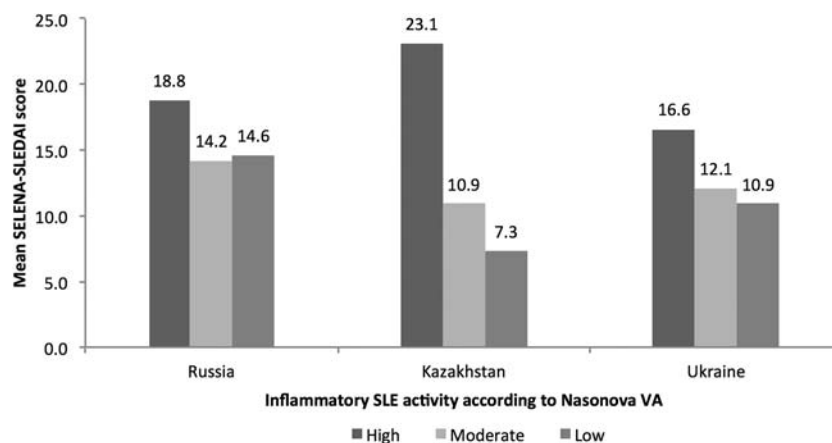
**Figure 3** Mean Safety of Estrogens in Lupus Erythematosus National Assessment-Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score at the last visit in 2010 and systemic lupus erythematosus (SLE) diagnosis.

Therefore, the great majority of the patients seemed to be evaluated during an active stage of the disease. High-disease activity in our patients is confirmed by frequent hospitalisations and emergency room visits (in >90% of patients) and unplanned visits due to flare (in up to 75% of patients). In Ukraine and Kazakhstan, the proportion of patients with an unplanned visit was higher than that with planned visits. Probably, the high level of SLE activity compared with that in Europe could be a result of the singular type of healthcare system in our study countries where patients are treated mostly during flares rather than having regular follow-up. These points indicate the need for reassessing the healthcare system to be more preventive rather than treating patients who show a high level of activity/disease severity.

The SLEDAI and SDI scoring systems are not used widely in our study countries, and the scores created retrospectively must be interpreted with caution. However, the implication of our results is that patients in our study countries who present to secondary care for diagnosis and management are those with advanced and severe manifestations of SLE. It is likely, then, that a large number of patients may remain undiagnosed or misdiagnosed. This also may explain the low prevalence of (diagnosed) SLE that was reported in an earlier publication from this study.<sup>12</sup>

This study also highlighted some differences in the clinical characteristics of patients with SLE between the participating countries. For example, it was noted that in Kazakhstan SLE activity at diagnosis was higher than in Russia or Ukraine (mean SELENA-SLEDAI score 18.6 vs 16.6 in Russia and 9.4 in Ukraine and the highest proportion of patients with high grade activity of inflammation as per the Nasonova criteria). Further studies should explore the survival rate of patients in different countries. Similarly, in Kazakhstan there was a higher burden of organ damage at diagnosis (SDI score 2.0 vs 1.2 in Russia and 1.1 in Ukraine). These differences could reflect differences in healthcare access and referral patterns or could be related to a difference in biological risk associated with Asian race/ethnicity.

**Figure 4** Correlation between mean Safety of Estrogens in Lupus Erythematosus National Assessment–Systemic Lupus Erythematosus Disease Activity Index (SELENA-SLEDAI) score and the grade of inflammatory disease activity according to Nasonova. SLE, systemic lupus erythematosus.



Furthermore, in Kazakhstan, SLE activity measured by the SELENA-SLEDAI score slightly increased between diagnosis and last visit in 2010. However, as such increase was only 0.8 points, it cannot be clearly interpreted as worsening of SLE activity in this country.

The study illustrated SLE treatment standards. Biological therapy in SLE was prescribed quite rarely. Almost all patients received glucocorticoids and at an average daily dose that was high relative to the doses reported in Western European settings,<sup>3 29 30</sup> but not dissimilar to the doses reported in the international SLICC inception cohort.<sup>31</sup> Almost half of the patients received antimalarial drugs, immunosuppressants and/or cytotoxic drugs.

More than 90% of patients had at least one inpatient (including emergency room) hospitalisation during the study period. In Kazakhstan and Ukraine, >70% of patients made unscheduled rheumatologist visits due to flare in 2010; such unscheduled visits were less frequent in Russia. In the LUCIE study, 54% of patients with severe disease were admitted to hospital over the course of a 1-year period.<sup>11</sup> Use of inpatient facilities in our study appears to be high relative to reports of use in other countries, again supporting the assumption that these are patients presenting with severe and acute disease manifestations that require more intensive

treatment and supportive care, although a lower threshold for hospital admission cannot be ruled out.

Some indicators of suboptimal SLE management were found in these post-Soviet countries. As mentioned above, antimalarial drugs (hydroxychloroquine), which are a part of standard SLE treatment, were administered in less than half of patients while high use of glucocorticoids (near 100% patients) was observed across these countries (a drug class with well-known long-term safety issues). NSAIDs were administered rarely in Russia. Another peculiarity was a large number of inpatient stays due to SLE while the rate of planned visits to specialists' outpatient consultations was lower.

The ESSENCE study has some limitations. Patients' clinical characteristics were assessed retrospectively based only on medical records. The SDI and SELENA/SLEDAI scores were applied retrospectively based on medical record information; given that these scoring systems are not widely used in routine practice in our study geography, some possibility of scoring system application error exists. Furthermore, an influence of missing or incomplete medical information on the total score cannot be excluded. The scores were only calculated when complete information was available in the chart and patients who had available information may not be representative of the entire study population.

**Table 2** Systemic lupus erythematosus treatment regimens during 2010

	Russia (n=196)	Kazakhstan (n=109)	Ukraine (n=92)
Oral glucocorticoids	192 (98.0%)	108 (99.1%)	89 (96.7%)
Daily dose of methylprednisolone mg/day (mean 2010 dose)	17.1 (11.9)	35.0 (7.1)	12.4 (10.2)
Daily dose of prednisolone mg/day (mean 2010 dose)	16.6 (12.0)	21.0 (13.7)	19.2 (12.8)
Antimalarial drugs	80 (40.8%)	20 (18.3%)	35 (38.0%)
Immunosuppressants/cytotoxic	92 (46.9%)	58 (53.2%)	19 (20.7%)
NSAIDs	15 (7.7%)	66 (60.6%)	49 (53.3%)
Biological therapy	25 (12.8%)	2 (1.8%)	0 (0.0%)
Drugs for osteoporosis	95 (48.5%)	25 (22.9%)	18 (19.6%)

Percentages were calculated from the valid data. Doses are presented as mean value (SD).

Immunosuppressants/cytotoxic drugs included azathioprine, chlorambucil, ciclosporin, cyclophosphamide, methotrexate and mycophenolate mofetil.

NSAIDs, non-steroidal anti-inflammatory drugs.

The potential for disease progression during the 1-year follow-up period was not measured. In addition, the 1-year study duration did not allow for capture of damage accrual over time and the long-term effects of the disease and medications.

In conclusion, the ESSENCE study provides a reliable insight into the SLE clinical profiles in the three post-Soviet study countries. The study results add to the global clinical picture of SLE, highlighting the differences in patient presentation across regions. This study information could also help in planning for healthcare resource use in these countries, hopefully leading to an improvement in SLE management.

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**Correction notice** This article has been corrected since it was published.

The first sentence in the methods section of the abstract should read: Methods: The ESSENCE study was a 1-year, retrospective, multicentre, observational study. The following sentence on page 1 should read: The aim of the ESSENCE study was to describe the presentation of SLE and disease management practices for adult patients with SLE with active, autoantibody-positive disease in selected cities from three countries (the Russian Federation, Ukraine and the Republic of Kazakhstan).

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**Competing interests** AG reports personal fees from GlaxoSmithKline, during the conduct of the study; personal fees from GlaxoSmithKline and Novartis Pharma, outside the submitted work. OI reports personal fees from GlaxoSmithKline, during the conduct of the study; personal fees from GlaxoSmithKline, MSD, Abbott, Servier and Roche, outside the submitted work. S Shevchuk reports personal fees from GlaxoSmithKline, during the

conduct of the study; personal fees from AstraZeneca and Boehringer Ingelheim, outside the submitted work. No information of collaboration with specific companies is provided by EN, S Soloviev, AL, RI, GT, CB and ZO. AV is employed by GlaxoSmithKline. JED and MHSP are employed by and own stock in GlaxoSmithKline.

**Patient consent** Obtained.

**Ethics approval** The study was reviewed and approved by Independent Ethic Committee in each participant country according to the specific local legal requirements. The study followed local data protection laws; patient and data confidentiality were respected. Independent Ethic Committees in each country are presented herein: The Independent Interdisciplinary Ethics Committee of Ethical Review for Clinical Trials in Russia (number 02), Central Commission on Ethics of the Ministry of Health of Ukraine in Ukraine (number 5.12-180 KE) and Central Ethics Committee of the Ministry of Health of Kazakhstan in Kazakhstan (number 14-B).

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**Data sharing statement** Information related to the study is available at: <http://www.gsk-clinicalstudyregister.com/>. GlaxoSmithKline eTrack study identifier: EP1116387. GlaxoSmithKline study acronym: ESSENCE.

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