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Analysis of the effectiveness of botulinum toxin type A procurement and access to tiered injections for children with spastic cerebral palsy in Ukraine

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The relevance of the study is determined by global changes in medicine, where an important request is to find effective methods of treatment of pediatric diseases, in particular cerebral palsy (CP), which is the main cause of pediatric disability. According to the World Health Organization, CP is common in 2–5 cases per 1,000 children, and 75% of them have a spastic form, which requires a special approach to treatment. Injections of botulinum toxin type A are one of the most effective methods of reducing spasticity. However, there are problems with access to these drugs in Ukraine, which emphasizes the need to analyze their supply and use in regions.

The aim of the study was to analyze the provision, availability, and use of medicines for the treatment of a spastic form of CP in Kyiv, Zhytomyr, Kharkiv, Dnipro, Zaporizhzhia regions and the city of Kyiv.

Materials and methods. The study covered the monitoring of botulinum toxin type A supply for the period 2019–2023. It consisted of two parts: data were obtained from open databases and official websites, including the Ministry of Health of Ukraine and medical institutions. To assess the drugs prescribed to patients and the level of satisfaction with the supply, surveys and interviews were conducted with patients and healthcare professionals. The survey covered 530 patients with a response rate of over 90%.

Results. The study showed that 40% of respondents complained about the lack of free medicines, and 20% noted their absence in medical facilities. A decrease in delays in supply and problems with treatment interruption were noted by 5% of respondents. Successful public procurement related to the increase in the volume of medicines procured has reduced costs during tenders.

Conclusions. The main factors limiting the provision of medicines for the treatment of children with CP are insufficient funding and an inefficient procurement system in Ukraine.

The authors declare no conflict of interest.

Keywords: health care facility, cerebral palsy, spastic form, botulinum toxin type A, botulinum therapy, supply monitoring.

Аналіз ефективності закупівель ботулінотоксину типу А та доступ до багаторівневих ін'єкцій для дітей зі спастичним церебральним паралічем в Україні

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Актуальність дослідження обумовлено глобальними змінами в медицині, де важливим запитом є пошук ефективних методів лікування дитячих захворювань, зокрема церебрального паралічу (ЦП), що є основною причиною дитячої інвалідності. За даними Всесвітньої організації охорони здоров'я, ЦП поширений у 2–5 випадках на 1 000 дітей, а 75% із них мають спастичну форму, що потребує особливого підходу до лікування. Ін'єкції ботулінотоксину типу А є одним із найбільш ефективних методів зниження спастичності. Проте в Україні існують проблеми з доступом до цих препаратів, що підкреслює необхідність аналізу їхнього забезпечення та використання в регіонах.

Мета: проаналізувати забезпечення, доступність та використання лікарських засобів для лікування спастичної форми ЦП у регіонах Київському, Житомирському, Харківському, Дніпропетровському, Запорізькому та в м. Києві.

Матеріали та методи. Дослідження охоплювало моніторинг постачання ботулотоксину типу А за період 2019–2023 років. Воно складалося з двох частин: дані отримано з відкритих баз та офіційних сайтів, зокрема Міністерства охорони здоров'я України та медичних закладів. Для оцінки призначених пацієнтам препаратів і рівня задоволеності постачанням проведено опитування та інтерв'ю з пацієнтами та медичними працівниками. Опитування охопило 530 пацієнтів із рівнем відповіді понад 90%.

Результати. Дослідження показало, що 40% респондентів скаржилися на недостатню кількість безкоштовних лікарських засобів, а 20% – зазначили їхню відсутність у медичних закладах. Зменшення затримок у постачанні та проблем із перериванням лікування було помічено у 5% опитаних. Успішні державні закупівлі, пов'язані зі збільшенням обсягів закупівлі лікарських засобів, дали змогу знизити витрати під час тендерів.

Висновки. Основними факторами, що обмежують забезпечення лікарськими засобами для лікування дітей із ДЦП, є недостатнє фінансування та неефективна система закупівель в Україні.

Автори заявляють про відсутність конфлікту інтересів.

Ключові слова: заклад охорони здоров'я, дитячий церебральний параліч, спастична форма, ботулінотоксин типу А, ботулінотерапія, моніторинг постачання.

Introduction

The first quarter of the 21st century is characterized by global transformations, innovations and globalization processes that cover all spheres of social life, including medicine. In the context of modern medical development, one of the key social demands is a scientific search for the most effective methods of treating various diseases, reducing the overall morbidity rate of the population, and ensuring access to quality medical services for citizens. According to the World Health Organization (WHO), the main causes of primary childhood disability are congenital developmental anomalies, diseases of the nervous system, and mental disorders. Among diseases of the nervous system, the main cause of childhood neurological disability is cerebral palsy (CP), with a prevalence of 2–5 cases per 1,000 children (an average of 2.5 cases per 1,000 births) [15]. In the group of premature infants, the proportion of CP cases is 1%, and in newborns weighing less than 1,500 g, the prevalence of CP increases to 5–15%, and in those weighing less than 1,000 g, it can reach 25–30% [18,19].

Cerebral palsy is a neurological disorder that affects muscle tone, movement, and motor skills in children. One of the most common symptoms of CP is spasticity, which is characterized by involuntary muscle contractions and stiffness [8]. CP is one of the most common childhood diseases, with 75% of patients having a spastic form. Spasticity is the biggest functional problem in these patients, and various methods are used to relieve it. One of these methods is botulinum toxin injections. The purpose of this study was to evaluate the efficacy and tolerability of Dysport (botulinum toxin type A – BoNT-A) in children with spastic CP to improve daily care or functional mobility [8,17].

Botulinum toxin type A is used to treat numerous conditions in many areas of medicine, including dystonia, spasticity, tics, and pain. This consensus was developed based on an evidence-based review, published information, and expert opinion based on clinical experience, after extensive discussion, summarizing the injection technique, level of recommendation for indications, warnings, contraindications, and safety issues for best practice in the therapeutic use of BoNT-A [4].

Spasticity and cervical dystonia (CD) are movement disorders that cause significant direct and indirect healthcare costs. Although several studies have discussed their clinical impact, few have estimated the economic burden of these disorders [20].

Patients with spasticity have impaired motor control, mobility, and function and are often dependent on caregivers for activities of daily living [2]. In many cases, spasticity requires lifelong medication, which leads to increased direct (e.g., injection costs) and indirect costs (e.g., disability) that have a significant impact on the lives of patients and their caregivers [1,7]. Spasticity management is aimed at improving the ease of patient care, comfort, function, and quality of life through therapeutic interventions and pharmacological therapy [14,16].

In families with children with CP, the disease becomes a «constant presence», which is why long-term childcare, services, support, and physical aspects of the environment can lead to a deterioration in the patient's quality of life [5]. The patient's quality of life can be compromised as spasticity negatively affects mobility, hygiene, self-care, sleep patterns, self-esteem, mood, and sexual function. It is important to evaluate the benefits and disadvantages that the patient derives from spasticity to determine treatment strategies and goals. Disadvantages may include impairment of activities of daily living, sleep problems, contractures, dislocations, skin damage, bladder and bowel dysfunction, respiratory distress, pain on sprains, and masking of the return of voluntary movement. BoNT-A has demonstrated good safety and efficacy in reducing spasticity, especially when administered by a multidisciplinary team of rehabilitation professionals. The main indications for its use are improvement of gait and upper extremity function, facilitation of hygienic care, pain reduction, prevention of musculoskeletal deformities, and even reduction of sialorrhea in patients without a functional prognosis for walking.

To the present moment, the Ministry of Health of Ukraine has recorded a clear trend towards an increase in the number of children diagnosed with various forms of CP [15,9]. According to national epidemiologists, the prevalence of registered cases of CP in Ukraine is 2.56 cases per 1,000 newborns [15,9]. This figure has remained stable over the past 40 years. About 40% of children with CP were born prematurely, and among severely preterm infants, the number of cases of CP can range from 40 to 100 per 1,000 live births [15,9].

Botulinum toxin injection is a safe and effective method, especially when combined with a multidisciplinary approach by the rehabilitation team, which increases the likelihood of functional improvement. Patients with significant functional impairment may

also benefit from assistance with daily care tasks such as hygiene, dressings, and reducing sialorrhea. Pediatricians should be familiarized with this treatment and its indications so that they can promptly assist patients refer them to specialists, as needed, and utilize their neuroplasticity. Further research on this topic is needed in developing countries [11].

Thus, one of the priorities of the Ukrainian medical industry is to find the most effective ways to overcome this nosology, one of which is the use of BoNT-A [9]. However, to date, there are still problems with the provision of medicines and access to them for patients with CP, which requires further study.

The aim of this research is to analyze the availability, accessibility, and use of medicines for the treatment of spastic CP in children in regions and cities of Ukraine (Kyiv, Zhytomyr, Kharkiv, Dnipro, Zaporizhzhia and the city of Kyiv) for the period 2019–2023. In addition, the study includes the distribution of medicines, in particular BoNT-A, procured at the expense of the State Budget of Ukraine in the period from 2019 to 2023, as well as an assessment of the level of satisfaction of patients (their legal representatives) and doctors with the distribution of these medicines.

Materials and methods

The study examined the issue of monitoring the delivery and availability of medicines with the international generic name BoNT-A for the treatment of children with spastic CP in Ukraine. The study consisted of two parts:

1. Collection of quantitative data on the supply of medicines from databases and websites.
2. Obtaining qualitative data through surveys and interviews to determine which medicines were prescribed to patients and how satisfied they were with their supply.

Data on supplies were obtained from the Ministry of Health of Ukraine websites, health department databases, and healthcare facilities (HCFs) (https://eliky.in.ua/ and https://liky.ua/), as well as from responses to official written requests sent to the Ministry of Health of Ukraine, Regional State Administrations (OSAs), health departments, HCFs, and the State Enterprise «Ukrmedpostach». Qualitative data were collected from responses to inquiries sent to region health departments and through interviews with medical specialists, patients, or their parents/guardians. A survey of 530 patients was conducted, resulting in a response rate of over 90%. Although the sample is not representative and does not rely on preliminary calculations of target p-values, it was formed using the «as many as possible» approach to ensure a comprehensive and multifaceted understanding of the situation regarding the availability of medicines in the study areas.

The geographical selection of regions was based on epidemiological data for different nosologies, ensuring broad geographical coverage. The study focused on the disease, which was included in the agenda due to complaints received by UNDP in 2019 regarding the lack of medicines. The surveys were conducted in two phases: from 2019 to 2021 and from 2021 to 2023. One of the innovations of the survey methodology was the «post-training» surveys conducted by researchers from the Departments of Pharmacy Organization and Economics, Palliative and Hospice Medicine of the Shupyk National Healthcare University of Ukraine (SNHUU), as well as employees of the Association of Hospice and Palliative Medicine. The surveys were conducted on the topic «Organizational, clinical, and practical aspects of botulinum therapy in spastic CP».

Quotas for the patient survey were determined based on the region and the following criteria: the total number of patients in the region with this nosology (20% of the total number of patients in the region receiving medicines at the expense of the state budget); the number of patients in need of medicines procured at the expense of the state budget; and the number of HCFs (including structural units) providing medical care to patients with this nosology (doctors providing medical care to at least 20% of patients in the region receiving medicines at the expense of the state budget). These indicators were determined based on morbidity statistics in the respective regions to ensure the representativeness of the obtained data. The information collected in the survey was subject to verification: 20% of patient questionnaires (or their legal representatives), 20% of questionnaires from medical staff (doctors)/administrative and managerial staff of HCFs, 20% of questionnaires from representatives of healthcare departments/divisions of regional (city) state administrations, and 100% of data collection forms.

The study was conducted in accordance with contemporary bioethical standards and approved by the Ethics Committee of the SNHUU. The survey of patients and their legal representatives was carried out in compliance with the principles of the Declaration of Helsinki. The Local Ethics Committee for

all participants approved the research protocol. The informed consent was obtained from patients or their legal representatives (parents of minors or guardians) prior to their participation in the study.

As part of this study, a specially designed questionnaire was developed for patients or their legal representatives who receive medications funded by the state budget. The questionnaire consisted of four mandatory sections:

• **Section A.** Socio-demographic characteristics of respondents: age, gender, education level, place of residence, type of employment, income level, membership in vulnerable groups, etc.

• **Section B.** Information about the supply of medications: availability and accessibility, cost-free provision, method of obtaining the medications, difficulties in receiving them, etc.

• **Section C.** Data on medication use: storage conditions, awareness of drug availability and range, and other related factors.

• **Section D.** Information on the specifics of delivery, accessibility, and usage of medications at the local level under quarantine and anti-epidemic measures.

The questionnaires followed a standardized structure, allowing for the systematization of data on medication supply, accessibility, and usage at the local level, based on surveys from three groups: patients (or their legal representatives), healthcare providers/administrative staff, and representatives of healthcare institutions. Additionally, a specific form was used to gather data on medication supplies and availability. This form included information on the name of the medication, its pharmaceutical form, dosage, delivery dates to the State Enterprise «Ukrmedpostach,» the Ministry of Health of Ukraine, and HCFs; information on the distribution of medications by region; the number of patients and demand for medications; supply issues, and more.

This approach allowed for the identification of deep and widespread issues related to insufficient access to medications, particularly to BoNT-A. Administrative, logistical, and educational barriers that hindered the effective provision of these medications were identified. It is important to note that respondents tended to provide more «formal» answers to the closed-ended questions in the questionnaire, but were more candid when responding to open-ended, clarifying questions. This applied to both the legal representatives of patients and healthcare professionals, as well as representatives of health authorities. Both «formal» and «informal» responses were included in the analysis, providing a more comprehensive and nuanced understanding of the current situation.

In the context of the years 2019–2023, particular attention was paid to the impact of the COVID-19 pandemic on the processes of medication supply and usage. During this period, the burden on the healthcare system significantly increased, exacerbating existing problems related to access to essential medications, including BoNT-A. Additional barriers were identified, including those related to quarantine restrictions, supply chain disruptions, and logistical difficulties. The study highlighted the urgent need to address these challenges in order to ensure timely access to necessary medications for patients.

Information about the study regions. As of January 1, 2019–2020, 1,097 patients diagnosed with CP were registered in Kyiv, and by January 1, 2020–2023, the number of patients decreased to 1,080. The Kyiv City Children's Clinical Hospital No. 1 provides medical care for these patients, where the 25-bed neurological hospital mainly treats acute conditions, which creates logistical difficulties for organizing rehabilitation activities, including botulinum therapy, which is not urgent. The program «Health of Kyiv residents for 2020–2022» provided for the allocation of funds for the purchase of BoNT-A for 250 children in 2020 (UAH 425,160), 2021 (UAH 455,280), and 2022 (UAH 481,050), but in practice, only 200 children needed this therapy.

In the Kyiv region, 671 patients with CP were registered as of January 1, 2020, and 543 as of January 1, 2021. No data were provided on the number of patients in need of botulinum therapy. In 2019, no orders for Botox or Dysport were placed, and there were no drug balances as of January 1, 2020, and December 31, 2021 [10–13]. In the Zhytomyr region, 495 patients with CP were registered as of January 1, 2020, and 483 as of January 1, 2022. Of these, 40 patients needed botulinum toxin therapy in 2020 and 30 in 2022. Treatment was provided at the Zhytomyr Regional Children's Hospital. In the Kharkiv region, 816 children with CP were registered as of January 1, 2020, but as of January 1, 2023, the number decreased to 699. In Dnipropetrovsk region, the number of registered children with CP also decreased – from 816 in 2020 to 699 in 2023. In Zaporizhzhia region, on the contrary, there was an increase in the number of patients – from 670 on January 1, 2019 to 703 on January 1, 2020. About

Table 1

Overview of medication supply studies for the treatment of spastic cerebral palsy in children

Region, city	Healthcare facilities for botulinum therapy	Total number of patients in the region with this nosology (persons)		Total number of registered patients	Number of patients as a percentage of the total population	Number of parents/ caregivers interviewed	Respondents in percentage of the total number of patients	Number of doctors surveyed
		January 01, 2019–2020	January 01, 2020–2023					
Kyiv	Kyiv City Children's Clinical Hospital No. 1	1097	1080	130	0.001	100	77	12
Kyiv region	Ukrainian Medical Center for Rehabilitation of Children with Organic Disorders of the Nervous System of the Ministry of Health, Kyiv City Children's Clinical Hospital No. 1	671	543	120	0.0067	60	50	7
Zhytomyr region	Zhytomyr Regional Children's Clinical Hospital	495	483	95	0.0079	80	84	10
Kharkiv region	Kharkiv Regional Children's Clinical Hospital No. 1, City Polyclinic 5 KhMR (City polyclinic No. 5)	816	699	90	0.0034	100	90	14
Dnipropetrovsk region	Dnipropetrovs'k Regional Children's Clinical Hospital	816	699	120	0.0038	90	75	12
Zaporizhzhia region	Zaporizhzhia Regional Children's Clinical Hospital No. 5	670	703	150	0.009	100	67	9
Total		4565	3508	705	0.0318	530	443	61

422 children needed botulinum therapy. A total of 530 patients participated in the study, 443 of whom responded (77% of the total number of respondents).

Statistical Analysis and Regional Insights (2019–2023). The collected data across the regions provided valuable insights into the specifics of medication delivery, availability, and usage at the local level. Key aspects analyzed include the timeliness of medication deliveries from central authorities to HCFs, causes for delays in these deliveries, the ratio of delivered medications to actual patient needs, the availability of free or affordable medications for patients, and the level of awareness among stakeholders (patients, healthcare workers, and administrative personnel) regarding medication distribution and usage.

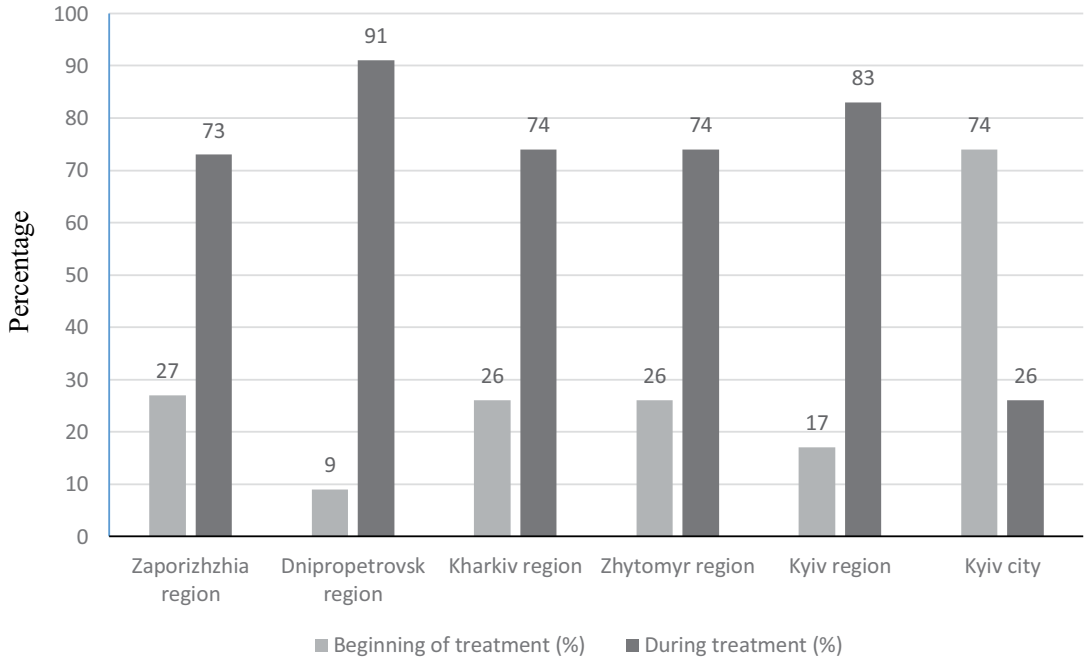
The study also highlighted significant disparities between the documented needs and actual provisions of BoNT-A therapy across regions. For example, in Kyiv, there was a discrepancy between the allocated budget for treatment and the reported number of patients requiring BoNT-A therapy, which the local Department of Health attributed to age restrictions and contraindications. Similar discrepancies in the provision of botulinum toxin therapies were noted in other regions, often exacerbated by delayed or insufficient requests from local healthcare providers and a lack of region-specific programs to ensure consistent access to medications.

Overall, this approach – gathering and analyzing data from patients, healthcare providers, and administrative staff – enabled a comprehensive assessment of the challenges and inefficiencies in the delivery and accessibility of medications for CP patients at the regional level. These findings underscore the need for better coordination, timely needs assessments, and the implementation of targeted programs to improve access to essential treatments for CP and other neurological conditions.

Research results and discussion

The total number of patients diagnosed with CP in the study regions, according to official data from the State Health Service, was 4743 as of January 01, 2020, and 4579 as of January 01, 2021. Among them, the number of patients who needed to be provided with Botox or Dysport procured at the expense of the state budget was 1504 as of January 01, 2020, and 1450 as of January 01, 2021 (Table 1).

Survey of patients or their legal representatives. The study, conducted between 2019 and 2023 across five regions of Ukraine and the city of Kyiv, analyzed the provision of free BoNT-A therapies, including



Notes: Kyiv N respondents = 100, Kyiv region N respondents = 60, Zhytomyr region N respondents = 80, Kharkiv region N respondents = 100, Dnipropetrovsk region N respondents = 90, Zaporizhzhia region N respondents = 100

Fig. 1. Period of receiving free medicines

Dysport and Botox, for patients with CP at HCFs. Despite the availability of free medications, a notable proportion of patients, or their legal representatives, declined the therapy. This refusal was primarily attributed to a lack of awareness and distrust in the treatment's efficacy and safety.

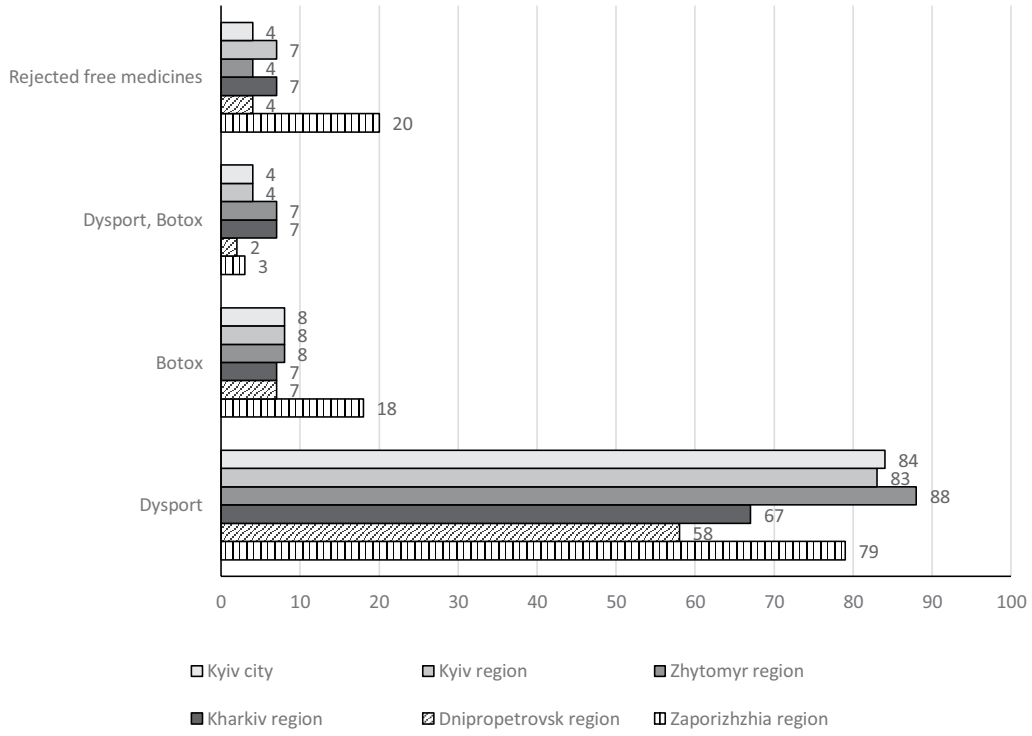
The distribution of free botulinum toxin therapies varied by region, and patients received medications at different stages of their treatment. The data shows the following breakdown of patients who received free medications at the start of treatment versus during therapy: Kyiv: 21.0% received medications at the beginning of treatment, while 79.0% received them during treatment. Kyiv Region: 17.0% received medications at the start, and 83.0% during treatment. Zhytomyr Region: 26.0% received medications at the beginning, and 74.0% during treatment. Kharkiv Region: 26.0% received medications at the start, and 74.0% during treatment. Dnipropetrovsk Region: 9.0% received medications at the start, while 91.0% received them during treatment. Zaporizhzhia Region: 27.0% of patients received medications solely during treatment, with no recorded provision at the start.

The overall results were calculated using the statistical software R, and the data reveals clear regional differences in the timing and distribution of medication (Fig. 1). This indicates that the process for providing botulinum toxin therapies is not uniform across regions, with some patients experiencing delays in receiving necessary treatment. These discrepancies underscore the need for a more consistent and efficient distribution system, as well as educational outreach to improve patient trust and understanding of the benefits of BoNT-A therapy.

When respondents were asked about the continuous provision of medications during the 2019–2023 period, 95% reported receiving botulinum toxin therapy without significant interruptions. However, 5% of respondents indicated that they experienced treatment delays, typically lasting up to one month. These interruptions were most commonly reported in the Kyiv, Zaporizhzhia, and Zhytomyr regions.

In Kyiv region, interruptions in botulinum toxin therapy were often attributed to a lack of available quotas for ordering Dysport and Botox. As a result, many patients' legal representatives were forced to travel to Kyiv or neighboring regions to purchase the medications at their own expense.

Breakdown of Free Medication Provision. Respondents were also asked about the medications provided free of charge in HCFs between 2019 and 2023. The data revealed regional variations in the type of botulinum toxin therapy provided: Kyiv: Dysport: 84% (84 patients); Botox: 8% (8 patients); Both



Notes: Kyiv N respondents = 100, Kyiv region N respondents = 60, Zhytomyr region N respondents = 80, Kharkiv region N respondents = 100, Dnipropetrovsk region N respondents = 90, Zaporizhzhia region N respondents = 100.

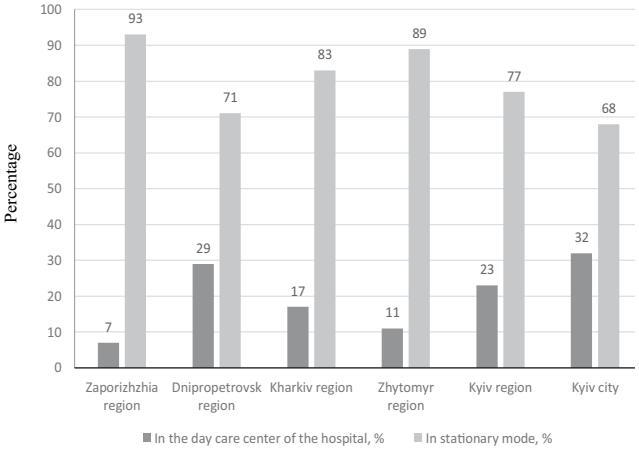
Fig. 2. Distribution of refusals and drug use among patients by region (%)

Dysport and Botox: 4% (4 patients); Refusal of free medications (due to side effects or perceived low efficacy): 4% (4 patients). Kyiv region: Dysport: 83% (50 patients); Botox: 8% (5 patients); Both Dysport and Botox: 2% (1 patient); refusal of free medications: 7% (4 patients). Zhytomyr region: Dysport: 67.5% (54 patients); Botox: 17.5% (14 patients); Both Dysport and Botox: 7.5% (6 patients); refusal of free medications: 7.5% (6 patients). Kharkiv region: Dysport: 88% (88 patients); Botox: 7% (7 patients); Both Dysport and Botox: 3% (3 patients); refusal of free medications: 2% (2 patients). Dnipropetrovsk region: Dysport: 79% (71 patients); Botox: 0%; Both Dysport and Botox: 17% (15 patients); refusal of free medications: 4% (4 patients). Zaporizhzhia region: Dysport: 58% (58 patients); Botox: 18% (18 patients); both Dysport and Botox: 4% (4 patients); refusal of free medications: 20% (20 patients).

These results illustrate significant regional differences in the availability and use of Dysport and Botox. While Dysport was the most commonly provided medication across all regions, the proportion of patients receiving Botox or a combination of both drugs varied. Notably, Zaporizhzhia region had the highest rate of refusal-free medications, with 20% of patients declining treatment due to concerns about side effects or the perceived inefficacy of the therapy.

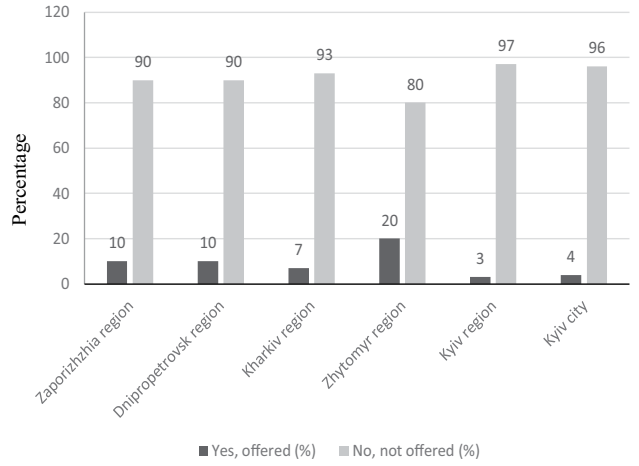
The statistical data is visually represented in Figure 2, which underscores these regional variations in medication provision and patient satisfaction. This information highlights the need for addressing both logistical challenges and patient education to ensure equitable access to botulinum toxin therapy across all regions.

The survey of patients' legal representatives regarding their preferred place of treatment during the 2019–2023 period revealed the following results: In Kyiv, 68% of patients received inpatient treatment, while 32% were treated in day-care facilities. In Kyiv region, 77% of patients were treated as inpatients, and 23% as day-care patients. In Zhytomyr region, 89% of patients were treated as inpatients, with only 11% receiving care in day-care settings. In Kharkiv region, 83% of patients underwent inpatient treatment, while 17% were treated as outpatients. In Dnipropetrovsk region, 71% of patients received inpatient care, and 29% were treated as outpatients. In Zaporizhzhia region, 93% of patients were treated as inpatients, with just 7% receiving outpatient care. Despite the predominance of inpatient care, patients frequently reported that hospital stays were inconvenient due to poor physical accessibility to medical facilities. Many



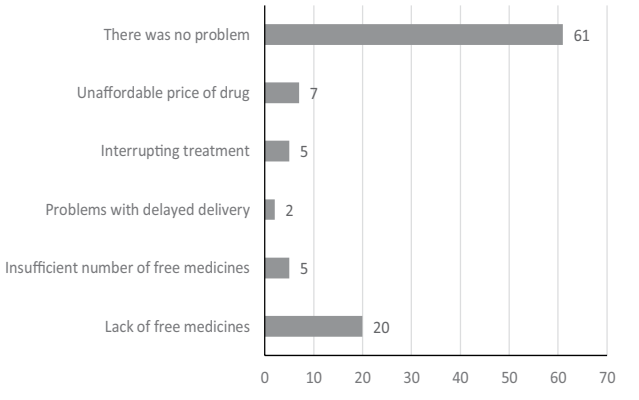
Notes: Kyiv N respondents = 100, Kyiv region N respondents = 60, Zhytomyr region N respondents = 80, Kharkiv region N respondents = 100, Dnipropetrovsk region N respondents = 90, Zaporizhzhia region N respondents = 100.

Fig. 3. Preferred place of treatment for patients in 2019 (%)



Notes: Kyiv N respondents = 100, Kyiv region N respondents = 60, Zhytomyr region N respondents = 80, Kharkiv region N respondents = 100, Dnipropetrovsk region N respondents = 90, Zaporizhzhia region N respondents = 100

Fig. 4. Illegal benefits of hospital staff in HCFs experienced by patients



Notes: Kyiv N respondents = 100, Kyiv region N respondents = 60, Zhytomyr region N respondents = 80, Kharkiv region N respondents = 100, Dnipropetrovsk region N respondents = 90, Zaporizhzhia region. N respondents = 100.

Fig. 5. Main problems with access to medicines and their absence in healthcare facilities, %

expressed a preference for receiving treatment at home, citing greater convenience and accessibility. These findings are highlighted in Fig. 3, with calculations based on total values shown in Figure 3.

Patients' legal representatives were informed about the arrival of medications at HCFs during the 2019–2023 period as follows: in Kyiv, 86% were notified by doctors, 5% by nurses, and 9% by other patients. In Kyiv region, doctors, 8% by nurses, 8% by other patients, and 2% by Non-Governmental Organizations (NGOs) informed 82%. In Zhytomyr region, doctors, 7% by nurses, and 29% by other patients notified 64%. In Kharkiv region, doctors, 3% by nurses, 21% by other patients, and 5% by HCF administrative staff informed 71%. In Dnipropetrovsk region, doctors, 7% by nurses, and 7% by other patients notified 87%. In Zaporizhzhia region, doctors, 20% by nurses, and 13% by other patients informed 67%. When summarizing the data from all five regions and Kyiv, the overall response distribution showed that 91.0% of patients' legal representatives were notified by doctors, 7.0% by nurses, 2.5% by HCF administrative staff, and 1.0% learned about medication availability through other patients or NGOs.

Regarding the survey on whether hospital staff requested or expected unlawful benefits (the so-called «gratitude») to facilitate or expedite the receipt of medications that should be provided free of charge, the following results were observed: in Kyiv, 4.0% of respondents reported offering an unlawful benefit, while 96.0% did not. In Kyiv region, 3.0% reported offering such a benefit, while 97.0% did not. In Zhytomyr region, 20.0% of respondents offered a benefit, while 80.0% did not. In Kharkiv region, 7.0% offered, while 93.0% did not. In Dnipropetrovsk region, 10.0% offered, while 90.0% did not. In Zaporizhzhia region, 11.0% offered a benefit, while 89.0% did not. These findings are visually represented in Figures 4 and 5, which highlight both regional variations in notification methods and the prevalence of unlawful benefit offers across different areas.

According to the survey results on the refusal of free medications by the legal representatives of patients during the 2019–2023 period, the following data were obtained. In Kyiv, 1.0% of respondents refused the medications due to side effects, 3.0% due to the low efficacy of therapy, and 96.0% had no issues with taking the medicines. In the Kyiv region, 2.0% refused because of side effects, 5.0% because of low efficacy, and 93.0% had no problems with taking the medications. In the Zhytomyr region, 2.5% refused due to side effects, 5.0% due

to low efficacy, and 92.5% took the medications without any issues. In the Kharkiv region, no side effects were recorded, with only 2.0% refusing because of low efficacy, while 98.0% had no problems accepting the medications. In the Dnipropetrovsk region, no refusals were due to side effects, but 4.0% refused due to the low efficacy of therapy, and 96.0% had no problems with taking the medications. In the Zaporizhzhia region, 6.0% refused the medications because of side effects, 14.0% due to low efficacy, and 80.0% had no issues with the treatment.

Additionally, legal representatives indicated that they purchased medications such as Dysport and Botox at their own expense for the treatment of their primary diagnosis. In Kyiv, 15.0% of respondents (15 individuals) reported purchasing medications on their own, while in Kyiv region, 25.0% (15 respondents) did so. In the Zhytomyr region, 2.5% (2 respondents) reported purchasing medications directly from hospital staff, with one respondent noting that they were offered the option to buy medications from a pharmacy, although healthcare workers did not supervise the purchase or recommend specific pharmacies.

Overall, across all surveyed regions and the city of Kyiv, several challenges faced by the legal representatives of patients during botulinum toxin therapy were identified. The most common issue, reported by 20.0% of respondents, was the unavailability of free medications funded by the state budget at the hospital. An additional 5.0% reported that the amount of free medication provided was insufficient, 2.0% faced delays in medication deliveries, and 5.0% experienced interruptions in treatment. For 7.0% of respondents, the high cost of medications was prohibitive, while 61.0% of respondents reported no issues during treatment.

According to the survey on the level of satisfaction among patients' legal representatives with the quantity and stability of medication supplies funded by the state budget for the treatment of CP in Kyiv, Kharkiv, and Zaporizhzhia regions from 2019 to 2023, there was a noticeable improvement. From 2019 to 2021, satisfaction levels increased by 5 to 8 points compared to 2013, reflecting a positive trend. However, from 2021 to 2023, there was no significant further improvement, with satisfaction levels stabilizing. In the Kyiv region, the provision of medicines remained relatively stable, fluctuating between 5 and 6 points during the 2019–2022 period. In the Dnipropetrovsk region, satisfaction increased to 8–10 points in 2019, compared to 5 to 7 points during the 2015–2018 period. In the Zhytomyr region, satisfaction with the supply of medications was rated at 9 points from 2021 to 2022, but in 2019, it dropped to 7 points, indicating some variability in satisfaction levels across different regions and years.

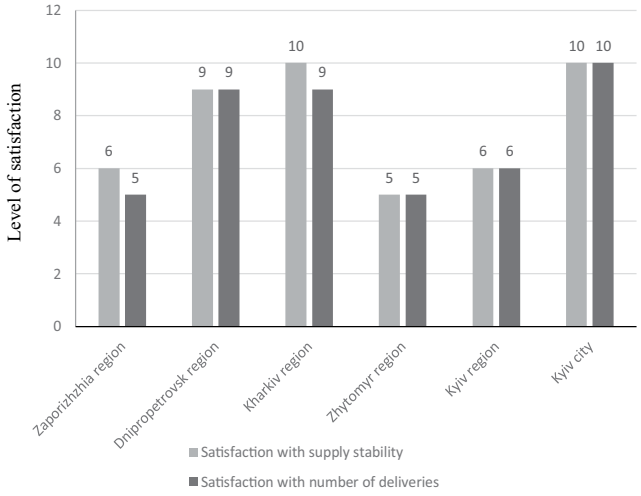
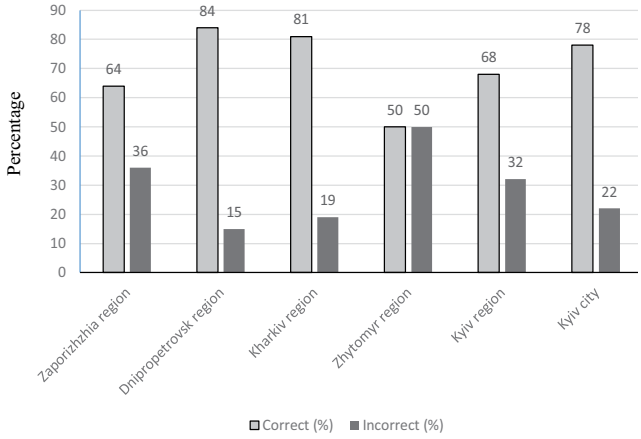


Fig. 6. Distribution of responses from patients' legal representatives regarding satisfaction with the quantity and stability of procured medicines in 2019 (median values, max = 10)



Notes: Kyiv N respondents = 100, Kyiv region N respondents = 60, Zhytomyr region N respondents = 80, Kharkiv region N respondents = 100, Dnipropetrovsk region N respondents = 90, Zaporizhzhia region. N respondents = 100.

Fig. 7. Supply of medicines to hospitals of healthcare facilities in 2019 (%)

In 2019–2023, according to the legal representatives of patients, HCFs were reported to provide full coverage of medication needs for patients with CP. The survey results indicated the following distribution: in Kyiv, 83.0% of respondents stated that patients received 100% of the necessary medications, while 17.0% believed that the provision ranged between 51–75%. In the Kyiv region, 51.0% of respon-

dents reported full provision, but 32.0% indicated there was no provision of medicines at all. In the Zhytomyr region, 81.0% believed that patients were fully supplied, yet 44.0% also stated that patients received no medications. In the Kharkiv region, 85.0% of respondents reported full provision, but 15.0% said there was a complete lack of medicines, and another group indicated that patients were only 26–50% supplied. In the Dnipropetrovsk region, 83.0% believed patients received all required medications, while 17.0% noted a lack of supply. In the Zaporizhzhia region, 69.0% of respondents believed patients were fully covered, while 31.0% reported coverage of only 51–75%. Respondents also expressed a desire to try treatments using Botox or Xeomin, although these drugs were not available in their localities.

Regarding the medication supply schedule to HCFs in 2019, patients' legal representatives had the following opinions: in Kyiv, 78.0% considered the schedule to be appropriate, while 22.0% found it incorrect. In the Kyiv region, 68.0% rated the schedule as correct, while 32.0% found it incorrect. In the Zhytomyr region, opinions were evenly split, with 50.0% agreeing with the schedule and 50.0% disagreeing. In the Kharkiv region, 81.0% believed the schedule was correct, and 19.0% did not. In the Dnipropetrovsk region, 84.0% supported the accuracy of the schedule, while 16.0% disagreed. In the Zaporizhzhia region, 64.0% considered the schedule to be appropriate, while 36.0% found it incorrect. These results highlight the importance respondents place on continuous medication supply, the availability of different treatment options, and ensuring physical access to care.

In the period from 2019 to 2023, legal representatives utilized various resources to access up-to-date information on the availability of medicinal products in Kyiv. The most frequently accessed resources included printouts on hospital stands, which accounted for 36.0% of usage, followed by the e-Liky website at 21.0%, the Ministry of Health of Ukraine website at 15.0%, the website of the regional (city) state administration also at 21.0%, and the hospital website at 7.0%. In the Kyiv region, legal representatives predominantly relied on printouts at hospital stands (38.0%), with the e-Liky website being used by 15.0%, the healthcare department or office website by 77.0%, the Ministry of Health of Ukraine website by 15.0%, and the hospital website by 15.0%. In the Zhytomyr region, the most commonly accessed resource was again printouts at hospital stands (36.0%), followed by the eLicense website at 24.0%, the NGO website at 13.0%, the HCFs or department website at 15.0%, and the hospital website at 13.0%. In the Kharkiv region, the predominant sources were printouts at hospital stands (18.0%), the MoH website (2.0%), the eLiky website (8.0%), the hospital website (57.0%), and printouts at the stands of civil society organizations (15.0%). In the Dnipropetrovsk region, legal representatives most commonly accessed information via printouts at hospital stands (20.0%), the eLiky website (9.0%), the MoH website (27.0%), the NGO website (22.0%), and the healthcare department or office website (22.0%). In the Zaporizhzhia region, the most frequently used resources were printouts at hospital stands (42.0%), the e-Liky website (17.0%), the MoH website (9.0%), and the hospital website (32.0%). Overall, the survey revealed that printouts at hospital stands and the e-Liky website were the most common sources of information accessed by legal representatives across the regions.

Conclusions

The study found that in 2019–2023, patients with CP in five regions of Ukraine and the city of Kyiv had access to free medicines for botulinum therapy, but the level of provision varied by region. Some patients refused therapy due to a lack of awareness and distrust, which indicates the need for better information support. Interruptions in treatment were caused by a lack of drug quotas, forcing patients to seek medications on their own. The most common sources of information on the availability of medicines were printouts on stands in hospitals and the e-Liky website. In some regions, patients faced demands for undue advantage to receive free medicines. Side effects and low efficacy of medicines were the main reasons for refusing therapy, indicating the need to improve the quality of treatment. Respondents noted improvements in the provision of medicines from 2019 to 2021, but there was no significant progress from 2022 to 2023. Patients expressed a desire to have access to other drugs, such as Botox and Xeomin, which were not always available in their regions. Inpatient treatment proved to be inconvenient due to a lack of physical accessibility to hospitals, so patients wanted to be able to receive therapy at home. These findings emphasize the need to improve the supply of medicines, increase patient awareness, and create conditions for home-based therapy.

The authors declare no conflict of interest.

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