Analysis of the availability of botulinum toxin type A in the treatment of children with spastic cerebral palsy in Ukraine: a survey of doctors

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In Ukraine, about 100,000 children suffer from nervous system disorders, with cerebral palsy (CP) being the leading cause of childhood disability. The European Registry of Children with Cerebral Palsy emphasizes the urgency of this problem. The objective: to analyze the supply, availability, and use of Botulinum toxin type A for the treatment of spastic cerebral palsy in children in Ukraine.

Materials and methods. The study was conducted from October 2019 to December 2020, and it included monitoring the supply and availability of medicines, collecting quantitative and qualitative data from various sources, and interviewing 64 doctors.

Results. This research highlights disparities in medicine supply satisfaction across Ukraine, with surveys of doctors indicating varying degrees of effectiveness in regions like Kyiv and Kharkiv compared to challenges in Zhytomyr and the Kyiv region. Key issues include surplus medicines, unethical distribution practices, and systemic inefficiencies such as lack of patient registries and insufficient funding. The findings suggest an urgent need for regulatory reforms, enhanced healthcare logistics, and infrastructure improvements to achieve equitable healthcare access nationwide.

Conclusions. This study highlights significant challenges in delivering Botulinum toxin type A for spastic cerebral palsy in Ukraine, including systemic inefficiencies, funding shortages, and procurement delays. It emphasizes the need for policy reforms, improved communication, and digital information access to ensure equitable and efficient healthcare. Urgent improvements are advocated to address these issues and enhance patient care nationwide.

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

The first quarter of the XXI century is a period of the international community’s entry into a new era of transformations, globalization processes, and innovations in all spheres of public life, and the medical field is no exception. Thus, in the current conditions of development of various branches of medicine, the public order is a scientific search for the most effective means and methods of treating citizens for any diseases and nosologies, helping to reduce the overall morbidity of the country’s population and providing citizens with affordable and high-quality medical services.

According to the World Health Organization (WHO), congenital anomalies, nervous system diseases, and mental disorders are the leading causes of primary childhood disability. 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) [1]. In the group of preterm infants, the proportion of CP is 1%, while in newborns weighing less than 1,500 g, the prevalence of CP increases to 5–15%, and in infants weighing less than 1,000 g, it can reach 25–30% [1]. The most frequent spastic variants of the disease are observed in 70–85% of children: spastic diplegia (36.6%), spastic hemiparesis (29.6%), and double hemiplegia (18.3%).

In recent years, Ukraine has been pursuing a consistent policy of transition from a medical to a biopsychosocial model of care for children. The experience of implementing botulinum therapy drugs in Ukraine for the treatment of children with spastic forms of cerebral palsy began in 2008 when the first free pharmaceutical supply program for children with cerebral palsy in Kyiv was introduced at the Kyiv City Children’s Clinical Hospital No. 1. Since 2012 and up to the present day, the program has expanded to cover all regions of Ukraine. [2, 3].

Medical assistance to children with cerebral palsy is provided in accordance with the Order of the Ministry of Health of Ukraine No. 286 dated April 9, 2013. «Cerebral Palsy and Other Organic Brain Disorders in Children Accompanied by Motor Disorders», updated in the form of adapted clinical guidelines in 2018. It is recommended to use the International Classification of Functioning, Disability and Health (ICF), ICF, Disability and Health for Children and Youth (ICF-DY), which are the main tools for obtaining complete information about the patient’s impairment of functions and structures, limitations of activity and participation, and personal needs. The ICF conceptually ensures the possibility of a child’s participation in public life through inclusive education and a barrier-free environment because it is the child’s active participation in self-care, education, and social life that is an integral part of the rehabilitation process [4, 5].

In 2016, the Ukrainian Classifier of Occupations in the Healthcare Sector was amended to include new rehabilitation professions: doctors of physical and rehabilitation medicine, physical therapists, and occupational therapists. This made it possible to engage specialists with higher nonmedical education to work with patients and provide multidisciplinary rehabilitation care following international standards [1]. The principles of the ICF should be the basis for determining the degree of impairment and limitation of life, assigning the category «Child with a disability» or «Child with a disability of subgroup A» to children during medical and social examination by medical advisory commissions and developing an individual rehabilitation program [1].

During the examination and rehabilitation interventions, the main attention is given to assessing the level of functioning and activity limitations and participation in certain life situations of a child with a disability or risk of disability, as well as determining how to improve the patient’s functional capabilities for maximum social adaptation [6]. The discussion is still focused on the criteria for assessing the functioning, life and health of persons with disabilities, followed by determining the degree of limitation of activity and participation, formulating an individual rehabilitation program, determining training opportunities, and professional orientation.

At present, the Ministry of Health of Ukraine (MHU) indicates a clear trend in Ukraine toward an increase in the number of children diagnosed with various forms of CP [7]. In particular, according to national epidemiologists, the prevalence of registered cases of CP in Ukraine is 2.56 cases per 1,000 newborns [8]. This indicator has not changed significantly over the past 40 years. Approximately 40.0% of children are born prematurely. Among profoundly premature babies, the number of CP cases is up to 40–100 per 1,000 live births [7]. Accordingly, one of the priorities of the domestic medical industry of Ukraine is to find the most effective and efficient ways to overcome this nosology, one of which is the use of Botulinum toxin type A (BoNT type A).

Thus, botulinum therapy is one of the most rapidly developing and innovative areas of modern medicine. At the same time, the use of BoNT type A for the medical treatment of patients with CP has been carried out for more than 20 years [9]. During this period, extensive practical experience in the use of various BoNT type A drugs has been gained through clinical trials, and European and international consensus agreements have been published that define the fundamental principles of this type of CP treatment [10]. However, despite this, today, as before, the feasibility of using BoNT type A drugs in CP remains controversial, which is primarily due to the variety of forms of the disease and the variability of clinical manifestations, which in turn makes it impossible to adopt a unified international protocol for injection procedures with BoNT type A drugs and calculation of their doses in CP, such as doctor’s experience, detailed analysis of the patient’s neurological and orthopedic status, and practical application of standardized functional scales for assessing the child’s motor abilities and communication capabilities [11].

In 2000, for the first time in Ukraine, BoNT type A was registered as a medicinal product (MP), which became a new stage in the drug treatment of patients with CKD in Ukraine [11]. Therefore, in the context of the intensification of the process of reforming the domestic healthcare sector and with the assistance of the United Nations Development Program (UNDP), the practice of using BoNT type A medicines is gradually spreading in Ukraine due to their free provision to domestic citizens in all regions of the country. Still, the problem of prompt delivery of medicines to healthcare facilities and their availability to patients on the ground is acute and requires a detailed study.

MATERIALS AND METHODS

The objective of our study is to comprehensively analyze the availability and supply of BoNT type A for the treatment of children with spastic cerebral palsy in six regions of Ukraine: Kyiv city, Kyiv, Kharkivska, Dnipropetrovsks, Zhytomyr, and Zaporizhzhia regions. The study is aimed at identifying the main problems and barriers in the system of medicine supply, assessing the level of satisfaction of medical and administrative staff with the availability of treatment, and developing recommendations to improve access to necessary medicines and increase the effectiveness of treatment of children with this pathology for the MHU, health care organizations, and public organizations (community organizations). We wanted
to answer several important research questions to understand the current situation in more depth:

1. What factors influence delays in the supply of medicines to health facilities and how do these delays affect patient care? This question is central because supply delays directly affect the availability and timeliness of treatment, which is critical for patients with chronic and acute conditions.

2. What are the major challenges in the medication ordering process, including insufficient financial quotas and lack of needed medications on the National List, and how do they affect treatment availability? The importance of this question is to identify systemic weaknesses in the mechanisms for ordering and financing medicines, which is key to improving the logistics and availability of medicines.

3. What are the main challenges and barriers to long-term planning for medicines supply, and what measures can be taken to overcome them? This question focuses on the strategic aspect of medical supply management, exploring ways to optimize and improve the efficiency of the healthcare system as a whole.

The methodology of our study consisted of two phases: collection of quantitative and qualitative data on medicine supply, including analysis of data from MHU websites and interviews with medical and administrative staff. The aim was to establish a reliable database on the current supply status and to identify administrative, logistical, and educational barriers. Strict verification was carried out to ensure the validity of the data. Specialized questionnaires developed allowed systematic analysis of data at the local level, including availability and use of medicines. In the qualitative data collection phase, we focused on obtaining in-depth knowledge through surveys and interviews, assessing patient satisfaction with the supply of medicines.

We used specialized questionnaires in Ukrainian for different groups of respondents to collect data on sociodemographic characteristics, medicine supply and utilization. These surveys, conducted in October-November across 2019 and 2020, focused on «Organizational, Clinical, and Practical Aspects of Botulinum Therapy in Spastic Cerebral Palsy», offering valuable insights into the practical application of botulinum therapy in the real-world clinical. The surveys covered 64 doctors and administrative staff, showing a high response rate of over 90%. These questionnaires allowed systematic analysis of data at the local level on the availability and use of medicines.

RESULTS

In Kyiv, a survey involving 12 respondents, including 10 doctors and 2 administrative staff, was conducted to assess the situation regarding medicine supply. Most doctors indicated that the supply of medicines adequately met 100% of patient needs. However, notable concerns were raised:

1. Some respondents observed an excess in medicine quantities compared to patient numbers, potentially linked to low treatment adherence among some patients.

2. There were reports of delivery delays to hospitals, with 2 doctors experiencing one-month delays and another 2 reporting delays of 2–3 months.

3. All respondents actively informed patients about medicine availability, primarily due to doctors’ initiatives.

4. Interestingly, 10 out of 12 doctors reported receiving propositions for undue advantages in exchange for hastening the free medicine distribution, though no specific instances were cited.

5. No cases were reported where patients had to personally finance their medications.

6. One respondent highlighted issues providing free medicines for non-registered individuals in Kyiv.

7. All respondents confirmed that medicines were received in hospitals and patients could personally verify the packaging.

The respondents also highlighted several issues in ordering medicines, including insufficient financial quotas, absence of necessary medicines in the National List, time constraints for application completion, overtime work, and the lack of a patient registry. There were also concerns about the absence of a regulatory framework to calculate total needs accurately, challenges in long-term planning for medicine supply, and insufficient disease diagnosis/detection.

In the Kyiv region, interviews with 7 doctors highlighted a consensus that the supply of medicines does not fully satisfy patient needs, a situation attributed to several factors, including insufficient funding quotas, the lack of comprehensive patient registries, and suboptimal adherence to treatment regimens by patients. Despite these challenges, it was unanimously reported that patients are consistently informed about the availability of medicines in hospitals. Nevertheless, the region has not placed orders for medicines, with professionals indicating they would notify patients upon availability.

The respondents demonstrated a proactive approach to managing the constrained supply of state-funded free medicines. There were no instances reported of unethical practices related to medicine acquisition, nor were there reports of patients needing to self-finance their medications. However, the unanimous recognition of the shortage of free medicines in hospitals underscores a significant issue. The process of ordering medicines is hampered by the absence of a patient registry and diagnostic challenges, with no redistribution of medicines from other hospitals reported. The primary concern identified by the majority (6 out of 7) was the delays and inconsistencies in medicine supply, with the supply schedule criticized for its inaccuracies. The satisfaction with the quantity and stability of the supplies was moderate, averaging a median value of 2, although some respondents rated it higher.

In the Zhytomyr region, a survey of 10 doctors revealed that the majority believe the quantity of medicines does not meet patient needs, primarily due to inadequate funding and diagnostic challenges. The level of medicine supply was estimated to be between 26–50% and 51–75% by most respondents. All doctors reported routinely informing patients about new medicine arrivals, with no unethical practices observed in acquiring medicines. Challenges highlighted during the medication ordering phase included insufficient funding, the absence of a patient registry, and inadequate diagnostics.

Notably, some patients from Zhytomyr region seek treatment in Kyiv, potentially reflecting on regional healthcare disparities. Irregularities in supply throughout the year were a concern, though the accuracy of the medication list received mixed reviews. Satisfaction with the
quantity and stability of medicines was notably low, with a median value of 0. In the Kharkiv region, interviews with 14 healthcare professionals yielded mixed perceptions regarding medicine supply, with some believing it meets patient needs, while others disagreed. The absence of a patient registry, inadequate funding, and poor treatment adherence were identified as key challenges. However, all professionals ensured patient awareness of medicine availability. Satisfaction with medicine supply varied, with no reported supply interruptions.

Ethical practices in medicine provision were maintained, with a unanimous concern over the scarcity of budget-funded free medicines. Ordering challenges included time constraints and the lack of a patient registry, but no delivery issues were reported. The accuracy of the supply schedule received mixed feedback. Satisfaction levels with the quantity and stability of medicines were high, reflecting a more positive situation compared to other regions.

In Zaporizhzhia region, feedback from a survey involving 9 participants, predominantly doctors, portrayed a highly positive view of the medicine supply, asserting it successfully meets 100% of patient needs, as depicted in Fig. 1. Despite this encouraging perspective, challenges were nonetheless identified. During the ordering phase, issues such as the absence of a patient registry, as mentioned by 4 respondents, and inadequate patient adherence to prescribed treatments, noted by 3, were significant concerns. It was unanimously reported that healthcare professionals ensure patients are informed about the arrival of medicines at healthcare facilities.

Ethical practices were upheld with no undue benefits offered for the receipt of free medicines, nor were there any instances of patients being compelled to self-fund their treatments. However, treatment interruptions due to issues with medicine provision were recognized as a universal concern. All respondents affirmed that medicines were indeed received at healthcare facilities, allowing patients to verify the integrity of the medication packaging. Financial constraints, specifically inadequate funding quotas for certain diseases, were highlighted by five respondents, with three indicating the impact of limited working hours and the need for overtime.

Regarding medicine acquisition, the irregularity of supply throughout the year was identified as an issue. There was a consensus that no redistribution of medicines occurred between healthcare facilities and the formation of the supply schedule was generally approved, reflected in median satisfaction scores of 7 for medicine quantity and 8 for supply stability.

Conversely, in Dnipropetrovsk region, feedback from 12 respondents painted a different picture, with the majority deeming the medicine supply sufficient; only three respondents viewed it as adequate. The predominant issue, as cited by half of the respondents, was insufficient funding. The perceived fulfillment of medicine needs varied, with most respondents estimating it between 26-75%, and a minority sensing it fell within the 76-99% range, as illustrated in Fig. 1. Notably, supply interruptions extending up to a month were reported by three participants.

Communication regarding medication availability to patients was a common practice among doctors. There were no reported instances of patients resorting to informal payments for medications. It was confirmed that treatments were administered within hospital settings, with patients able to personally inspect medication packaging. Diagnostic challenges, difficulties in maintaining contact with patients for precise need assessments, and hurdles in long-term planning for medicine supply were additional concerns voiced by the respondents. Despite these challenges, no issues were reported at the stage of medicine receipt, nor was there any indication of medicine redistribution between hospitals. The formation of the supply schedule was unanimously approved. Satisfaction levels regarding the number of medicines and the stability of the supply were relatively high, with median values of 7 and 6.5 respectively, indicating a favorable degree of contentment among the respondents.

Figure 2 presents a compelling overview of the challenges faced by healthcare systems across various regions in Ukraine, highlighting significant disparities in their capacity to deliver effective medical care. This analysis encompasses responses from healthcare professionals in the Zaporizhzhia, Dnipropetrovsk, Kharkiv, Kyiv City, Kyiv, and Zhytomyr regions, offering insights into systemic issues that hinder patient care and treatment efficacy. The focus will be on the most notable obstacles such as the lack of working time, difficulties in diagnosis and detection, challenges in contacting patients, the absence of a patient registry, and concerns regarding the availability of necessary medicines. This will help illustrate the disparities and commonalities in healthcare delivery challenges across the regions.

Zaporizhzhia region, the most notable obstacles include a significant lack of working time (33.33%), paralleled by issues related to long-term planning, treatment protocols, and diagnosis capabilities (each at 22.22%). Interestingly, there are no reported problems with the availability of a regulatory framework or necessary medicines, suggesting specific areas where the system functions adequately or at least does not represent a primary concern for the respondents.

Dnipropetrovsk region shows a striking 50% difficulty in diagnosis and detection, with a considerable percentage of respondents (41.67%) reporting challenges in contacting patients. Despite these significant issues, a surprising 91.67% of respondents stated there were no problems, indicating a possible misinterpretation of the question or a reflection of a varied perception of healthcare challenges.

Kharkiv region healthcare system appears to be particularly strained by the unavailability of working time (42.86%) and a significant lack of a patient registry (28.57%). These factors, combined with a noteworthy percentage facing difficulties in contacting patients (14.29%) and a lack of qualified doctors (21.43%), underscore the multifaceted nature of the healthcare delivery challenges.

Kyiv city and Kyiv region both report considerable challenges, with Kyiv City noting an acute inability to contact patients (38.33%) and an absence of a patient registry (58.33%). Kyiv Region, albeit with fewer respondents, echoes the difficulty in contacting patients (57.14%) and diagnosing conditions (42.86%), alongside a notable concern regarding the unavailability of necessary medicines in the National List (28.57%).

Zhytomyr region stands out with the highest rates of difficulty in contacting patients (80.0%) and insufficiency
in diagnosis/detection (60.0%), alongside a significant lack of a patient registry (60.0%). These figures starkly illustrate the critical gaps in basic healthcare infrastructure and patient management systems.

This analysis reveals a complex landscape of healthcare challenges in Ukraine, with significant variations across regions. The data underscores the urgent need for targeted interventions to address the specific deficiencies in each region, focusing on improving diagnostic capabilities, patient communication, and the availability of essential medical resources. The absence of a regulatory framework or treatment protocols in certain areas suggests a broader systemic issue that may require comprehensive policy reforms to ensure a cohesive and efficient healthcare delivery system nationwide.

**Fig. 1.** In 2019, to what extent was the hospital (HCF) where the respondent works provided with medicines for the nosology (in % of the total need)?

*Note* Kyiv city n = 12, Kyiv region, n = 7, Zhytomyr region, n = 10, Kharkiv region, n = 14, Dnipropetrovsk region, n = 12, Zaporizhzhia region n = 9.

**Fig. 2.** What problems did the hospital (healthcare facility) where the respondent works face in 2019 at the stage of ordering medicines to be procured from the state budget?

*Note* Kyiv city n = 12, Kyiv region, n = 7, Zhytomyr region, n = 10, Kharkiv region, n = 14, Dnipropetrovsk region, n = 12, Zaporizhzhia region n = 9.
In a comprehensive survey of 64 doctors providers from six regions, we examined various problems in the drug supply chain, including non-compliance with the cold cycle, drug delivery, limited expiry dates of delivered medicines, and the inability to store large batches of medicines. Figure 3 provides detailed insights into geographic differences in supply chain issues, revealing important insights for health policymakers and administrators.

Zaporizhzhya region shows, first of all, with drug delivery a significant issue – 51.36%. The region also shows problems with non-compliance with the «cold cycle» (15.34%) and inability to store large batches (29.91%), while concerns about medicines with limited shelf life are minimal (3.39%).

Dnipropetrovsk region is particularly affected by the inability to store large batches of products: 56.61% of respondents cited this as a problem. This region also has moderate problems with medicine delivery (25.55%) and cold cycle compliance (15.86%), but to a lesser extent with medicines approaching their expiration date (1.99%).

Kharkiv region shows strikingly low concern about cold cycle compliance, at only 0.02%, but has serious problems with medicine delivery (65.53%). There are also problems with storage of large batches (15.16%) and delivery of medicines with limited expiry period (19.29%), indicating the need to improve stock turnover and storage solutions.

Zhytomyr region, there is a balanced distribution of problems in the supply chain, with a particular focus on expired medicines (45.08%) and medicines with limited shelf life (26.98%). The region is less concerned about large lot storage (7.96%) and cold cycle compliance (19.98%), suggesting that while temperature control is effective, stock management requires attention.

Kyiv region has serious problems with cold cycle compliance (42.69%), indicating serious problems in maintaining the required storage and transportation temperatures. The region also experiences difficulties with medicines (37.49%) and storage capacity (11.92%), with medicines with limited expiry dates (7.90%) being of lesser concern.

Kyiv city faces medium and high severity problems on all fronts: 47.12% of respondents cited problems with expired medicines, followed by problems with limited expiry date of medicines (24.03%) and storage capacity (7.65%). Cold-cycle compliance was of lesser concern (21.20%) but still worthy of attention. This detailed breakdown, complete with percentages, highlights the specific nature and extent of supply chain challenges faced by each region. It highlights critical areas where targeted interventions can lead to significant improvements in the delivery of health care and patient care.

This study article examines the multifaceted challenges encountered in the medicine supply process across various Ukrainian regions, as evidenced by surveys conducted among healthcare professionals in Kyiv, Kyiv region, Zhytomyr, Kharkiv, Dnipropetrovsk, and Zaporizhzhia. These challenges encompass a range of issues from the logistics of medicine delivery to the adequacy of healthcare infrastructure and the regulatory environment, underlining the complexity of healthcare in Ukraine.

In Kyiv, feedback from healthcare professionals indicates that the medicine supply generally meets patient needs. However, issues such as surplus medication, delivery delays, and ethical concerns regarding the distribution of free medicines highlight systemic inefficiencies and ethical challenges [12, 13]. These findings suggest the need for a more streamlined and ethical supply chain. Contrastingly, the Kyiv region and Zhytomyr face challenges with insufficient funding and diagnostic capabilities, pointing to broader issues in resource allocation and healthcare infrastructure [14]. Despite these obstacles, the consistent effort by healthcare professionals to inform patients about medicine availability underscores a strong commitment to patient care.

The lack of a comprehensive patient registry and difficulties in long-term planning are significant challenges across all surveyed regions. This impedes accurate need assessment and efficient medicine distribution, suggesting a crucial infrastructural and regulatory gap within the Ukrainian healthcare system. Moreover, maintaining the “cold cycle” for medicine preservation, especially in the Kyiv region, highlights the infrastructural challenges in ensuring medicine quality and safety. Disparities in satis-
Conclusions

This study’s findings reveal a complex landscape of challenges in the medicine supply process across Ukraine, marked by systemic inefficiencies, infrastructural and regulatory gaps, and ethical concerns. The dedication of healthcare professionals to patient care, despite these challenges, provides a foundation for improvement. However, significant policy and systemic reforms are necessary to address the identified challenges, ensuring equitable, efficient, and ethical healthcare delivery across Ukraine.

The study identified a number of problems related to the delivery and availability of BoNT type A drugs for the treatment of SCP at the local level. In particular, this includes insufficient state funding for the procurement of medicines, ineffective procurement systems in the country, constant delays in deliveries and issuance of orders, lack of free medicines in healthcare facilities, lack of registries of patients with different neologies, insufficient communication in the medical environment, insufficient number of qualified specialists in BoNT type An injections, and lack of quality diagnostic equipment in healthcare facilities. All of these factors negatively affect the provision of quality medical care to patients with CP and the development of the medical sector in general.

Upon reviewing the feedback from respondents, several critical insights have been uncovered regarding the challenges encountered during the medicine ordering process. Predominantly, the issues highlighted were the insufficient engagement with patients for precise demand forecasting and the challenges associated with executing long-term procurement strategies. These findings underscore the necessity of establishing more robust communication channels between healthcare providers and patients to enhance the accuracy of medicine needs assessments. Furthermore, it has been identified that the primary sources of information regarding the availability of medicines within hospitals are the MHU website and the website of the State Agency of Healthcare Organizations (SAHO). These platforms are instrumental in disseminating information about medicinal product availability. Moreover, a significant portion of data concerning the availability of medicines is accessible through the MHU’s website and the e-Liky portal.

This analysis underscores the importance of leveraging digital platforms for information dissemination and highlights the need for improved patient-provider communication mechanisms. Addressing these challenges could significantly enhance the efficiency and effectiveness of the medicine ordering and procurement processes, ultimately leading to better healthcare outcomes. In this context, a set of practical recommendations was developed for the Ministry of Health, health departments of regional (city) state administrations, health care facilities and NGOs. Implementation and enforcement of these recommendations will help to solve problems and ensure the availability of medicines at the local level for patients with spastic cerebral palsy.

Conflicts of Interest. The authors declare no potential conflicts of interest.

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