NEUROETHICAL REGULATION OF PEDIATRIC DEEP BRAIN STIMULATION (DBS) IN THE RUSSIAN FEDERATION: RISKS OF UNJUSTIFIED USE

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The study covers the problem of insufficient regulation of pediatric deep brain stimulation (DBS) in Russia, which causes neuroethical dilemmas and risk of unjustified expansion of indications. The study is relevant because of growing use of DBS in children with severe neurological disorders and lack of adapted standards. The aim of the study is to identify gaps in regulatory system and develop recommendations for ethical and clinical regulation of DBS in children. The current clinical recommendations of the Ministry of Health of the Russian Federation, international consensuses and protocols of leading Russian centers were used as a basis for the research. The main methods included analysis of regulatory documents, comparative and critical analysis of existing standards and ethical approaches. The results show that Russian practice lacks age-specific standards and assessment algorithms despite the regulations. The risks of expanded indications and pressure on patients and their families, which may lead to unregulated experimentation, have been identified. As a conclusion, the need to develop specialized recommendations and strengthen ethical standards to ensure safety and effectiveness of DBS use in children is proposed.

Keywords: neuroethics, DBS, dystonia, cerebral palsy, Tourette's syndrome, pediatrics, neurosurgery

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НЕЙРОЭТИЧЕСКОЕ РЕГУЛИРОВАНИЕ ДЕТСКОЙ DBS В РФ: РИСКИ НЕОБОСНОВАННОГО ПРИМЕНЕНИЯ

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Проблема исследования заключается в недостаточной регуляции применения глубокой стимуляции мозга у детей в России, что вызывает нейроэтические дилеммы и риск необоснованного расширения показаний. Актуальность обусловлена ростом использования DBS у педиатрической группы с тяжелыми неврологическими расстройствами и отсутствием адаптированных стандартов. Цель исследования — выявить пробелы в нормативной базе и разработать рекомендации по этическому и клиническому регулированию применения DBS у детей. В качестве материала использованы действующие клинические рекомендации Минздрава России, международные консенсусы и протоколы ведущих российских центров. Основные методы включали анализ нормативных документов, сравнительный и критический анализ существующих стандартов и этических подходов. Результаты показали, что российская практика страдает отсутствием возрастных стандартов и алгоритмов оценки, несмотря на наличие регламентов. Обнаружены риски расширения показаний и давления на пациентов и их семьи, что может привести к нерегулируемому экспериментированию. В качестве вывода предложена необходимость разработки специализированных рекомендаций и усиления этических стандартов для обеспечения безопасности и эффективности применения DBS у детей.

Ключевые слова: нейроэтика, DBS, дистония, детский церебральный паралич, синдром Туретта, педиатрия, нейрохирургия

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INTRODUCTION

Deep brain stimulation (DBS), which has demonstrated its effectiveness in severe neurological disorders in adults (Parkinson's disease, essential tremor), is increasingly being introduced into pediatric practice. When used in children with drug-resistant forms of dystonia (DYT1, PKAN), epilepsy (Lennox-Gastaut syndrome), Tourette's syndrome, and cerebral palsy, a significant improvement in motor functions and a decreased frequency of seizures was found [1, 2]. However, pediatric treatment has certain specifics due to continued development of the brain, impossibility of obtaining a full informed consent, and high vulnerability, giving rise to a complex of serious neuroethical dilemmas that go beyond medical risks.

The purpose of this study is to conduct a critical neuroethical analysis of the existing regulatory system of using DBS in children in the Russian Federation (based on current regulatory documents and clinical practices). It is done to identify potential risks of unjustified expansion of indications, pressure on patients and their families, and use of off-label methods that can turn therapeutic intervention into unregulated experimentation.

MATERIALS AND METHODS

While preparing for this study, the following categories of documents were analyzed.

1. Current clinical recommendations of the Ministry of Health of the Russian Federation (2023–2025) on nosologies involving pediatric use of DBS (dystonia G24, epilepsy G40, cerebral palsy G80, Tourette syndrome F95.2) [3, 4].
2. International Consensus on Neurostimulation in Children (CAPSIT-PD): CAPSIT-PD (Core Assessment Program for Surgical Interventional Therapies in Parkinson's Disease):

– Designed to standardize assessment of patients with Parkinson's disease before neurosurgical interventions, including DBS. However, the protocol is aimed at adults only and not adapted for children. It includes neuropsychological testing, assessment of motor functions (UPDRS) and quality of life, but its use in children is limited due to differences in pathogenesis and age-related cognitive features [5, 6].
– Critical limitation: a study performed in 2015 showed that only 40% of adult patients could absolutely tolerate preoperative CAPSIT-PD testing due to fatigue and complexity of tasks. In children, these risks are increased multiple times [6, 7].

Protocols of ethical committees of the leading neurosurgical centers of the Russian Federation:

1) Bekhterev Psychoneurological Research Institute (Saint Petersburg)
– Two-level informed consent: Signature of parents and written consent of a child who is 14 years or older. Mandatory inclusion of paragraphs about the risks of cognitive impairment and irreversibility of stimulation effects.
– Peer review: for children with psychiatric comorbidities (for example, ASD), the decision is made by a council consisting of a neurosurgeon, a pediatric psychiatrist and a bioethicist.
2) Burdenko National Medical Research Center for Neurosurgery (Moscow) — Off-label use restriction: prohibition of DBS for unapproved indications (for example, autism without autoaggression) without approval of the central ethics committee.

Analysis of the existing regulatory system, including current clinical guidelines of the Ministry of Health of the Russian Federation, international consensus (CAPSIT-PD) and protocols of the ethics committees from leading centers revealed that there are no sufficient validated and directly adapted data for pediatric practice of deep brain stimulation despite availability of regulatory documents applicable to DBS in general. The paradox is that formal availability of structured approaches (including requirements for informed consent and ethical assessment) presents a contrast to the acute shortage of specific, age-sensitive algorithms for patient selection, preoperative assessment and prediction of outcomes in children.

STUDY RESULTS

Analysis of the regulatory documents of the Ministry of Health of the Russian Federation (2023–2025), international consensuses (CAPSIT-PD) and protocols of the ethical committees of leading neurosurgical centers in Russia have shown that the existing system for regulating the use of deep brain stimulation (DBS) in children has significant gaps. Despite the formal existence of regulatory acts and requirements for informed consent, there are no adequately adapted clinical guidelines for pediatrics and standardized algorithms for patient selection, preoperative assessment and prediction of outcomes.

The international CAPSIT-PD protocol, which is aimed at adult patients with Parkinson's disease, does not take into account age-specific characteristics and cognitive differences in children. This limits its applicability in pediatric practice. Additionally, ethical difficulties related to obtaining informed consent and need for a comprehensive assessment of patients with psychiatric comorbidities have been identified.

Protocols of the leading Russian centers provide for collegial decision-making and restriction of off-label use of DBS. However, practice shows the risk of unjustified expansion of indications and pressure on patients and families. As a result, there is a lack of clear regulatory and ethical guidelines, which can lead to unregulated experiments with treatment of children suffering from severe neurological disorders.

Thus, the results emphasize the need to develop specialized, age-appropriate clinical guidelines and ethical standards to use DBS in pediatric patients in Russia, taking into account neuroethical aspects and protection of the rights of minors.

DISCUSSION OF THE RESULTS

A study of pediatric DBS regulation in the Russian Federation showed as follows:

1. The need for pediatric adaptation: current clinical guidelines contain general provisions on DBS, but detailed selection and evaluation algorithms that take into account the child's development have not been fully developed yet.
2. CAPSIT-PD limitations: use of this protocol in pediatrics is hampered because its focuses on adults with Parkinson's disease and the tests are too complex for children [6, 7].
3. Ethical challenges: existing approaches to informed consent (including consent of adolescents) require further development of methods that provide a deep understanding of long-term aspects of child and family treatment.

These observations are consistent with international experience where pediatric DBS standards are required and ethical approaches have to be clarified [8, 9].

We also identified some factors influencing the situation:

Relatively recent introduction of DBS in pediatrics, objective difficulty of creating universal standards for the developing brain, and need in additional resources.

CONCLUSIONS

The study revealed a gap between a formal regulation and a real shortage of adequate pediatric instruments and standards for DBS in the Russian Federation. Elimination of this gap through development of specialized recommendations, adapted assessment protocols, and strengthening the neuroethical component is a top priority that ensures safety, effectiveness, and ethics of using this method in children.

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