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Enhancing Patient-Centric Approaches and Regulatory Measures in Valproate Use

Shampa Ghosh, Jitendra Kumar Sinha

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Abstract

Valproate is an effective treatment for bipolar disorder, migraine, and seizures. It is a flexible medication for neurological illnesses. In addition to its immediate benefits, the neuroprotective capabilities of this substance, which may be attributed to its antioxidant and anti-inflammatory properties, contribute to its complexity. Nevertheless, the presence of significant negative consequences such as pancreatitis, liver failure, teratogenicity, and an elevated risk of suicide present considerable difficulties. Significantly, its capacity to block histone deacetylase motivates investigation into possible epigenetic impacts for the treatment of AIDS and cancer. The article discusses the issue surrounding the use of valproate in neurology. It agrees with the guidelines set by the MHRA (Medicines and Healthcare products Regulatory Agency), but also emphasises the need for further considerations in patient care and regulatory enhancements. The statement emphasises the need of providing clear guidance to patients and carers, while highlighting the need for comprehensive education of neurologists worldwide, with the backing of government. The paper advocates for allocating funding to support in-depth understanding through preclinical and clinical investigations, emphasising the importance of a well-rounded approach that prioritises the needs of patients. The aim is to create a flexible framework that can respond to changing medical knowledge by incorporating risk assessment, patient education, and thorough monitoring after regulatory changes. The objective of this strategy is to achieve a balance between ensuring reproductive safety and promoting the well-being of those who are reliant on valproate. This involves taking into account both the practical and emotional aspects of patient care.

Shampa Ghosh, and Jitendra Kumar Sinha*

GloNeuro, Sector 107, Vishwakarma Road, Noida, Uttar Pradesh 201301 India

***Correspondence:** Dr. Jitendra Kumar Sinha, GloNeuro, Sector 107, Vishwakarma Road, Noida 201301 India. Phone: +91 8919679822; Email: jitendrakumarsinha@gmail.com

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Valproate is a medication that is well-known for its adaptability. It is beneficial in the treatment of a number of neurological illnesses, including migraine, bipolar disorder, and seizures. The effectiveness of this treatment extends to several neurological diseases, making it an important therapeutic choice [1]. Additionally, valproate exhibits neuroprotective properties, which may be the consequence of mechanisms that are anti-inflammatory and antioxidant in nature. These properties are in addition to the immediate benefits that valproate offers [2]. However, the utilisation of valproate is accompanied by significant challenges due to the severe bad effects that are linked to it. The detrimental consequences encompass hepatic failure, pancreatic inflammation, teratogenicity (resulting in congenital malformations), and an elevated susceptibility to suicide. To accurately assess and recommend this medication, it is imperative to have knowledge of and exercise caution regarding these potential risks [3]. One noteworthy feature of valproate's pharmacological profile is that it inhibits histone deacetylase, which has raised concerns about possible epigenetic implications. This function entails controlling the activity of histone deacetylase, a pivotal enzyme involved in the regulation of gene expression. The enzyme is inhibited by valproate, indicating its involvement in altering gene expression patterns. This discovery has led to further investigation into potential uses of valproate in the treatment of cancer and AIDS. The complex interplay between valproate's ability to inhibit histone deacetylase and its impact on epigenetic mechanisms presents opportunities for comprehending and utilising these effects in therapeutic settings. This area is currently being actively explored in the dynamic field of medical research and treatment approaches. Recently [4], the controversy surrounding valproate in neurology has arisen when balancing its benefits against the increased risk of major congenital malformations, making it intricate. We endorse the MHRA's recommendations to abstain from initiating valproate treatment in women of reproductive age due to the potential hazards of congenital malformations. However, we also recognise the significance of evaluating the risks of sudden unexpected death in epilepsy (SUDEP) in new mothers [5]. To address the difficulties encountered by neurologists, it is crucial to emphasise the importance of a thorough and individualised assessment carried out by two experts. Adopting this strategy is essential to guarantee that patients are provided with tailored and ideal options, particularly in light of the continuous advancements in our comprehension of the detrimental long-term consequences linked to specific therapies. By supporting a method of evaluation that considers each situation individually, we recognise the intricate complexity of medical choices. This approach highlights the significance of customised solutions that take into account the unique characteristics of patients, their medical backgrounds, and the ever-evolving body of research. Although healthcare practitioners may face more responsibilities, the long-term advantages of personalised care and treatment adjustments emphasise the importance of this approach, in line with the dedication to patient-centered healthcare practices.

To ensure the most effective utilisation of valproate in the treatment of neurological illnesses, a comprehensive strategy encompassing guidelines, advisories, education, and ongoing monitoring is necessary. This comprehensive strategy seeks to achieve a balance between the advantages of valproate and its possible hazards, with a focus on the welfare of patients and the changing field of medical understanding. Moreover, concise advisories are essential, as they offer vital information to both patients and carers [6]. These cautions should be readily available, emphasising potential hazards and facilitating well-informed decision-making. Governments have a crucial role in enhancing the effectiveness of advisories. It is imperative that they not only approve of transparent communication, but also actively promote and provide incentives

for enhanced neurologist education.

Global governments should devote resources to improve the education of neurologists worldwide. Enhanced training ensures that healthcare providers are adequately prepared to handle the intricacies involved with valproate consumption, providing more refined and tailored care. In order to enhance our comprehension of the effects of valproate, it is imperative to allocate significant financial resources towards targeted preclinical and clinical investigations. These studies should include a variety of issues, including the drug's immediate impact on neurological problems and its possible long-term repercussions. Investing in research will provide vital insights, which will help clinicians and regulators improve guidelines and ensure patient safety. Performing a thorough risk assessment before to prescription valproate is of utmost importance. This evaluation should address the patient's medical history, current status of seizure management, and factors related to mental health. An comprehensive assessment guarantees a customised strategy by detecting possible risk factors and adapting treatment strategies to suit individual requirements.

Enhancing patient education initiatives is necessary to empower individuals in making well-informed choices regarding their health. It is important for patients to have a thorough understanding of the advantages and potential drawbacks of valproate, in order to enable collaborative decision-making with healthcare professionals. By adopting this proactive approach, patients are empowered to take charge of their own treatment and a more cooperative healthcare environment is created. After regulatory changes, it is necessary to have a strong monitoring system that can quickly discover any unanticipated adverse impacts. This proactive surveillance guarantees that any emerging problems are swiftly dealt with, ensuring the safety and welfare of patients. The foundation of a flexible framework that adjusts to advancing medical knowledge is built upon consistent revisions to guidelines, which include the integration of emerging research. This iterative process demonstrates a dedication to using evidence-based methods and promotes a healthcare system that is adaptable and responsive.

It is essential to incorporate the viewpoints of patients into the decision-making processes to ensure a regulatory approach that prioritises the needs and preferences of patients [7]. Regulators can enhance the patient-centeredness of healthcare guidelines for valproate by taking into account the personal experiences and preferences of individuals using the medication. This approach promotes a healthcare system that is more compassionate and inclusive. By incorporating these suggestions, it is possible to strike a delicate equilibrium between ensuring reproductive safety and promoting the welfare of those who rely on valproate. This approach recognises and takes into account both the scientifically proven and emotional aspects of patient care, guaranteeing a comprehensive plan that gives importance to the health and independence of the patient. In essence, this comprehensive strategy aims to enhance the utilisation of valproate, minimising potential hazards, and maximising advantages in the intricate realm of neurological conditions.

References

1. [^] Moshé, S.L.; Perucca, E.; Ryvlin, P.; Tomson, T. *Epilepsy: new advances. The Lancet* 2015, *385*, 884-898, doi:10.1016/s0140-6736(14)60456-6.

2. [^]Chen, J.-Y.; Chu, L.-W.; Cheng, K.-I.; Hsieh, S.-L.; Juan, Y.-S.; Wu, B.-N. Valproate reduces neuroinflammation and neuronal death in a rat chronic constriction injury model. *Scientific Reports* 2018, 8, doi:10.1038/s41598-018-34915-5.
3. [^]Nanau, R.M.; Neuman, M.G. Adverse drug reactions induced by valproic acid. *Clinical Biochemistry* 2013, 46, 1323-1338, doi:10.1016/j.clinbiochem.2013.06.012.
4. [^]The Lancet, N. Reducing the uses of valproate: a controversial decision. *The Lancet Neurology* 2024, 23, doi:10.1016/s1474-4422(23)00507-0.
5. [^]Hope, O.A.; Harris, K.M.J. Management of epilepsy during pregnancy and lactation. *Bmj* 2023, 382, doi:10.1136/bmj-2022-074630.
6. [^]Kwame, A.; Petrucka, P.M. A literature-based study of patient-centered care and communication in nurse-patient interactions: barriers, facilitators, and the way forward. *BMC Nursing* 2021, 20, doi:10.1186/s12912-021-00684-2.
7. [^]Tringale, M.; Stephen, G.; Boylan, A.-M.; Heneghan, C. Integrating patient values and preferences in healthcare: a systematic review of qualitative evidence. *BMJ Open* 2022, 12, doi:10.1136/bmjopen-2022-067268.