



Association of British Neurologists

ABN reply to Cumberlege report July 2020



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The Association of British Neurologists (ABN) shares the major concerns regarding the teratogenic risks associated with valproate usage and recognises the impact that this has had on the lives of many women and their families. The ABN has participated in the MHRA-led Valproate Stakeholder Network and has disseminated information and guidance around the MHRA regulations. We welcome the report by Baroness Cumberlege and will continue to advocate for the implementation of the recommendations.

As clinicians, we share the view that stringent processes should be in place to prevent pregnancy in women who are uninformed about the risks of taking valproate. We also recognise that there are some difficult situations for individual women. For example, women with some types of epilepsy experience worsening of their seizures after changing from valproate to alternative antiepileptic drugs or have failed to respond to other drugs and therefore need valproate for seizure control. The Cumberlege report acknowledges seizure control as the reason the drug should remain available for patients. Problems accessing the medication for those women who need it may place them at risk of uncontrolled seizures, injury and Sudden Unexpected Death in Epilepsy (SUDEP). Some women wishing to continue valproate, rather than undergo withdrawal or change, may choose to avoid specialist clinics and consequently miss out on important care and information. The ABN has established a Valproate Working Group to inform and promote safe practice.

In her report, Baroness Cumberlege highlights that more should have been done to ensure that healthcare professionals were aware of and followed guidelines and that regulators and professional organisations should reinforce their use through their professional standards and inspection. The ABN has developed an audit of practice and compliance with the MHRA guidelines and will request that all members audit their own practice. This will complement other surveys in identifying gaps and unmet needs.

A further recommendation in the report is that a clear process should be agreed to ensure women are able to obtain appropriate counselling related to their epilepsy treatment and contraceptive choices. In this regard, the ABN jointly produced a guidance document with several Royal Colleges and other professional bodies in March 2019 outlining best practice for clinicians, including from whom specialist contraceptive advice could be obtained.

The Cumberlege report recommends a register for all Valproate users. A mandatory national register of valproate users has been discussed by the MHRA for some time, but this has not yet been initiated. The ABN strongly recommends the swift introduction of this register. We also welcome the recommendation that NHSE&I write directly to all women and girls of childbearing potential on Valproate, as well as their GP, asking women to see their GP or specialist for a review. The ABN also strongly supports the implementation of an online system for the pregnancy prevention programme, including confirmation that the Risk Acknowledgement Form has been signed within the previous year, thus ensuring all the relevant healthcare professionals can access this information.

The ABN is aware that there are a number of pregnancies each year in women taking Valproate. The ABN Valproate Working Group has recently highlighted the need for an in-depth analysis of each of these pregnancies to better understand the circumstances, establish if appropriate counselling had been provided and, if not, where the failings occurred. This will enable informed learning to improve practice. The ABN runs a national survey system allowing regular collection of information on specific neurological questions, which it will use to gather detailed information about pregnancies on valproate. The system will also collect information on other important outcomes such as the loss of seizure control, SUDEP and status epilepticus following either the withdrawal of valproate or switch to an alternative antiepileptic medication. As clinicians, we are aware that there are risks associated with other antiepileptic drugs taken during pregnancy, and strongly advocate the prospective registry suggested by Baroness Cumberlege for all women on antiepileptic drugs who become pregnant. This should include mandatory reporting of data

relating to women and their child(ren) collated over lifetimes to complement the current voluntary registers, such as The UK Epilepsy and Pregnancy Register. This would facilitate the earlier detection of teratogenic risks for other drugs.