

To: Dr Henrietta Hughes  
Patient Safety Commissioner for  
England

By email:  
[commissioner@patientsafetycommissio  
ner.org.uk](mailto:commissioner@patientsafetycommissioner.org.uk)

Professor Sir Stephen Powis  
NHS England  
Wellington House  
133-155 Waterloo Road  
London  
SE1 8UG

30 January 2024

cc. Aidan Fowler and David Webb

Dear Henrietta,

Thank you for your letter of 2<sup>nd</sup> November 2023 in which you made the following helpful recommendation:

“The Patient Safety Commissioner recommends for NHS England to have a fully funded and resourced system for improving the safe use of the most potent teratogenic medications, through a National Quality Improvement Programme for Integrated Care Systems, starting with the safe use of sodium valproate. The Commissioner believes that this should be implemented by September 2024 for sodium valproate, before expanding to cover any medication with a Pregnancy Prevention Programme by September 2025”.

We welcome your call for a national quality improvement programme. Since February 2023 NHS England has taken an improvement approach to supporting the quality of care for patients taking, or considering taking, valproate. This approach is a complement to the work of NHS IMPACT which describes a broad framework for improvement.


Over the past few months, a national quality improvement programme has been codesigned by our patient safety team, representatives from ICBs from across England, and NHS England’s National Clinical Directors and Speciality Advisers.

Focussing initially on the immediate needs relating to valproate, the programme sets out to:

- support fully informed shared decision making when making choices around the use of valproate.
- improve the reliability of the Pregnancy Prevention Programme.
- address inequalities in valproate use and harms by applying the principles of Core20plus5.
- reduce the prescribing of valproate such as in bipolar disorder and its unlicensed uses such as in mood stabilisation where suitable alternatives exist.
- reduce variation in care that seen across the country, particularly in migraine, neuropathic pain and possibly focal epilepsy.

The programme will achieve this by using data and intelligence to understand local problems and the circumstances that lead to reliable, person-centred care. It will then share learning between Integrated Care Boards that can be used to adapt and adopt solutions that result in measurable improvements in care. Participants are leaders and activists in their local systems. The co-design





group agreed to extend the remit to other potent teratogenic medicines with a pregnancy prevention programme once sufficient progress and learning had been achieved in valproate. The patient safety team will assess progress every 3 months to ensure that by September 2025 the programme encompasses all potent teratogenic medicines that have a pregnancy prevention programme.

Participants in the programme held their first meeting on the 21<sup>st</sup> November 2023.

Across England, we continue to see a fall in the number of women aged 13 to 54 who are prescribed valproate. We expect this to continue as we support ICBs to improve and implement the new measures being introduced by the MHRA.

We continue to monitor progress and identify opportunities for improvement across England through analysis of primary care prescribing data provided by NHS Business Services Authority. This allows us to draw insights into the prescribing of valproate, isotretinoin and topiramate all of which have, or are expected to have, a pregnancy prevention programme.

We also continue to monitor the Medicines in Pregnancy Registry and analyse the data by ICB to enable them to assure their systems and processes. Two other drugs, used only in secondary care, have a pregnancy prevention programme that is stringently monitored by the MHRA.

Thank you, once again, for your support and the work you do for patients.

Yours sincerely,



**Professor Sir Stephen Powis**

National Medical Director

NHS England