**Consultation on the adoption of the National shared care protocol: Valproate medicines for patients of child-bearing potential – shared care protocol to reflect updated safety advice for all prescribers**

**Executive Summary**

The Humber and North Yorkshire ICS are seeking views from all stakeholders regarding the adoption and implementation of the national shared care protocol for valproate medicines. Feedback is sought on the feasibility of adopting the protocol as a working document and what barriers, if any, exist which could prevent this being implemented in all localities of the ICS.

The system views will be collated and used to inform the roll-out of this shared care protocol as well as to guide the ICB’s strategy for the potential adoption of the remaining national shared care protocols.

**Background**

In July 2022 a national shared care protocol document was published to support the safe use of valproate medicines for patients of child-bearing potential. The current advice on reducing the risks of valproate prescribing to women and girls of child-bearing potential can be found on the UK Government’s [Valproate use by women and girls - GOV.UK (www.gov.uk)](https://www.gov.uk/guidance/valproate-use-by-women-and-girls) site:

* Valproate must no longer be used in any woman or girl able to have children unless she has a pregnancy prevention programme in place. This is designed to make sure patients are fully aware of the risks and the need to avoid becoming pregnant.
* If valproate is taken during pregnancy, up to 4 in 10 babies are at risk of developmental disorders, and approximately 1 in 10 are at risk of birth defects.
* Valproate must not be used in any woman or girl able to have children unless there is a pregnancy prevention programme (PPP) in place.
* Healthcare professionals who seek to prescribe valproate to their female patients must make sure they are enrolled in the PPP. This includes the completion of a signed risk acknowledgement form when their treatment is reviewed by a specialist, at least annually.
* No woman or girl should stop taking valproate without first discussing it with their doctor.

To promote a standard approach to Shared Care Protocols including valproate medicines (SCPs), on behalf of the national Regional Medicines Optimisation Committees (RMOCs) system, RMOC (North) led the development of [Shared Care for Medicines Guidance – A Standard Approach](https://www.sps.nhs.uk/articles/rmoc-shared-care-guidance/), followed by an initial [18 shared care protocols](https://www.england.nhs.uk/publication/shared-care-protocols/) for medicines which met the criteria. See [NHSE’s shared care protocols](https://www.england.nhs.uk/medicines-2/regional-medicines-optimisation-committees-advice/shared-care-protocols/) page for more information on the development and rationale for national shared care protocols.

It is the responsibility of local systems to adopt the national documents, and Humber and North Yorkshire ICS have chosen valproate as the first of a potential 18 shared care protocols for implementation, this is because of the significant safety concerns surrounding the use of this medicine.

**Process**

Humber and North Yorkshire ICS are seeking the views of all stakeholders on the feasibility of implementing the national document and all its recommendations. The consultation will actively seek input from specialists and generalists in both primary and secondary care settings and will be open for responses from individuals and organisations as well as from the general public.

**The clinical content in the document has already undergone a robust national consultation and the ICS is not seeking feedback on this**. Any significant clinical errors or omissions will be brought to the attention of the NHSE medicines policy team for amendment of the national document as necessary.

The consultation will be open for 6 weeks on the ICB website [IMOC Consultations - Humber and North Yorkshire Health and Care Partnership](https://humberandnorthyorkshire.org.uk/imoc/imoc-consultations/) from 24/10/2022 to 5/12/2022 and will ask:

1. Do you/your organisation support the implementation of this shared care protocol?
2. What barriers may prevent you/your organisation from implementing the full shared care protocol?
3. If there are barriers to implementation, what, in your opinion, would help resolve these?

Following the closing of the consultation, the responses will be collated by an independent NHS partner organisation and shared with the ICB Integrated Medicines Optimisation Committee (IMOC) and will be used to guide how the ICB looks to implement the valproate safety recommendation and also inform the strategy that may be adopted should the ICB wish to continue with the implementation of the remaining national shared care protocols.

If you have any questions, or for further information please contact the Regional Drug and Therapeutics Centre (RDTC) via; [nuth.nyrdtc.rxsupp@nhs.net](mailto:nuth.nyrdtc.rxsupp@nhs.net).