Frimley Health and Care

Implementing MHRA sodium valproate guidance for women and people of childbearing potential (aged under 55 years)

Developed by NHS England South East in consultation with clinicians and ICBs in SE Region

The purpose of this document is to share information about implementing the MHRA valproate guidance based on experience of carrying out the annual valproate reviews and completing the annual risk acknowledgement forms (ARAFs) across NHS South East.

Changes may be implemented to the guidance in the coming months but we want to try to establish good practice with the existing guidance as it is. We think it will then be easier to address the changes as and when they arise.

1. This is a person-centred risk minimisation process which at all times respects the wishes and choices of the person and/or their carers. Every woman or person who could become pregnant with capacity is able to choose whether or not they take valproate and/or whether or not they engage with the MHRA guidance.
2. This is not about taking people off medication that is working well for them, nor is it about forcing people to use contraception when they do not want to.
3. This guidance does not apply to Sodium Valproate (SV) administered in an emergency situation which can be prescribed when clinically indicated.
4. For some women and people who could become pregnant, valproate may be the only drug that controls their condition and so they will make the decision to become pregnant whilst taking this drug, hopefully with the full support of the specialist and the other professionals involved in their care.
5. The MHRA guidance applies only to women, girls and people of childbearing potential. ARAF should be completed on at least one occasion. The discussion should be clearly documented in medical records and relevant correspondence, and the position should be reviewed at least annually in case of changes in circumstances.
6. Patients in box 1 are excluded:

Box 1: People are excluded if they	
•	Are over 55 years (unless they are planning a family)
•	Have had a total or partial hysterectomy
•	Have had a bi-lateral oophorectomy or bilateral salpingo-oophorectomy (and are not considering IVF)
•	Have a confirmed menopause or documented no period for 12 months plus
•	Have been sterilised
•	Have another documented reason for infertility
•	Wish to be permanently excluded from the annual review (see point 6 below)

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NOTE: girls who have not yet started their periods should NOT be excluded.

7. People who have been excluded from the pregnancy prevention programme should have a final ARAF recorded.
8. Women, girls and people who could become pregnant who have a learning disability are not automatically excluded. However, for many people in this group, risk of pregnancy is negligible because they are supervised 24/7 by carers or family. ARAF should be completed on at least one occasion. They may also have co-morbidities that mean they would not be able to become pregnant. As part of the LD annual health check reviewing whether an ARAF has been done or the sexual situation has changed in women is recommended.
9. Should a women or person with a learning disability become pregnant clinicians should use a needs-led personalised care approach, incorporating individual capacity and risk assessments and agreeing management of any identified risks. Where safeguarding concerns are identified, these should be raised through the appropriate channels and processes and managed supportively.
10. If the person's condition and circumstances are unlikely to change, the specialist may decide to annotate the ARAF to permanently exclude the person, especially if undertaking the annual reviews are distressing for the patient/carer. This is acceptable. The person no longer requires annual review.
11. If the person's risk of pregnancy in the next 12 months is considered low (See box 2) the specialist may annotate the ARAF to reflect this, giving the reason. This is acceptable.

Box 2: Lower risk of pregnancy	
•	Woman or person is at older end of age range (45 +)
•	Woman or person is peri-menopausal
•	Woman or person is in monogamous relationship where partner has had a vasectomy
•	Sexually active exclusively with female partner(s)
•	Girl/woman/person not currently sexually active and unlikely to be so in next 12 months

12. If the person's likelihood of pregnancy is not low and they decline the annual review and decline the PPP once the information on risk to a baby should pregnancy occur has been shared, this should be documented. Annual reviews should continue to be offered.
13. Women and people who are of child bearing potential and sexually active or likely to be so in the foreseeable future should be offered highly effective contraception (HEC) as defined by the MHRA – see box 3. This should be documented. It should be recognised that this is the woman or person's choice, and the clinician should take a pragmatic view.

14. If the woman or person declines highly effective contraception prescribers should clearly document discussions and decisions in clinical letters/systems. this may include sexual health clinics and community pharmacies. For some women or people hormonal contraceptive may exacerbate their epilepsy. For some women or people with learning disability the insertion of an intrauterine device may necessitate a general anaesthetic.

Box 3: Highly effective contraception*	
•	Copper intrauterine device
•	Levonorgestrel intrauterine device
•	Progestogen only implant **
•	Progestogen only injection ***
•	'doubling up' of two user dependent methods e.g. combined oral contraceptive plus barrier method (this is a less reliable form of contraception relying on users)

* Confirm that HEC is within manufacturer's licensed duration of use:
Intrauterine contraception (fsrh-guideline-intrauterine-contraception-sep-2019.pdf)
Progestogen only implant (2fsrh-guideline-progestogen-only-implant-feb-2021.pdf)
** may not be suitable if the patient is using other enzyme inducing anti-seizure medicines
** considered HEC if there is documented evidence that repeat injections have been administered on schedule.

15. Undertaking the annual valproate risk acknowledgement consultation remotely can be a good use of time for people and specialists alike. Experience has shown there are often issues getting the form signed and returned however. It is better to get a form annotated as 'verbally acknowledged' by the person/responsible person. Ultimately the form is just confirmation that the actual consultation has taken place which is key.

16. There have been a number of cases where practices have withheld valproate from people because the ARAF has not been completed. It is down to the prescriber to decide whether they wish to prescribe outside the license, of course, however not prescribing can have devastating and even life-threatening consequences and in nearly all cases the valproate should be prescribed.

References:

- Valproate use by women and girls: information about the risks of taking valproate medicines during pregnancy 2023 (online) Valproate use by women and girls - GOV.UK (www.gov.uk)
- MHRA. Valproate use by women and girls. 2018 [online]. www.gov.uk/guidance/valproate-use-by-women-and-girls
- Pan Colleges' Guidance on valproate (2020)
- Pan_College_Guidance_Document_on_Valproate_Use V2.1.pdf (rcpch.ac.uk)