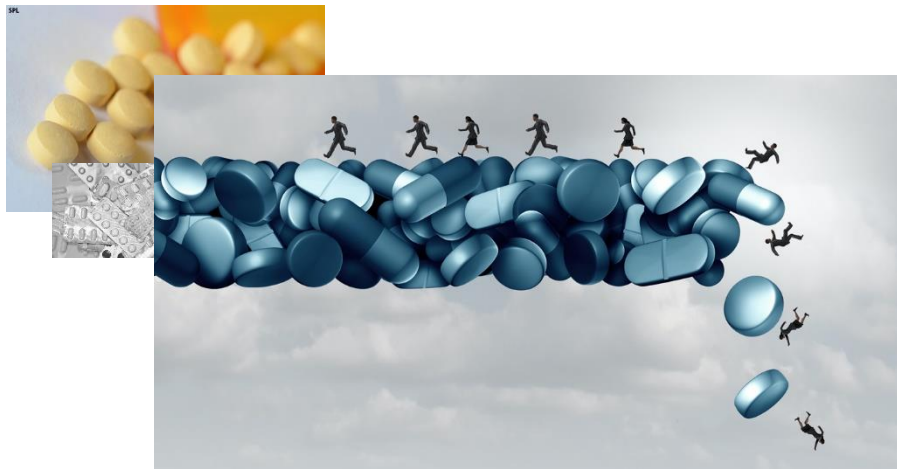


Bitesize Education and Training Session 10

Valproate

17th September 2024



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Speaker:

- Tara Gallagher - Network Pharmacy Director, Lancashire & South Cumbria NHS Foundation Trust and Chair of the Lancashire & South Cumbria Valproate Steering Group

Welcome & Housekeeping

Thank you for joining us today!

- ✓ The session is for 30-minutes (20-minute presentation and 10-minute Q&A session).
- ✓ Please switch off your cameras and put yourselves on mute.
- ✓ Please use the chat function if you want to ask a question or for comments.
- ✓ Please respect others' views and opinions. (We have prescribers from across the system on the call – primary, secondary care and community).
- ✓ Please use the chat function to network with your peers and share ideas.
- ✓ At the end of the session there is a short feedback questionnaire – the link to access this will be put into the chat.

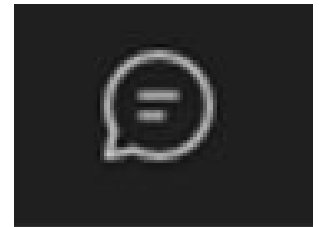
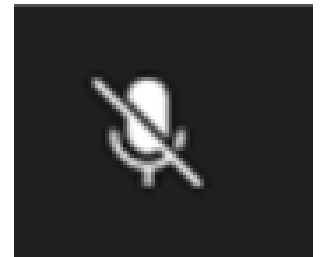
Please note the 20-minute presentation will be recorded, and the slides and the recording will be uploaded to the LSC Training Hub website for you to download.



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CPD update – Valproate

September 2024

Tara Gallagher

Network Pharmacy Director, Lancashire & South Cumbria NHS
Foundation Trust

Chair of the Lancashire & South Cumbria Valproate Steering Group

Valproate and risk of congenital defects and neurodevelopmental disorders

Valproate use in females:

- Valproate can cause birth defects in 1 in 10 children
- 1 in 3 (30-40% risk) can have serious development problems e.g. autism, learning disability, and possibly ADHD

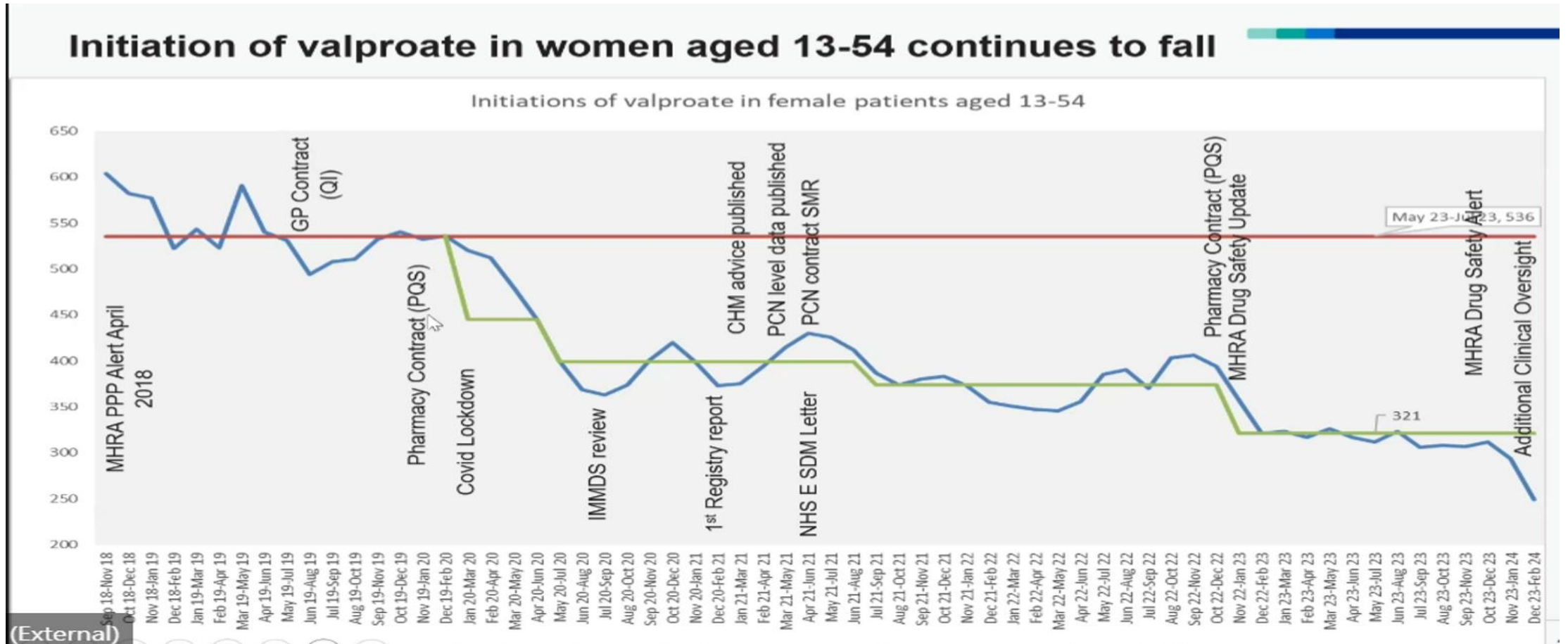
Valproate use in males:

- Approximate 5% increased risk of neurodevelopmental conditions in a child conceived by a male taking valproate
- In addition potential risk of infertility and testicular toxicity

Valproate: Regulatory Requirements

- Valproate medicines must not be used in women of childbearing potential unless the Pregnancy Prevention Programme is in place.
- If you are **involved in the care** of female patients on valproate in the UK, see a reminder of actions required for this medicine.
- Valproate must not be started in new patients (male or female) under the age of 55 unless two specialists independently consider and document that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply
- At their next annual specialist review, women of childbearing potential and girls should be reviewed using a revised valproate Risk Acknowledgment Form (RAF), which will include the need for a second specialist signature if the patient is to continue with valproate and subsequent annual reviews with one specialist unless the patient's situation changes
- Men taking valproate and their partners are being advised by the Medicines and Healthcare products Regulatory Agency (MHRA) to use effective contraception because of new data suggesting a potential small increased risk of harm to children if valproate is used by a father at conception.

Valproate Prescribing in England



Valproate Prescribing in L&SC

	December 2023	August 2024
Total number of patients under 55 years (male or female) prescribed valproate	3,493	2,863 (↓18%)
Females 13-54 years prescribed valproate	697	650 (↓7%)
Females 0-55 years prescribed valproate*	756	684 (↓10%)
Female 13-54 years with Epilepsy	488	461 (↓6%)
Female 13-54 years with Mental Health diagnosis	118	109 (↓8%)
Female 13-54 years with neither Epilepsy nor Mental Health diagnosis	105	80 (↓24%)
New initiations of valproate in females aged 13-54 years*	December 2023 - March 2024 11	April - June 2024 9 (↓18%)
Males under the age of 55 years	2,346	2,156 (↓8%)

- 2,868 patients (712 female and 2,156 male) under the age of 55 years in receipt of a prescription for valproate.
- Female: Male ratio of valproate prescribing for all indications remains stable at 1:3
- 650 females between the age of 13-54 years prescribed valproate, 461 (70%) of which have a diagnosis of Epilepsy, 109 (17%) have a mental health diagnosis and 80 (12%) of patients prescribed valproate have neither a tagged diagnosis of Epilepsy nor a Mental Health condition.
- 107 female patients have been reviewed and identified as not requiring any further annual review. Of the remaining 543 females aged 0-54 years prescribed valproate, 172 (32%) have had an annual review by a specialist documented in their primary care clinical record.

* Data retrieved from the valproate dashboard on ePACT2, April 2024 – June 2024

How all NMP's can support safe use of valproate

Act now to use the following to support the new Valproate Pregnancy Prevention Programme:

- Patient Card – to be given by pharmacists to all female patients who are dispensed valproate medicines to inform them of the risks
- Patient Guide – to be provided to girls (of any age) and women of childbearing potential (or their parent/caregiver/responsible person) taking any medicine containing valproate
- Guide for Healthcare Professionals – for all prescribers, pharmacists, and other healthcare providers involved in the care of women and girls of childbearing potential using valproate medicines
- Risk Acknowledgement Form – for the specialist and patient (or their parent/caregiver/responsible person) to sign at initiation and at treatment reviews at least every year. The patient should receive a copy of the form; one copy should be filed in the specialist notes, and one copy sent to the patient's GP

- Check the patient is informed of the risks
- Confirm that females are using highly effective contraception and males effective contraception
- Enquire as to when they last had a review by a Specialist
- Inform and signpost

Useful references

- [Valproate use by women and girls \(March 2018, last updated Jan 2024\)](#)
- [NPSA Valproate: organisations to prepare for new regulatory measures for oversight of prescribing to new patients and existing female patients](#)
- [Valproate use in men: as a precaution, men and their partners should use effective contraception](#)
- [Patient Guide: What you need to know about valproate \(updated Dec 2023\)](#)
- [Guide for Healthcare Professionals Information on the risks of valproate use in all patients \(updated Dec 2023\)](#)



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Thank you!

Thank you for listening

Please complete our short feedback questionnaire by clicking on the link that has been put into the chat.

Please note: all feedback will be anonymous



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Next session: 15th October 2024

Part 2 of Depression & Anxiety Management in
Primary Care

Vicki Jordan

Senior Primary Care Mental Health

*Practitioner/Independent Prescriber, Primary Care
Clinical Advisor in Mental Health*

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Question and Answer



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