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2022/23 Community Pharmacy Contractual Framework National Clinical Audit

Reducing the potential for harm from valproate prescribing in patients of childbearing age who are biologically able to be pregnant

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1. Introduction

1.1 NHS England and the Pharmaceutical Services Negotiating Committee (PSNC) have agreed that in 2022/23, the national clinical audit to be undertaken by all community pharmacy contractors will focus on preventing harm from valproate prescribing in patients of childbearing age who are biologically able to be pregnant following the publication of the recommendations of the previous audit[1] carried out in 2019/20.

2. Background to the audit topic

2.1 As part of the Medicines and Healthcare products Regulatory Agency (MHRA) Drug Safety Update 2018,[2] all pharmacies were sent information and educational materials in June 2018 (the MHRA guidance and educational materials for healthcare professionals)[3] advising them of the need to identify those of childbearing potential currently being prescribed valproate. This also detailed a series of actions for health professionals, including pharmacists, to undertake.

2.2 Valproate use in pregnancy is associated with an increased risk of children being born with congenital abnormalities and developmental delay.[4] Valproate is contraindicated in patients of childbearing age who are biologically able to be pregnant unless the conditions of the valproate pregnancy prevention programme are fulfilled. This is designed to make sure patients are fully aware of the risks and the need to avoid becoming pregnant while taking valproate.

2.3 All community pharmacy teams have the potential to encounter patients who do not engage with other care services regularly due to their accessibility and are therefore in an ideal position to carry out this audit and ensure people understand the risks.

2.4 A valproate audit was previously conducted as part of the 2019/20 Pharmacy Quality Scheme (PQS). This audit has been analysed and learnings, findings and recommendations can be found here.[5] All contractors should familiarise themselves with and adhere to the recommendations provided in this report.

[1] https://www.england.nhs.uk/publication/community-pharmacy-preventing-harm-from-valproate-pharmacy-quality-scheme-audit-report-2019-20/
[2] https://www.gov.uk/drug-safety-update/valproate-medicines-epilim-depakote-contraindicated-in-women-and-girls-of-childbearing-potential-unless-conditions-of-pregnancy-prevention-programme-are-met
[3] https://www.gov.uk/guidance/valproate-use-by-women-and-girls
[4] https://www.epilepsy.org.uk/info/daily-life/having-baby/valproate-pregnancy
[5] https://www.england.nhs.uk/publication/community-pharmacy-preventing-harm-from-valproate-pharmacy-quality-scheme-audit-report-2019-20/

3. Purpose of the audit

3.1 The Terms of Service of NHS pharmacists[6] includes a requirement to participate in a single annual audit set by NHS England. For 2022/23, this audit will focus on preventing harm caused by valproate prescribing in patients of childbearing age who are biologically able to be pregnant.

3.2 The MHRA safety requirements[7] for the use of valproate in a sizeable minority of patients of childbearing age who are biologically able to be pregnant are not being fully met. In October 2022, the General Pharmaceutical Council (GPhC) reminded pharmacy staff of the importance of these requirements.[8] In the previous audit cycle undertaken as part of PQS in 2019/20, of the 12,068 patients who took part, 10.6% indicated they did not have a copy of the Patient Guide,[9] 11.1% indicated they did not have a copy of the Patient Alert Card[10] and 36.2% reported they were not using highly effective contraception.[11] This completes the audit cycle and will demonstrate any improvements made since the audit in 2019/20.

3.3 The aims of the audit are:

- To reduce the potential for harm from valproate prescribing in patients of childbearing age who are biologically able to be pregnant.
- To reinforce the actions that the MHRA has advised pharmacists need to undertake when dispensing valproate to patients of childbearing age who are biologically able to be pregnant.
- To assess the extent to which the recommendations of the 2019/20 valproate audit have been embedded into practice.

[6] https://www.legislation.gov.uk/uksi/2013/349/schedule/4/made
[7] https://www.gov.uk/guidance/valproate-use-by-women-and-girls
[8] https://www.pharmacyregulation.org/news/update-valproate-0
[9] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/950801/107995_Valproate_Patient_Booklet_v05_DS_07-01-2021.pdf
[10] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/950800/107995_Valproate_Patient_Card_v05_DS_07-01-2021.pdf
[11] https://www.england.nhs.uk/wp-content/uploads/2022/07/B1504_Community-Pharmacy-Quality-Scheme-2019-20-valproate-audit-report-July-2022.pdf

3.4 The audit standards are:

Standard 1
100% of patients are provided with a Patient Card by the pharmacy **every time** valproate is dispensed.

Standard 2
100% of patients have received the Patient Guide.

Standard 3
100% of patients who have not received a review from a specialist in the last 12 months are referred/signposted to their GP practice or specialist.

Standard 4
100% of patients who are not on highly effective contraception in line with the pregnancy prevention programme are referred/signposted to their GP practice or specialist, where appropriate.

3.5 It is expected that pharmacists familiarise themselves with the actions described in the MHRA Drug Safety Update 2018.[12] To refresh understanding of this guidance it is recommended that it is read in full as well as the GPhC update[13] before starting the audit. In addition, a joint resource[14] has been published by the Community Pharmacy Patient Safety Group and the Royal Pharmaceutical Society in partnership with the pharmacy organisations represented on the MHRA's Valproate Stakeholder Network. This builds on the MHRA's national toolkit for all healthcare professionals and assists pharmacists in understanding where they can advise and help patients.

3.6 The GPhC also has a sodium valproate resources and information page on their website,[15] which highlights that Epilim boxes now have a perforated patient card which can be flipped up or removed to reveal a space for the patient label. It is important to make sure that this patient card is kept with the box and is given to the patient along with their medicine, and that the patient label is not placed over the warning labels or warning sticker on the box.

4. When should the audit be completed?

4.1 The 2022/23 audit should be conducted at any point during the financial year (finishing no later than 31 March 2023). Data must be collected for six weeks.

[12] https://www.gov.uk/drug-safety-update/valproate-medicines-epilim-depakote-contraindicated-in-women-and-girls-of-childbearing-potential-unless-conditions-of-pregnancy-prevention-programme-are-met
[13] https://www.pharmacyregulation.org/news/update-valproate-0
[14] https://pharmacysafety.org/2018/06/25/valproate-safety/
[15] https://www.pharmacyregulation.org/standards/guidance/sodium-valproate-resources-and-information

4.2 The audit will be conducted during this period as it allows contractors the flexibility to decide when to carry out the audit.

4.3 **Undertaking the audit is a contractual requirement**.

5. Undertaking the audit

5.1 To undertake the audit, contractors should:

a. Choose a six-week consecutive period between the audit launch and 17 February 2023 when you will commence the data collection (please ensure you complete the audit no later than 31 March 2023).
b. Ensure the pharmacy team are familiar with the actions described in the MHRA Drug Safety Update 2018[16] and review the recommendations of the 2019/20 valproate audit report found here.[17]
c. Check if you have packs of information (Patient Guides, Patient Cards, warning stickers, etc.) to support and inform patients of childbearing age who are biologically able to be pregnant who are taking valproate of the risks of pregnancy and the need to be enrolled in the Pregnancy Prevention Programme. If not, these can be ordered from Sanofi's medical information department on 0845 372 7101 or by emailing UK-Medicalinformation@sanofi.com.
d. Print out a copy of the data collection sheet found in Appendix A.
e. Identify patients who are prescribed valproate, consult these patients and collect the data required on the data collection sheet for 6 weeks. Contractors should make a record of the start and end date of the audit as this will need to be entered into the Manage Your Service (MYS) portal.[18] The information will need to be obtained through a conversation with the patient or patient's representative (if appropriate).
f. Include each patient once during the audit period eg, during the consecutive six-week audit period, if a patient has their valproate dispensed on two occasions, the information should only be recorded once for the audit. The details of the discussion should be recorded on the PMR or appropriate patient record.
g. Ensure that the provision of advice to a patient representative should only be made if appropriate; it may be more appropriate to follow up directly with the patient. It is important that patients do not stop taking valproate without first discussing this with their prescriber.

[16] https://www.gov.uk/drug-safety-update/valproate-medicines-epilim-depakote-contraindicated-in-women-and-girls-of-childbearing-potential-unless-conditions-of-pregnancy-prevention-programme-are-met
[17] https://www.england.nhs.uk/publication/community-pharmacy-preventing-harm-from-valproate-pharmacy-quality-scheme-audit-report-2019-20/
[18] https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dispensing-contractors-information/manage-your-service-mys

h. Once the data collection is completed, visit the Valproate Audit 2022/23 tab on the MYS portal[19] and enter the data from the data collection sheet onto the web-based form. Do not enter any patient identifiable information onto MYS.
i. Ensure if no suitable patients are found to participate in the audit during the six-week period, the 'No eligible patients' box is ticked within the Valproate Audit 2022/23 tab on MYS and submit this information. This will create a record which will act as evidence that the audit has been completed even though no patient data has been added to MYS.
j. Ensure they have received a confirmation email following submitting their data on MYS. Contractors should retain this as evidence of having submitted their data.
k. Ensure that if a confirmation email is not received, that the audit results have been submitted on MYS and check the junk email folder in case the email has been filed there. If the audit results have been submitted and a confirmation email can still not be found, contact nhsbsa.mys@nhs.net for further help.

6. Action to be taken following the audit

6.1 Once the data has been submitted, contractors should consider the pharmacy's compliance with the audit standards and whether there are changes which should be made to improve compliance levels in line with GPhC and MHRA advice.

6.2 A record of these changes can be made using the template in Appendix B. This should be retained in the pharmacy as evidence of having completed the audit. Contractors who are participating in the PQS 2022/23 could also consider incorporating the results of their audit into their Patient safety report (which is a gateway criterion for the 2022/23 Scheme).

6.3 Once all pharmacies have submitted their audit data, NHS England will communicate findings to contractors.

Thank you for taking part in this audit. If further guidance on this audit is required, please contact your local NHS England team.[20]

[19] https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/dispensing-contractors-information/manage-your-service-mys
[20] https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-contract-teams/

Appendix A: Audit data collection sheet

Summary of actions for pharmacists

1. Ensure the Patient Card[21] is provided every time valproate is dispensed (or where incorporated into packaging, this is highlighted to the patient).
2. Remind patients of the risks in pregnancy and the need for highly effective contraception (https://www.fsrh.org/news/mhra-contraception-drugs-birth-defects-fsrh-guidance/).
3. Remind patients of the need for an annual review by a specialist and refer/signpost to the GP practice or specialist where appropriate.
4. Ensure the patient has received the Patient Guide[22] and note this in the PMR or appropriate record where appropriate.
5. Dispense valproate in the original package. In situations where repackaging cannot be avoided, always provide a copy of the package leaflet, and add a label with the warning to the outer box.
6. If a patient of childbearing potential reports that they are not taking highly effective contraception, refer them to their GP practice or specialist, where appropriate (including by contacting the GP practice if necessary).

For further information:

- MHRA Drug Safety Update – Valproate (2018) (https://www.gov.uk/drug-safety-update/valproate-medicines-epilim-depakote-contraindicated-in-women-and-girls-of-childbearing-potential-unless-conditions-of-pregnancy-prevention-programme-are-met)

- Valproate Pregnancy Prevention Programme (https://assets.publishing.service.gov.uk/media/5e173cf3ed915d3b0f31a5cc/valproate-pharmacy-2020.pdf)

- Pregnancy Risks and the need for highly effective contraception: https://www.gov.uk/drug-safety-update/medicines-with-teratogenic-potential-what-is-effective-contraception-and-how-often-is-pregnancy-testing-needed

21 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/950800/107995_Valproate_Patient_Card_v05_DS_07-01-2021.pdf

22 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/860760/Patient-booklet.pdf

Patients who are of childbearing age and have been dispensed a prescription for valproate: Start date: End date:

								Sheet Totals		
	Patients' initials:									
	Y = Yes N = No DK = Don't know ***If the patient's representative does not know the answer record as don't know.**	**Y/N/DK**	**Y/N/DK**	**Y/N/DK**	**Y/N/DK**	**Y/N/DK**	**Y/N/DK**	**Total Y**	**Total N**	**Total DK**
1.	Has the patient/representative agreed to discuss their valproate medicine with the pharmacist? Y or N – if no, please answer Q4/4a only									
2.	Has the patient/representative been provided with advice and information in line with the MHRA Drug Safety Update on valproate 2018 concerning the potential impact on an unborn child? * Y / N or DK									
3.	Does the patient already have a copy of the Patient Guide? * Y / N or DK **If yes, move to Q3b.**									
3a.	If not, has the patient/representative now been provided with a copy of the Patient Guide by the pharmacist? Y or N **If no, move to Q4.**									
3b.	Is it recorded, or now recorded, on the PMR or other appropriate record that the patient has a copy of the Patient Guide? Y or N									
4.	Has the patient/representative been provided with a Patient Card by the pharmacist (this should be provided each time valproate is dispensed and can include patient cards incorporated into medication packaging where this is highlighted to the patient)? Y or N **If no, move to Q5.**									
4a.	Is it recorded on the PMR or other appropriate record that the Patient Card has been supplied? Y or N									
5.	Has the patient seen their specialist to discuss their use of valproate in the past 12 months? * Y / N or DK **If yes, move to Q5b.**									
5a.	If not, was the patient referred/signposted back to their GP practice or specialist for an annual review? Y or N									
5b.	Has this conversation been recorded on the PMR or other appropriate record? Y or N									
6.	Does the patient have highly effective contraception in line with the pregnancy prevention programme? * Y / N or DK **If yes, move to Q6b.**									
6a	Was the patient referred/signposted back to their GP practice or specialist to discuss contraception? (Only if appropriate**) Y or N									
6b.	Has this conversation been recorded on the PMR or other appropriate record? Y or N									

* If the patient's representative does not know the answer record as don't know.

** Contractors should record as 'not applicable' (N/A) if it is not appropriate for the patient to be referred back to their GP practice or specialist if for example the patient has had a hysterectomy, is post-menopausal or for any other compelling reason to indicate there is no risk of pregnancy.

Appendix B: Pharmacy contractor review of the audit results

The audit standards were:

1. 100% of patients are provided with a Patient Card by the pharmacy **every time** valproate is dispensed.
2. 100% of patients have received the Patient Guide.
3. 100% of patients who have not received a review from a specialist in the last 12 months are referred/signposted to their GP practice or specialist.
4. 100% of patients who are not on highly effective contraception in line with the pregnancy prevention programme are referred/signposted to their GP practice or specialist, where appropriate.

In this pharmacy __% patients were provided with a Patient Card by the pharmacy **every time** valproate was dispensed.
In this pharmacy __% patients have received the Patient Guide.
In this pharmacy __% patients who have not received a review from a specialist in the last 12 months were referred/signposted to their GP practice or specialist.
In this pharmacy __% patients who are not on highly effective contraception in line with the pregnancy prevention programme were referred/signposted to their GP practice or specialist, where appropriate.

Discuss with your pharmacy team any changes which could be made to your processes to improve compliance levels for reducing the potential of harm from valproate prescribing in patients of childbearing age who are biologically able to be pregnant and record them below:

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Wellington House
133-155 Waterloo Road
London
SE1 8UG

Contact: enquiries@england.nhs.uk

This publication can be made available in a number of alternative formats on request.