North Central London

Valproate Risk Minimisation Guideline

Table of Contents

1. Target audience

This guidance is aimed at all healthcare professionals across all sectors of healthcare in North Central London (NCL) involved in the care of patients who are prescribed valproate.

2. Purpose

This guidance outlines the roles and responsibilities of healthcare professionals involved in the management of those (female and male) who are

(i) prescribed a valproate-containing medicine; and

(ii) the patient either resides within NCL and/or their specialist service is within NCL. This guidance intends to support the safe management of patients prescribed valproate and details local processes and activities to minimise the associated risks (including patient identification, referral, review, clinical coding, prescribing, dispensing, counselling, contraceptive choices, incident reporting and ongoing audits).

3. Introduction

Valproate is a medication used to treat epilepsy, mental health disorders (including bipolar disorder and depression), migraine prophylaxis and pain management. It is an active ingredient licensed under several brand names (Epilim®, Depakote®, Convulex®, Episenta®, Epival®, Kentilim®, Orlept®, Syonell®, Valpal®, Belov®, Dyzantil® and generic sodium valproate). Valproate is associated with a significant risk of physical birth defects (10%), neurodevelopmental disorders (30-40%) and a higher risk of lower weight at birth for gestational age in children born to mothers who take valproate during pregnancy.

Since its introduction in 1974, the risks to unborn children have been increasingly understood and consequently prescribing warnings have been strengthened (coinciding with several MHRA alerts).[1] In recent times, valproate has been the subject of the 'First Do No Harm' report[2] which outlined the history of valproate use and described the impact on the children of patients who took valproate whilst pregnant. In 2018, valproate became **contraindicated** in females and people of childbearing potential unless they meet the conditions of a Pregnancy Prevention Programme (PPP, also known as '*prevent*').[3] In a public assessment report published by the MHRA, the Commission on Human Medicines (CHM) highlighted concerning evidence of testicular toxicity in animal studies as well as the known risk of male infertility and the uncertain but potential epigenetic effects of valproate and potential for transgenerational risk transmission of harm.[4] Following advice from the CHM, the MHRA further strengthened the regulations pertaining to the use of valproate for all people under the age of 55 years. Since January 2024:

1.	Valproate must not be started in new patients (female or male) younger than 55 years, 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.
2.	At their next annual specialist review, females of childbearing potential and girls should be reviewed using the updated valproate ARAF (annual risk acknowledgement form), which includes the need for a second specialist signature if the patient is to continue on valproate while subsequent annual reviews require one specialist signature unless the patient's situation changes.

Further guidance was published in September 2024 relating to male patients of all ages. This resulted from a retrospective observational study that indicated a possible association between valproate use by men around the time of conception and an increased risk of neurodevelopmental disorders in their children:

3.	Inform male patients who may father children of the possible increased risk and the recommendation to use effective contraception during valproate treatment and for at least 3 months after stopping valproate.

In June 2025, updated safety and educational materials were published to support healthcare professionals and patients to implement the existing regulatory requirements. The updates reflect:

- precautionary advice on the potential risk of neurodevelopmental disorders in children fathered by men taking valproate around the time of conception
- a risk of lower weight at birth for the gestational age in children exposed to valproate during pregnancy.

4. Supporting information/guidance

All healthcare practitioners who prescribe valproate should be aware of the supportive risk management materials available from the MHRA:

MHRA	Health Care Professional	Patients
MHRA updated safety and educational materials to support patient discussion on reproductive risks	Booklet for healthcare professionals (for all patients)	Patient guide for women
MHRA guidance on change to regulations	Annual Risk Acknowledgement Form (ARAF) for Female Patients	Patient guide for men
MHRA guidance for contraception during treatment with medicines of teratogenic potential	Risk Acknowledgement Form (RAF) for Male Patients starting Valproate	Patient card
MHRA review of the safety of antiepileptic drug use during pregnancy	MHRA infographics clarifying in which situations a review by two specialists may be required: • for female patients under 55 years old • for male patients under 55 years old • for male and female patients 55 years and older	
MHRA advice on valproate use in men	Valproate dispensary poster	

	Warning stickers for non-original pack dispensing	
	Advice for male patients on valproate to use contraception	
	Visual risk communication diagram to be used by a healthcare professional when counselling on the risks	

Further supportive materials are available from:

Guidance on drug interactions with hormonal contraception	Guidance produced by the Faculty of Sexual & Reproductive Healthcare of the Royal College of Obstetricians and Gynaecologists.
NCL referral information for emergency intrauterine device or long-acting reversible contraception	A document with the relevant contact information for referral into sexual health services, and a complete list of commissioned GP practices who can administer long-acting reversible contraception in NCL.
Contraceptive choices	A website designed to help patients understand the different contraceptive options available to them.
Comparison table of all contraceptive options	The website features the most effective at the top ('highly effective' options are the first 3 rows).

4.1. Contraceptives

Advice for female patients and people of childbearing potential:

At least one 'highly effective' method of contraception or **TWO** complementary forms of contraception (including a barrier method) should be used in females and people of childbearing potential prescribed valproate.

Type of contraception	Includes

Highly effective contraceptive options have <1% failure rate.
Highly effective contraception is considered to be **user-independent** forms, including:
	• Long-acting reversible contraception (LARC), such as:
	  ○ Intrauterine device (IUD); also known as a copper intrauterine device (Cu-IUD)
	  ○ Levonorgestrel intrauterine system (LNG-IUS)
	  ○ Progestogen-only implant (IMP) - Please note effectiveness of the IMP is reduced if taking any enzyme inducing medicines.
	• Female sterilisation

Complementary forms of contraception are **user dependent** methods of contraception have a failure rate >1%.	This includes Combined Hormonal Contraceptives (CHC) including combined oral contraceptives, the Progestogen-Only contraceptive Pill (POP), Depot Medroxyprogesterone Acetate (DMPA) injections which are not considered highly effective since the typical use incorporates user failure risks.

	Failure rates with DPMA injections are due to repeat injections being missed or administered late; if there are regular documented administrations, this may be deemed as a highly effective form of contraception.
When choosing a contraceptive method, individual circumstances are evaluated, and the patient should be involved in discussion to ensure engagement and compliance. Even if the patient has amenorrhoea, they must follow all the advice on highly effective contraception.	

Note regarding menopause and perimenopause: The contraceptive methods described above should be used in patients of childbearing age (those under 55 years) and needs to continue until menopause is confirmed.

Perimenopause is the period of time where a patient could potentially suffer from symptoms of menopause but still has childbearing potential. To avoid misdiagnosis of menopause instead of perimenopause, ensure the patient has been confirmed as having entered menopause before adding the diagnosis and/or SNOMED code to their record.

Menopause is confirmed in otherwise healthy women aged ≥45 years if they have not had a period for ≥12 months only if they are not using hormonal contraception (patients using hormonal contraception should discuss options for alternative contraceptive methods from the age of 50 onwards with their GP or sexual health service). The FSRH recommends that:

If amenorrhoea is experienced in patients between 40-50 years of age, contraception should be continued for a further two years before stopping. If amenorrhoea is experienced in patients >50 years of age, contraception should continue for one year before stopping.
Where using a contraceptive method that obscures menopause (e.g. progestogen-only implant, progestogen-only pill or levonorgestrel intrauterine-system), contraception can be stopped at age 55.

Further information can be found in the FRSH guidance for contraception in females aged over 40 years.

Advice for male patients:

As a precaution, recommend that male patients use effective contraception (condoms, plus contraception used by the female sexual partner) throughout the valproate treatment period and for 3 months after stopping valproate, to allow for one completed sperm cycle not exposed to valproate
Advise men not to donate sperm during valproate treatment and for 3 months after stopping valproate

4.2. Guidance on completing ARAFs during virtual clinics

Initiation of valproate should ideally be conducted via a face-to-face consultation; however, it is acknowledged that for the completion of an ARAF the use of virtual clinics can provide a time and capacity benefit for patients and specialists alike. It is also acknowledged that the use of virtual clinics can cause delays getting signed ARAFs returned to the specialist and GP.

Where obtaining a patient's signature is likely to cause delays due to the use of virtual clinics, the specialist prescriber should:

1.	Ensure the patient/responsible person has received copies of the valproate patient guide and ARAF via an electronic method (e.g. email) prior to attending the virtual clinic. Where the patient does not have access to a method to receive electronic files, this should be recorded in the notes and paper copies sent to the patient via post.
2.	Go through the ARAF during the virtual clinic and get verbal confirmation that the patient and/or responsible person acknowledges the risks of using valproate during pregnancy and the measures needed to reduce the risks.
3.	Document the verbal confirmation in the patients notes. The ARAF should be signed by the reviewing specialist on behalf of the patient stating, "Virtual clinic - verbally acknowledged by patient/responsible person." The completed ARAF should be sent to the patient and their GP, ideally via an electronic method.
4.	Ask the patient to confirm (via email /other messaging service if available) receipt of the ARAF and that it reflects the discussion with the specialist and that they acknowledge the requirements of the PPP.

5. Patient pathway

To better understand the roles and responsibilities detailed in this guidance, it is important to understand the patient pathway and where each healthcare professional has an active role.

- **Figure 1** – Best practice pathway for females and people who can bear children under 55 years prescribed valproate in NCL.
- **Figure 2** – Best practice pathway for males and people who can father children prescribed valproate in NCL.

Figure 1 – Best practice pathway for females and people who can bear children under 55 years prescribed valproate in NCL

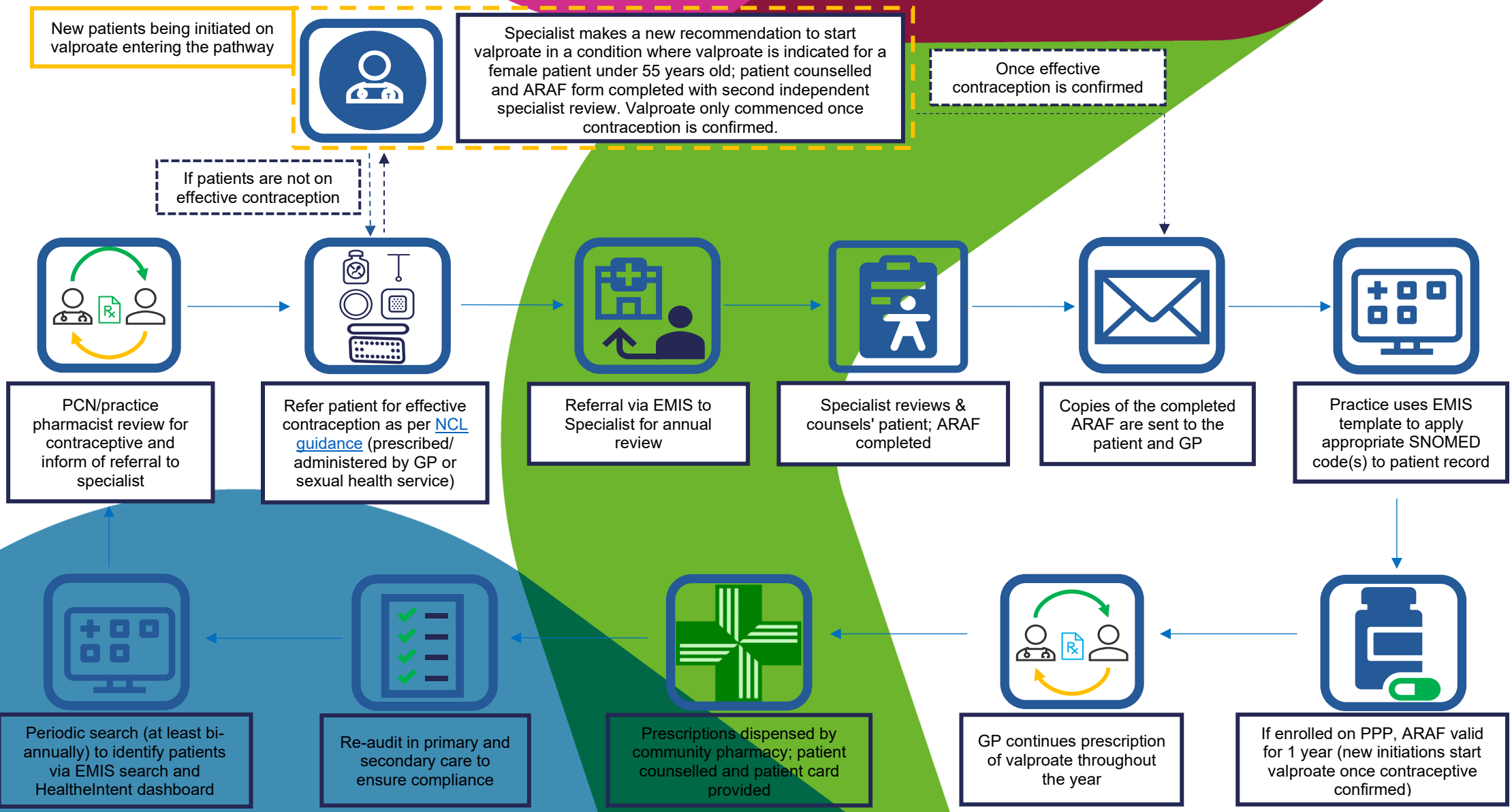
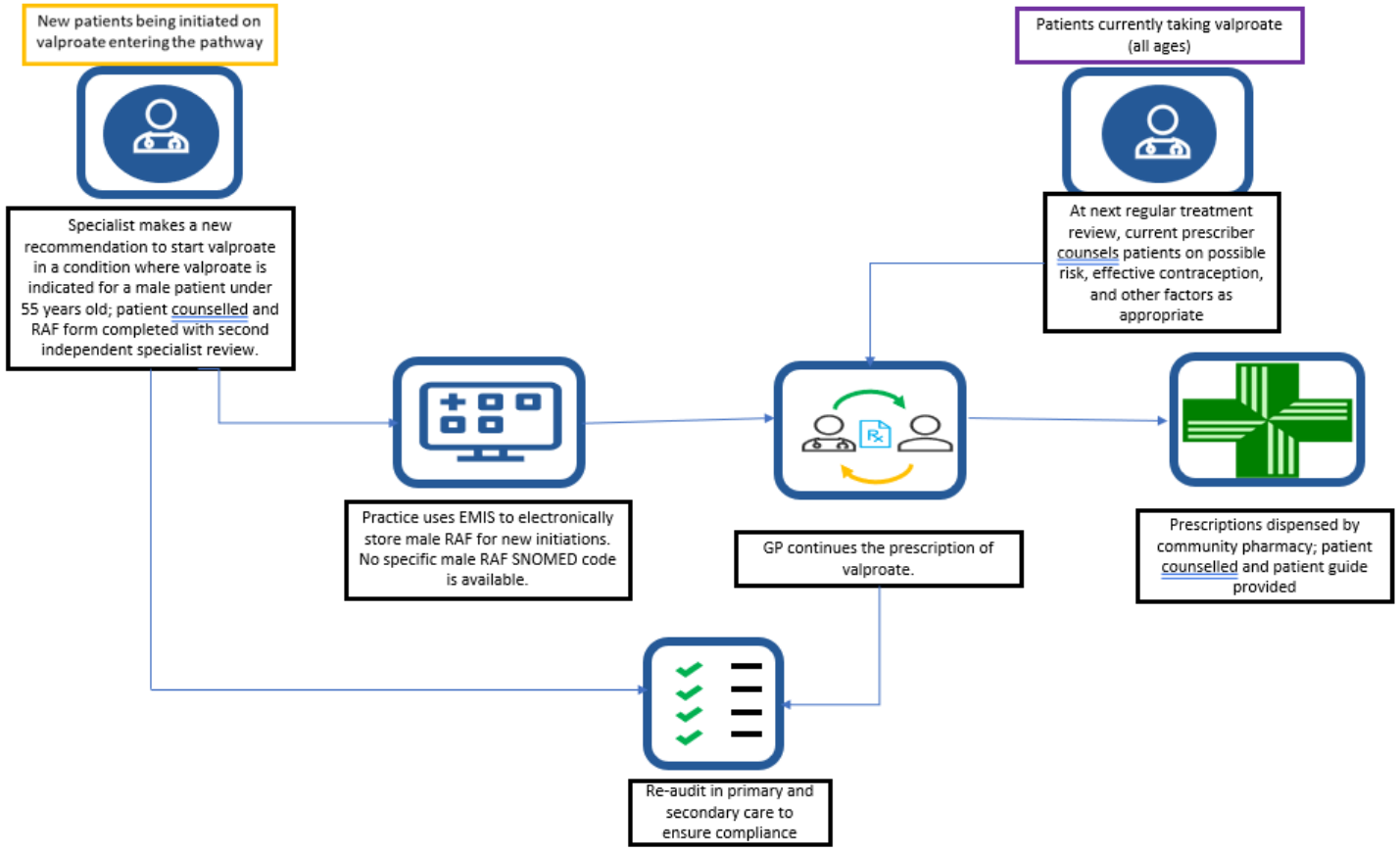


Figure 2 - Best practice pathway for males and people who can father children prescribed valproate in NCL



6. Roles and Responsibilities (for females under 55 years)

It is the responsibility and duty of all healthcare professionals to ensure that females and people of childbearing potential are aware of the risks and are prescribed valproate in line with *'prevent'*. Any use outside of *'prevent'* is contraindicated and considered **off-label**, with the prescriber assuming full responsibility. The conditions of the '*prevent'* are such that females and people of childbearing potential under 55 years should receive:

1.	Counselling on the teratogenic risks of valproate and the need for 'highly effective' contraception, throughout treatment with valproate, without stopping or interruption.
2.	Counselling on what to do if they are planning pregnancy or become pregnant.
3.	Counselling on the risks of stopping valproate without medical advice.
4.	A negative pregnancy test (ideally serum) before starting valproate and if needed further pregnancy tests at appointments thereafter.
5.	One 'highly effective' method of contraception or **TWO** complementary forms of contraception (including a barrier method) without stopping or interruption.
6.	A copy of the *'prevent'* patient guide
7.	A signed ARAF with a countersigning specialist signature where required.
8.	Have a review with their specialist at least annually.

Female children who have not reached menarche do not need to fulfil the conditions of *'prevent'* but they and their responsible person need to be aware of the risks for the future. A patient guide should be provided, and the responsible person informed they must contact their GP and specialist team when the female child experiences menarche. Upon being notified, for children who are not under a specialist, the GP is responsible for referring the female child to their specialist prescriber for the completion of an ARAF.

All new initiations as well as all females under 55 years currently prescribed valproate must have two specialists independently consider and document that there is no other effective or tolerated treatment or compelling reasons that the reproductive risks do not apply. For initiation of valproate at least one specialist should be of a consultant grade while the second (countersigning) specialist should meet the following criteria:

1.	Be a registered healthcare professional with suitable experience and knowledge within the field of practice relating to the patient's condition, which enables them to provide additional clinical oversight on valproate prescribing. • Having the legal authority to prescribe may provide an additional level of parity between specialists, although this is not mandated*.
2.	Must **NOT** be directly line managed by the specialist consultant prescriber.
Examples of a second specialist prescriber may include another specialist consultant or a specialist pharmacist or nurse practitioner. ***The patient's GP does not qualify as a countersigning specialist.*** *Discussion of cases via a multidisciplinary team (MDT) meeting can substitute for the second specialist review. However, a named individual of the MDT should provide a signature.*	

However, there is no legal precedent on individual accountabilities for initiating and countersigning specialists; therefore, until one is established it is recommended that the second specialist be a prescriber. The second signatory prescriber must NOT be under line management of the primary signatory.

Further guidance on the risk minimisation measures for female patients **under 55 years old** can be found here in the MHRA infographic.

Further guidance on the risk minimisation measures for female patients **55 years and over** can be found here in the MHRA infographic.

6.1. Specialist prescribers of valproate

The specialist prescriber will:

<table>
<tr><td>1.</td><td>Accept primary care referrals for new initiations and females <55 years old on valproate requiring a review (including emergency referrals in the case of unplanned pregnancy, or urgent referrals in the case of planning a pregnancy and those who have recently entered menarche).</td></tr>
<tr><td>2.</td><td>Only initiate or continue valproate where two specialists have independently considered and documented that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply.
Where valproate is discontinued the patient and responsible person should be advised on the risks of valproate withdrawal including that that some patients will have recurrence or worsening of symptoms with potentially serious consequences.</td></tr>
<tr><td>3.</td><td>Exclude pregnancy ideally by a negative serum pregnancy test prior to initiation.
Note: should be repeated 3 weeks after latest unprotected sexual intercourse.</td></tr>
<tr><td>4.</td><td>If the person lacks capacity to make an informed decision to consent to treatment with valproate, there should be a best interests discussion around initiating valproate; the details should be recorded in the patient's electronic notes and ARAF.
There should be an additional capacity assessment regarding the need for highly effective contraception (refer to Appendix 3 for more information).</td></tr>
<tr><td>5.</td><td>Discuss and reaffirm with the patient and responsible person the need to be on and the conditions of the prevent programme.</td></tr>
<tr><td>6.</td><td>Only initiate valproate once highly effective contraception has been confirmed (refer to Appendix 3, for information on situations where contraception may not be appropriate).
Unless competent and confident to discuss contraception with the patient themselves, make a referral to sexual health services (or GP, if commissioned) to discuss contraceptive options with the patient and arrange for administration of a patient-independent method or prescription (see the section on highly effective contraception above).</td></tr>
<tr><td>7.</td><td>Complete and sign a copy of the ARAF (ideally, in an electronic format)
<table>
<tr><th>Situation</th><th>Completing the ARAF</th></tr>
<tr><td>If the absence of pregnancy risk is considered permanent (e.g. menopause)</td><td>Complete Step 1 of the ARAF only with rationale clearly documented</td></tr>
<tr><td>If the compelling reason(s) suggesting the absence of pregnancy risk may be subject to change (e.g. pre-menarche)</td><td>Complete Steps 1, 2, 3 and 4, with the reasons clearly documented</td></tr>
<tr><td>If prevent applies</td><td>Complete Steps 2, 3 and 4</td></tr>
</table></td></tr>
</table>

	If the patient or responsible person declines *prevent*	The ARAF is not furnished; the specialist will write to the GP to inform them that *prevent* was declined. - Refer to Appendix 3 scenarios
8.	Upload the ARAF to the electronic patient record and send a copy via secure email to the GP (if completed by hand, a copy should be scanned for uploading before emailing). A copy should also be printed and given to the patient.	
9.	Where an annual review is required and electronic systems allow, specialist to book a patient in for their next annual review in 12 months' time. If this is achieved, inform the GP practice of the patient's next appointment date.	

Patients who have recently experienced menarche

Patients who have experienced menarche are required to meet the conditions of *prevent.*

- Recently entering menarche constitutes a change in the patient's circumstances and therefore, the ARAF should be furnished with a second independent specialist signature if the patient is to continue valproate.

Transferring from paediatric to adult services

The referring paediatric consultant should communicate all relevant information relating to on-going treatment with valproate to appropriate adult specialist team and GP, including:

- The risk versus benefit assessment of on-going treatment with valproate.
- Discussions with the patient or their responsible person about treatment with valproate, including the need to use effective contraception.

Patients who are pregnant or planning pregnancy

Where a patient present with an unplanned pregnancy the specialist should consider whether switching to another treatment is appropriate. Use of valproate during pregnancy is off-label and any considerations to use valproate in this situation should be discussed with the multidisciplinary team as preference and if not the second specialist prescriber.

Epilepsy	Bipolar disorder
Valproate must **NOT** be prescribed unless two specialists independently consider and document that there is no other effective or tolerated treatment	Valproate must **NOT** be prescribed

For more information on safety of antiseizure medications during pregnancy, see the MHRA review.

Review patients who are planning pregnancy:

- Ensure the patient understands the risks associated with taking valproate in pregnancy.
- Switch to another therapeutic option which is suitable in pregnancy, if appropriate. The conditions of *prevent* should continue until valproate is discontinued.
- Advise not to stop contraception until the switch is achieved and the patient is no longer taking valproate.

Valproate may be the most appropriate option for the emergency treatment of uncontrolled seizures or status epilepticus. Clinicians may need to make rapid assessments and best-interests' decision in the acute setting; an urgent pregnancy test may be considered but should not delay treatment of this life-threatening emergency. Any use of valproate in these situations should be documented alongside the clinical rationale; however, the requirement for an ARAF does not apply. If valproate is to be continued once the patient has stabilised, the clinician should ensure the patient is enrolled onto *'prevent'* as they would for a non-emergency initiation of valproate.

6.2. Providers of contraception and sexual health

The commissioned GP/sexual health service specialist will:

1.	Accept referrals from specialists intending to initiate or continue valproate to arrange a consultation to discuss contraception with the patient.
2.	Discuss the contraceptive choices available with the patient, and work with them to agree on the most suitable and appropriate choice.
3.	For children or for patients without the capacity to make an informed decision, discuss contraception with the responsible person, and ensure they understand the content.
4.	Arrange for administration of a user-independent form of contraception if this is the preferred option.
5.	Write to the referrer to inform them of the contraceptive choice and, if a user-independent form is chosen, the date of administration. • If the patient opts for a combined hormonal contraceptive (CHC) or POP, ensure the referrer and the patients GP is aware so that they may continue prescriptions. Inform the patient that this option is not considered highly effective contraception and additional contraceptive methods (such as barrier methods) should be used as well. • If the patient opts out of contraception, ensure this is clearly communicated to the referrer (note for service provider: it is crucial to inform the referrer as soon as possible as valproate is contraindicated in females and people of childbearing potential who do not have effective contraception, and therefore any prescribing is off-label).
6.	If a fitted LARC is removed and not replaced, ensure this is clearly communicated to the patient's GP (and if they are still taking valproate and have childbearing potential, counsel the patient to discuss with their GP). **Whilst it is not routine to send communications to the GP for removing and not re-fitting LARC, this is of particular importance when the patient is on a teratogenic drug like valproate**.

6.3. Primary care clinician who continues prescribing of valproate

The primary care prescribing clinician (e.g. GP, pharmacist, nurse) will:

1.	Upon receipt and accepting a request to continue valproate prescriptions, ensure all future valproate documentation is electronically stored in the patients records and appropriate SNOMED codes have been applied (refer to Appendix 1 where manual entry is required). • If *prevent* is not required due to a clinical reason, ensure an appropriate SNOMED code is applied to the patient's record (e.g. hysterectomy). • Other codes may be required depending on patient circumstance. These may include whether the patient has a learning disability and whether the patient is pregnant.
2.	Act in accordance, and prescribe valproate, within the remit of *prevent*, ensuring that: • The practice has received a valid ARAF (see section on ARAF referrals below). • The patient is using highly effective contraception, if indicated. • There is no change to the patients' circumstances since the ARAF was completed that may affect the status of the ARAF (e.g. patient has reached menarche). The responsibility to prescribe outside the remit of prevent lies with the individual prescriber. This would constitute off-label use and is contraindicated.
3.	Refer patients who have an expired, expiring, or absent ARAF or if the patient's situation has changed as soon as practically possible back to the specialist prescriber (see referral information below). • If a patient has been referred to their specialist, valproate prescriptions can continue but should only cover the period until their review date (note that if the ARAF is expired, this is off-label but is in the patients' best interests).
4.	If pregnancy is suspected, ensure that they: • Perform an urgent pregnancy test. • Refer the patient back to their specialist urgently for a review within days and make a follow-up call to confirm receipt of referral (see referral information below). • Inform the patient not to stop taking valproate until reviewed by the specialist.
5.	Ensure that any new medications initiated for the patient does not interact with their current medications, in particular valproate and contraceptives (see FSRH guidance, for information on interactions with hormonal contraception).
6.	GPs should respond to queries from other healthcare professionals in a timely manner where there are concerns regarding an issued prescription. For instance, where a community pharmacist identifies that a patient prescribed valproate may be pregnant.
Identifying patients with expiring/expired ARAF	
7.	Identify female patients under 55 years prescribed valproate via a search in their clinical system. • Periodic searches should be scheduled at least every six months. • A clinician/team should be identified to run periodic searches to identify patients who require reviews and undertake contraceptive reviews (as per below).
8.	Ensure that they immediately notify the GP and specialist if they identify any patient who is pregnant and being prescribed valproate and follow the appropriate local mechanisms for incident reporting (see Section 9).

9.	Identify female patients who require a referral for a specialist review for the completion of an ARAF, the clinician must assure themselves of the patient's current situation and whether this has changed since their last review/ARAF. Example situations where this is necessary are outlined below. A primary care clinician review for ALL patients should be conducted to determine any changes in circumstances.

Criteria	Initial ARAF with countersigning specialist	Annual referral for ARAF [a,b]
Female children who are pre-menarche	✓	✖
Females aged <55 years who have reached menarche but have a permanent absence risk of pregnancy	✓[c]	✖
Females aged <55 years who have reached menarche but has other compelling reasons which means the conditions of *prevent* are not applicable.	✓	✓[d]
Females aged <55 years who have reached menarche and do not have a permanent absence risk of pregnancy or other compelling reason why *prevent* does not apply	✓	✓

[a] *Assuming the patient's situation has not changed since their last ARAF with the countersigning specialist.*

[b] Subsequent *ARAFs require a single specialist review unless the patient's condition has changed since their review with a countersigning specialist.*

[c] *Valproate can continue to be prescribed via single prescriber. Second specialist review is not required. Use the ARAF (Step 1) to document the clinical decision. ARAF does not need to be completed annually.*

[d] A specialist and GP may agree that ongoing annual ARAFs are not in the best interest of the patient; however, this usage of valproate may be off label. Any agreement should be documented by the GP and the specialist in the patients' electronic medical records.

10.	If applicable, conduct a contraceptive review if one has not been conducted in the past year: • Check the patients electronic record to see if there is any information on a contraceptive review (e.g. letter from a sexual health service, or completion of the EMIS template for a contraceptive review). • If there is no evidence of a review for adequate contraception, contact the patient and perform a contraceptive review (completing the relevant form within the "Valproate Pregnancy Prevention Review" EMIS template). • If contraception is not adequate, refer to their GP or local sexual health service. • If unable to use the EMIS template, apply relevant SNOMED codes (see Appendix 1).
Referrals to specialist services	
11.	A referral is made on EMIS via ERS using the "Valproate risk assessment referral form". If this is being made from a premises without EMIS, a referral can be made by emailing the relevant clinic (please see the list of specialist centre clinics in Appendix 4). • Upon making a referral the SNOMED code "Referral for completion of Valproate ARAF" should be applied to the patients notes (note: if the NCL referral form is used, this SNOMED code will be applied automatically). • See Appendix 2 for information required if making a referral without EMIS. If the referral is being made for a patient who is planning a pregnancy or is pregnant, please ensure the referral is marked as '**URGENT**' (ensuring it contains direct contact numbers) and call the clinic to inform that the referral has been sent through to ensure receipt.

	• If the referral is being made by community clinicians with no direct communication to the specialist, and there is risk of pregnancy, refer urgently back to the GP for initial assessment. For clinical teams outside of NCL: Please note, if you are referring a patient to an NCL specialist, there is an expectation that you adhere to the NCL formulary.

6.4. Dispensing valproate in hospital

Hospital Medication Safety Officer (MSO) will:

1.	Ensure local electronic prescribing and medicines administration systems have appropriate alerts/warnings when a patient is on and dispensed valproate.

When dispensing a valproate prescription, the hospital pharmacist will:

1.	Ensure newly initiated patients are signed up to the *prevent* programme, by checking: • A valid ARAF has recently been completed including a second signature from a countersigning specialist where required. • That the patient has been counselled on the risks associated with valproate. • If highly effective contraception has been started prior to the initial prescription dispensing (or, if for continuation, a referral has been made for contraceptive review and consultation). • That a recent negative pregnancy test has been conducted and is documented in the patient notes prior to signing up to *prevent*. • That the patient has a *prevent* patient guide and a valproate patient alert card.
2.	The hospital pharmacist should document that they have checked for a valid ARAF, the date the form was completed, the pharmacist initials and the screening date.
3.	In exceptional circumstances, valproate may be initiated off-label/contraindicated in certain scenarios where the patient is not enrolled onto *prevent*. In these circumstances, an ARAF will not be furnished. The pharmacist should reassure themselves that this is an appropriate off-label/contraindicated use of valproate. • See Appendix 3 for further information regarding exceptional circumstances.
4.	Upon screening, the pharmacist should ensure there are no interactions with the chosen method of contraception and current concurrent medications (see FSRH guidance, for information on interactions with hormonal contraception).
5.	Valproate should be dispensed in the manufacturers' original pack (as this contains specific warnings and pictograms, including a patient card and patient information leaflet, alerting patients to the risks to unborn babies if used in pregnancy). • In exceptional circumstances, an exception to the requirement to dispense in the manufacturers' original pack can be made on an individual patient basis. This should only happen following a risk assessment that refers to the need for different packaging (e.g. in a monitored dosage system, or discharge medication for short-term leave from an inpatient unit). The pharmacist should inform the patient and/or responsible person why a full pack is not being dispensed and ensure a patient information leaflet is provided. If valproate is being dispensed from the original pack into an unmarked box, it is good practice to add a sticker warning of the teratogenic effects of valproate. This can be obtained from Sanofi medical information department (0845 372 7101 or UK-Medicalinformation@sanofi.com).

6.5 Dispensing valproate in community pharmacy

The community pharmacist will:

1.	Ensure females and people of childbearing potential are aware of *prevent* and where required that they are signed up to the *prevent* programme. • This can be upon discussion with the patient/responsible person (if not in person, then via telephone call), or by checking with the GP, checking for prescription endorsements, system notes or confirming via the local electronic records where appropriate and with patient consent. • In exceptional circumstances, valproate may be initiated off-label/contraindicated in certain scenarios where the patient is not enrolled onto *prevent*. In these circumstances, an ARAF will not be furnished. The pharmacist should reassure themselves that this is an appropriate off-label/contraindicated use of valproate.
2.	Ensure the patient is provided with a patient guide.
3.	Make a supply of valproate based on the individual patient circumstances: • If the pharmacist is reassured of the patient being signed up to *prevent*, a routine supply of valproate is completed. • If the pharmacist is not reassured that the patient is signed up to prevent or is aware that the patient is planning pregnancy – but there is no immediate risk of pregnancy – refer urgently to the GP for assessment and continue to dispense valproate. • If there is suspected pregnancy, refer the patient URGENTLY back to their GP, who can refer onward to the specialist for assessment within days; valproate should be continued until the specialist review. i. The patient should continue to take valproate until their specialist review but may not need to continue taking it thereafter. ii. If the patient has enough valproate to cover a period of at least 2 weeks, arrange with the patient to hold dispensing of the prescription until their review has concluded. iii. If the patient does not have enough valproate and the quantity prescribed is more than 2 weeks supply, consider discussing with the GP to prescribe a suitable quantity to cover the interim period until the review has concluded.
4.	Valproate should be dispensed in the manufacturers' original pack (as this contains specific warnings and pictograms, including a patient card and patient information leaflet, alerting patients to the risks to unborn babies if used in pregnancy). • In exceptional circumstances, an exception to the requirement to dispense in the manufacturers' original pack can be made on an individual patient basis. This should only happen following a risk assessment that refers to the need for different packaging (e.g. in a monitored dosage system, or discharge medication for short-term leave from an inpatient unit). The pharmacist should inform the patient and/or responsible person why a full pack is not being dispensed and ensure a patient information leaflet is provided. • If valproate is being dispensed from the original pack into an unmarked box, it is good practice to add a sticker warning of the teratogenic effects of valproate. This can be obtained from Sanofi medical information department (0845 372 7101 or UK-Medicalinformation@sanofi.com).

6.6 Medicines reconciliation in hospital

The healthcare professional conducting a medicines reconciliation will:

1.	Attempt to confirm and document in the patients notes the following information: • Is the patient aware of the risks of taking valproate while pregnant? • Is the patient enrolled on the *prevent* programme? • Does the patient have a valid ARAF (if applicable) • Is the patient using a highly effective method of contraceptive within its effect duration?
2.	If the patient answers "*NO*" to any of the above questions, inform the lead treating clinician on admission and GP on discharge. This should **not delay the supply of the valproate** if required, as this is in the best interest of the patient. • If the patient is using a non-highly effective method of contraception, the treating clinician on admission is responsible for ensuring that any assessment of the potential risks of reduced contractive effectiveness as a result of the current illness of treatment (e.g. reduced absorption or hepatic enzyme-inducing treatment) has been conducted. This may require a referral to a healthcare professional qualified in the provision of contraception (e.g. family planning or gynaecologist). • The lead treating clinician could seek advice from neurology or psychiatry if required. • Example wording for discharge summaries: ○ Confirmed ARAF [DATE OF LAST ARAF] ○ Unconfirmed ARAF – GP to follow up

7 Roles and Responsibilities (for males or people who can father children)

Further guidance on the risk minimisation measures for male patients under 55 years old can be found here in the MHRA infographic.

Further guidance on the risk minimisation measures for male patients 55 years and over can be found here in the MHRA infographic.

7.1 Specialist who initiates valproate

The specialist prescriber will:

1.	Accept primary care referrals for new initiations and ad hoc reviews for males wanting to conceive a child or discuss valproate following being informed of the associated risks by their GP.
2.	For patients <55 years old, only initiate valproate where two specialists have independently considered and document that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks to do not apply. • If the risks do not apply (e.g. if the patient is permanently infertile), the countersigning specialist is not required, although the reason for why these risks do not apply should be recorded in the patient's electronic notes and on the RAF.
3.	Discuss the risks of taking valproate with the patient: • inform male patients (of any age) who may father children of the possible risk at initiation of valproate or at their next regular treatment review – this counselling should be given irrespective of the indication for valproate and also after intravenous use of valproate. • as a precaution, recommend that male patients use effective contraception (condoms, plus contraception used by the female sexual partner) throughout the valproate treatment period and for 3 months after stopping valproate, to allow for one completed sperm cycle not exposed to valproate. • at the next regular treatment review, discuss with men on oral valproate treatment whether they are planning a family in the next year and if they are, refer to a appropriate specialist to discuss alternative treatment options. • if a female patient reports they are pregnant or planning a pregnancy with a man on valproate (including those undergoing IVF), refer for prenatal counselling. • advise men not to donate sperm during valproate treatment and for 3 months after stopping valproate. • N.B. The potential risk to the offspring of men taking valproate around conception apply to both those taking valproate orally and intravenously (IV), however discussions with men on treatment options apply only to those taking valproate orally. For those who receive IV valproate in an acute care setting, advise the use of contraception for 3 months after treatment.
4.	If the person lacks the capacity to make an informed decision to consent to treatment with valproate, there should be a best interests discussion around initiating valproate; the details should be recorded in documentation such as the patient's electronic notes. • Information on valproate and the risks of infertility and the potential risk of testicular toxicity should be provided to the patient in a format that they can understand.
5.	Give information to patients: • If they father a child while they are taking valproate or in the 3 months after stopping valproate, there is a potential small increased risk of the child being diagnosed with a neurodevelopmental disorder. • provide advice via MHRA's Advice for male patients on valproate to use contraception and visual risk communication diagram.
6.	Advise patients:

	• it is recommended that you and your female sexual partner should both use effective birth control (condoms and another form of female contraception) as a precaution while you are taking valproate and for at least 3 months after stopping valproate. • allow at least 3 months to pass after stopping valproate before trying to father a child. • do not donate sperm whilst taking valproate and for three months after stopping • do not stop taking valproate unless you are advised to do so by a healthcare professional.
7.	For newly initiated patients, complete and sign a copy of the male RAF • The completed male RAF should be saved on the patient's electronic notes. A copy should be sent to the patient's GP (electronic communication is preferred), and a printed copy should be given to the patient. Inform the patient to present their RAF to the pharmacy upon collection of their first prescription of valproate.
Patients who are planning to conceive	
8.	Counsel patient on the risks and support them to make an informed decision whether valproate is still the right treatment for them. • Where valproate is to be discontinued the patient should also be advised on the risks associated with valproate withdrawal. Patients should be advised to continue to use contraception for at least 3 months after stopping valproate.

7.2 Primary care clinicians who continue prescribing of valproate

The appropriate clinician in the practice (e.g. GP, pharmacist, nurse or other appropriately trained clinician) will:

•	Upon receipt and accepting of a request to continue valproate prescriptions in primary care, ensure all future valproate documentation is electronically stored in the patient's records. • The completed RAF should be stored with the SNOMED code "Risk Acknowledgement Form for Male Patients Starting Valproate completed" added to the patients notes.
•	Continue to issue prescriptions for valproate while it remains indicated for the patient's condition.
•	Reiterate information on the risks, give information and advise as outlined in specialist roles and responsibilities above in line with points 3-6. The specialist should also provide this counselling. This also applies to men who have undergone vasectomy (as this may not be 100% effective)
•	A record of the counselling should be added to the patients notes. The GP may wish to consider the benefit of periodic counselling on the risks. *When recording consultation on risks with SNOMED consider free text of 'valproate' and 'Risk of Neurodevelopmental Disorder' with SNOMED code 396080005*
•	Provide male patients with an updated male patient guide when available. In the meantime refer to MHRA's Advice for male patients on valproate to use contraception and visual risk communication diagram

Patients who father a child whilst taking valproate	
•	Determine if the use of valproate was within 3 months of conception
•	Advise patients if they father a child while taking valproate or in the 3 months after stopping valproate, there is a potential small increased risk of the child being diagnosed with a neurodevelopmental disorder
•	Explain that neurodevelopmental disorder can take many forms and may not be diagnosed until later in life.
•	Refer the child, patient and their partner to a specialist for neurodevelopmental disorders if they are concerned and the affected person displays signs of neurodevelopmental disorder

7.3 Dispensing by hospital and community pharmacy

The hospital or community pharmacist will:

1.	Provide male patients with a copy of the update patient guide when available. In the meantime refer to MHRA's Advice for male patients on valproate to use contraception and visual risk communication diagram
2.	If aware that a patient is planning to conceive a child, the patient should be advised to contact their specialist/GP to discuss, prior to stopping contraception.
3.	If a partner of a male taking valproate is pregnant and has questions, they should be advised to contact their GP in the first instance.
4.	Valproate should be dispensed in the manufacturers' original pack (as this contains specific warnings and pictograms, including a patient card and patient information leaflet) • In exceptional circumstances, an exception to the requirement to dispense in the manufacturers' original pack can be made on an individual patient basis. This should only happen following a risk assessment that refers to the need for different packaging (e.g. in a monitored dosage system, or discharge medication for short-term leave from an inpatient unit). The pharmacist should inform the patient and/or carer why a full pack is not being dispensed and ensure a patient information leaflet is provided. If valproate is being dispensed from the original pack into an unmarked box, it is good practice to add a sticker warning of the teratogenic effects of valproate. This can be obtained from Sanofi medical information department (0845 372 7101 or UK-Medicalinformation@sanofi.com).

8 Scenarios that require additional considerations

For information and guidance on scenarios that require additional considerations refer to the relevant section of Appendix 3.

9 Incident reporting

- If a patient is identified to have used valproate whilst being pregnant, a local incident report form (e.g. DATIX, InPhase, Learn from Patient Safety events (LFPSE) system) and, ideally, a root cause analysis, should be completed.

- Please follow local guidance for incident reporting.
- The healthcare professional identifying the pregnancy should ensure that the patients GP practice, specialist, and pharmacy are made aware of the case to ensure they also follow their local guidance for incident reporting.

10 Audit

Primary care/ICB will:

1.	Analyse the aggregate level data using the HealtheIntent dashboard or EMIS search for PCNs/practices across NCL (starting from one year following the publication of this guidance) to determine:
	• The number of females prescribed a medicine containing valproate, of which:
	  ○ Percentage who has a coded PPP entry in their EMIS record.
	  ○ Percentage enrolled on the PPP who have an ARAF coded within their EMIS record within the last 12 months.

2.	If patients are identified without a valid ARAF or without being enrolled on to *prevent*, contact the relevant PCN pharmacist to identify: • The proportion of patients without a valid ARAF that have had a referral made to their specialist versus those who have not. • The proportion of patients appropriately excluded from enrolment onto *prevent* versus those who are inappropriately excluded.
3.	Periodically report findings to the relevant medicines' safety group.

Trust Medicines Safety Group will:

1.	Organise for undertaking and feedback of annual audit: • The indication for which valproate is being prescribed: i. Epilepsy ii. Bipolar disorder iii. Schizophrenia/Schizoaffective disorder iv. Migraine v. Other (please state)
2.	Identify the number of male and female patients under 55 years who were newly initiated on valproate and of which the number of patients where the risks did not apply.
3.	Identify the number of females with childbearing potential and girls who were taking valproate and were reviewed by two independent specialists, of which: • Number of patients who continued valproate. • Number of patients who discontinued valproate (please specify to which alternative medicine). ○ of those, after attaining a stabilised dose, did the condition or symptoms (e.g. seizure frequency and intensity, symptom severity) worsen, improve, or stabilise?
4.	Identify the number of females of childbearing potential and girls who were reviewed for ARAF completion; of which: • Number of patients who were enrolled onto *prevent.* • Number of patients who did not require to be enrolled on to *prevent.* • Number of patients/caregivers who refused to be on *prevent*.
5.	Where *prevent* *was* refused/non-compliant: • Identify if valproate was continued (off-label)? • Identify if valproate was not continued, was valproate switched to an alternative medicine? (if so, please state which)

	○ After attaining a stabilised dose, did the condition or symptoms (e.g., seizure frequency and intensity, symptom severity etc) worsen, improve, or stabilise?
6.	Report findings to the relevant medicines' safety group.

11 Abbreviations and terminology

Childbearing potential	A person who can biologically become pregnant, who is between menarche and menopause and does not have a temporary or permanent biological absence of pregnancy risk. This includes women, girls, trans men and non-binary people who are biologically able to be pregnant.
Pre menarche	A person who has not yet reached menarche and therefore, is not currently of childbearing potential.
Responsible person	A parent/legal guardian or person capable of giving consent on behalf of patients who are minors or without the capacity to make an informed decision, or a person acknowledging that the treatment is in the best interests of the patient.
ARAF	The female 'Annual Risk Acknowledgement Form', should be completed by the specialist at least annually for patients with childbearing potential
RAF	The male 'Risk Acknowledgement Form' should be completed by the specialist when initiating any new males under 55 years on valproate
Prevent	The term given to the valproate pregnancy prevention programme
'Highly effective' contraception	The term given for user independent forms of contraception, which carry <1% risk of pregnancy
LARC	Long-acting reversible contraception
IUD	Intrauterine Device
Cu-IUD	Copper Intrauterine Device
LNG-IUS	Levonorgestrel Intrauterine System
IMP	Progestogen-only implant
COC	Combined Oral Contraceptives
CHC	Combined hormonal contraception
POP	Progestogen-Only contraceptive Pill
DMPA	Depot Medroxyprogesterone Acetate (a form of progesterone injection)
HeI	HealtheIntent - an electronic population healthcare platform utilised in NCL

Appendix 1: SNOMED codes for clinical coding of teratogenic medicines

1. Risk Management

1.1 Risk acknowledgement

Description	SNOMED Code
Valproate Annual Risk Acknowledgement Form (record artifact)	1659031000000103
Referral for completion of Valproate Annual Risk Acknowledgement Form (procedure)	1366381000000107
Valproate Annual Risk Acknowledgement Form completed (situation)	1366401000000107
Also note	
Medication side effects education (procedure)*	396080005
Risk Acknowledgement Form for Male Patients Starting Valproate completed (situation)	2078961000000109

*Can be used to code discussion of risks. Freetext needs to include description of risk eg. Testicular toxicity.

1.2 Pregnancy Prevention

Description	SNOMED Code
Pregnancy prevention programme (regime/therapy)	1129761000000105
Pregnancy prevention programme started (situation)	1129771000000103
Pregnancy prevention programme not needed (situation)	1129791000000104
Did not attend pregnancy prevention programme (situation)	1129831000000106
Pregnancy prevention programme declined (situation)	1129801000000100
Pregnancy prevention programme declined by parent (situation)	1129821000000109
Pregnancy prevention programme declined caregiver (situation)	1129811000000103
Pregnancy prevention programme discontinued (situation)	1129841000000102

2. Patient is ADHERENT to 'prevent' (Valproate Pregnancy Prevention Programme):

2.1 Pregnancy Prevention Programme

Description	SNOMED Code
Pregnancy prevention programme started (situation)	1129771000000103

2.2 Patient is on effective contraception

Description	SNOMED Code
Uses transdermal contraception (finding)	413116005
Uses depot contraception (finding)	268464009
Uses hormone releasing intrauterine device contraception (finding)	449038007
Contraceptive coil (physical objective)	312082008
Copper-containing intrauterine device (product)	714594000
Subcutaneous contraceptive implant present (finding)	428987008

2.3 Patient has a negative pregnancy test prior to initiating teratogen

Description	SNOMED Code
Pregnancy test negative (finding)	250425007

3. Patient NOT adherent to 'prevent':

Description	SNOMED Code
Pregnancy prevention programme discontinued (situation)	1129841000000102
Pregnancy prevention programme not needed (situation)	1129791000000104

- If patient not adherent to 'prevent' please document the reason using the appropriate SNOMED codes. Some examples are provided below however the list is not exhaustive.

3.1 Absence of pregnancy risk is permanent

Description	SNOMED Code
History of hysterectomy (situation)	161800001
Menopause present (finding)	289903006
Bilateral tubal ligation (procedure)	287664005
History of female sterilisation (situation)	275572005
Premature menopause (finding)	373717006

3.2 Not yet reached menarche

Description	SNOMED Code
Amenorrhea (finding)	14302001

3.3 Refused

Description	SNOMED Code
Pregnancy prevention programme declined (situation)	1129801000000100
Pregnancy prevention programme declined by parent (situation)	1129821000000109
Pregnancy prevention programme declined caregiver (situation)	1129811000000103

Appendix 2: NCL Specialist referral check list

1.	Patient details (name, address, contact details, registered GP practice details and NHS/hospital number if known)
2.	Whether the patient can understand English (or otherwise their first language)
3.	Whether the patient has a severe mental illness, learning disability or physical disability
4.	Details of the care giver or responsible person, if applicable
5.	Past medical history
6.	Drug history
7.	Allergies
8.	Valproate indication and dose
9.	Current specialist
10.	Whether contraception is required (or if not, please state the reason). If required, is contraception in use currently? Please provide details of the contraceptive (in the case of long-acting contraception, when it was administered if known).
11.	Whether an ARAF has been completed and date annual review is due
12.	Whether there are any known change since their last ARAF (e.g. has reached menarche)

Appendix 3: Scenarios that may require additional considerations

Patients that do not engage with services or *prevent*

- The decision of whether to continue off-label/contraindicated valproate in patients who do not want to engage with services, or those who attend but do not wish to comply with the criteria within *prevent*, must be balanced carefully with the individual circumstances of the patient.
- The benefits and risks must be carefully considered, and where appropriate discussed in an MDT setting. Where valproate is contraindicated, discontinuing treatment may prevent avoidable harm during potential pregnancy in the future. However, stopping treatment could cause the patients' condition to worsen; this is particularly concerning in patients with highly refractory epilepsy or those at risk of sudden unexpected death in epilepsy (SUDEP).
- Patients who choose not to engage with services may do so due to fears that valproate will be stopped or switched without their input. Where concerns arise, patients should be reassured that their thoughts and opinions are pivotal to their management plan.

If a patient does not attend appointments with the specialist:

- The specialist should inform the GP and offer the patient another appointment.
- If the patient does not attend several appointments, the specialist should contact the GP and discuss how best to proceed for the individual patient.

If a patient does not attend GP appointments:

- Primary care teams should make attempts to contact the patient to offer another appointment.
- If the patient does not attend several appointments, primary care teams should liaise with the patients' specialist for advice.
- The GP and specialist should discuss how best to proceed with the individual patient and agree a plan. If the patient has an immediate need for valproate, and there is no foreseeable risk at present, prescriptions for a limited duration of valproate should continue until a joint discussion with the specialist has taken place.

Following joint discussions between the specialist and GP:

- Where a specialist and GP make a joint decision that continuing valproate is in the best interest of the patient, this should be clearly documented in both the Trust and primary care electronic patient record, including rationale.
- Where a specialist and GP make a joint decision that discontinuation of valproate is in the best interest of the patient, this should be clearly documented in patient records and an ongoing management plan put in place.

Patients that engage but do not wish to sign up to *prevent*

- If a patient is engaging but does not wish to sign up to *prevent* (e.g. due to personal beliefs such as cultural or religious reasons, or because they do not wish to use contraception owing to possible adverse effects), then the responsible clinician should follow GMC advice on shared decision making with the patient[6].
- Where there is still concern, the responsible clinician should discuss with the GP/specialist to decide the best course of action, and the overall benefit/risk ratio (as per above).

Patients with severe physical and/or intellectual disability

- In patients who have childbearing potential but suffer from severe physical and/or intellectual disability and/or lack mental capacity, sexual intercourse may be unlikely. In

these circumstances, it may be distressing for patients and their families to require regular reviews to discuss pregnancy risk and contraception. Consideration should be given to prescribing in general practice without the completion of annual risk acknowledgement forms or for the patient to be on '*prevent*'.

- Clinicians must bear in mind that prescribing valproate in **any** patient with childbearing potential without adequate contraception and a valid ARAF remains off-label and contraindicated.
- The primary care clinician should ensure the appropriate SNOMED code is used and inform the patient's specialist Refer to Appendix 1 for options of SNOMED codes.

Patients who have childbearing potential that lack mental capacity

- **If newly initiated**, the specialist should evaluate the patient's situation; where the specialist deems there to be a permanent no risk of pregnancy, Step 1 of the ARAF should be completed. This should be discussed with the GP prior to transfer (as the GP will be asked to undertake off-label prescribing). If in agreement, the primary care team should ensure the appropriate SNOMED code is used. Refer to Appendix 1 for options of SNOMED codes.
- **For patients established on valproate**, in line with the updated regulatory measures all female patients under the age of 55 years should be reviewed by their specialist using the revised ARAF.

Patients who have childbearing potential with severe intellectual or physical disability and have mental capacity

- The patient should be involved in discussion. There should be careful evaluation over whether there is an absence of pregnancy risk, and whether the patient has capacity to consent to receive contraception as well as valproate. Although patients with capacity could be sexually active, the specialist should be alert to the possibility of sexual abuse. The specialist may wish to involve others (e.g. best interest meetings, adult safeguarding, sexual health services etc).
- Any use of valproate in a patient where the patient is not enrolled on to *prevent* should be discussed with the primary care physician before considering transfer of prescribing responsibility due to the potential off-label and contraindicated nature. Please apply the appropriate SNOMED code as above.

Starting or restarting valproate in patients of childbearing potential in the Psychiatric ICU

- Valproate is sometimes initiated in the Psychiatric ICU (PICU) for conditions such as bipolar affective disorder; however, two specialists must interpedently consider and document that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply.
- Patients should be counselled on the risks in pregnancy and enrolled on to *prevent* wherever possible.
- Unless clear evidence of exception (e.g. post-menopausal with a reliable history of no periods for at least one year and are not using hormonal contraception AND a negative pregnancy test), consider women under 55 to have childbearing potential.
- Valproate should be reviewed routinely; the patients' capacity for enrolment on to *prevent* should also be routinely reviewed if there is consideration for long term prescribing.
- Prior to stepping down/being discharged, the patient should either have a plan to reduce and stop valproate, or there should be a shared agreement between the PICU specialist and the clinician on the accepting ward.

- If transferred, the patient should be subject to routine review; patients should not be routinely discharged on valproate without being enrolled onto prevent /without a plan in place for ongoing prescribing of valproate.

Patients initiated on valproate from a private provider (including clinicians registered abroad)

- For reasons of equity, there is an expectation that medication initiated by private providers are only taken on by primary care prescribers once they are satisfied that prescribing is appropriate, responsible and is in line with what would be provided for any other NHS patients with the same condition, at the same stage of treatment.
- Medications suggested by a private provider which are not aligned with national or local guidance will not be routinely continued by the primary care prescriber; therefore, the private provider should only transfer prescribing if they are able to fulfil all the duties of the 'specialist' in this guidance, including acceptance of referrals for the completion of an ARAF.

Patients who withdraw from/have a change in circumstances since enrolment on the pregnancy prevention programme

- Patients may wish to withdraw from the pregnancy prevention programme or have a change in circumstances (i.e. new hysterectomy) since starting on *prevent*.
- The primary care clinician should apply the appropriate SNOMED code to demonstrate that the patient has discontinued *prevent* (1129841000000102) and inform the patient's specialist of the change in circumstances.

Supply of contraceptives in primary care, where the patient does not attend annual review

- Where the patient is prescribed oral contraceptives, however, does not attend their annual contraceptive review the GP practice should make all reasonable attempts to contact the patient and reschedule the appointment. The specialist team should also be informed.
- The use of valproate without adequate contraception, where this is indicated, is off-label/contraindicated.

Appendix 4: Specialist contact details

National Hospital for Neurology and Neurosurgery

Hospital switchboard:	020 3456 7890
Referrals	Via eRs
Advice	Use Advice and Guidance via eRs for patients currently not under UCLH care
Epilepsy nurse helpline (for current UCLH patients only)	Tel: 020 3448 8627
Patient contact:	Please contact the relevant consultant's secretary. The number should be included in the consultant's clinic letter. 020 3448 8625 020 3448 8619 020 3448 8609 020 3448 8623

Royal Free London neurology services

Hospital switchboard:	020 3758 2000
Referrals	Via eRs
Advice	Use Advice and Guidance via eRs
Epilepsy nurse helpline	020 7830 2864 rf.epilepsyteam@nhs.net
Patient contact:	Please contact the relevant consultant secretary via the RFL hospital switchboard (as above)

Practice based mental health services

Camden mental health team	Camden.mhct@candi.nhs.uk
Islington mental health team	Islington.mhct@candi.nhs.uk
Barnet mental health team	Complete the "*Mental Health Referral for Adults - Barnet – BEHMHT*" form and send to beh-tr.barnetmhreferrals@nhs.net. To discuss a non-urgent referral: beh-tr.barnetmhreferralsadmin@nhs.net or Tel: 020 8702 4382
Enfield mental health team	For practices with a link worker, referrals go via beh-tr.enfieldpclw@nhs.net or Tel: 020 8702 5530. For practices without a link worker, referrals go via the Enfield Assessment Service: assessmentservice.enfield@nhs.net or Tel: 0208 702 3329.
Haringey mental health team	Adults: Central Core team: beh-tr.central.haringey@nhs.net Tel: 020 8702 6210 West Core team: beh-tr.west.haringey@nhs.net Tel: 020 8702 5111 East Core team: beh-tr.east.haringey@nhs.net Tel: 020 8702 5111 Paediatrics: CAMHS Haringey: beh-tr.camhsreferral@nhs.net Tel: 0208 702 3400
North London Partners Specialist Perinatal Mental Health Service	nlft.NCL@perinatal.nhs.net South Team (Camden and Islington : 020 3317 7114 West Team (Barnet): 020 3317 7001 East Team (Enfield & Haringey): 020 3317 7198

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