Protocol for Using Valproate

In Women of Childbearing Potential and Girls

Version number	10.0
Consultation Groups	Medicines Committee
Approved by (Sponsor Group)	Medicines Committee
Ratified by:	Medicines Committee
Date ratified:	12 May 2021
Name and Job Title of last author:	Indreet Anand, Medication Safety Officer & Pharmacist Toby Baldwin, Speciality Doctor and Trust Digital Champion
Executive Director lead	Paul Gilluley
Implementation Date	May 2021
Last Review Date	May 2021
Next Review date:	May 2024

Services	**Applicable to**
Trustwide	X
Mental Health and LD	
Community Health Services	

Version control summary

Version	Date	Author	Status	Comment
1.0	July 2014	Dr Sarah Jones Jennifer Melville	Ratified: July 2014	
2.0	May 2015	Dr Sarah Jones Jennifer Melville	Ratified: May 2015	
3.0	Sept 2016	Alan Cottney	Ratified: Nov 2016	• Protocol format restructured • New prescriber checklist • Incorporated MHRA communication materials • Made forms electronically editable
4.0	April 2017	Alan Cottney	Ratified: May 2017	• Protocol name changed from; "Protocol for using valproate in women of childbearing potential" to "Protocol for using valproate in women of childbearing potential *and girls*" • Age range for inclusion in protocol requirements replaced by the wording, "any woman of childbearing potential, or girl" • Pregnancy testing section updated with statement about need to use serum hCG test in preference to urine dip for pregnancy test. • Guidance added about what to do for patients who lack capacity • Added statement about the need for a risk-minimisation plan. • RiO document code changed from "SOVA" to "VALP" to avoid confusion with "Safeguarding Of Vulnerable Adults (SOVA)" documentation.
5.0	May 2017	Alan Cottney	Ratified: May 2017 by Chairman's Action; July 2017 by Medicines Committee	• Pregnancy testing section amended to include mandatory 14 day delay before test in cases of unknown sexual history, and clarification about what to do for patients admitted on valproate. • Clarification that receiving ward should be involved in developing care plan after PICU step-down
6.0	September 2017	Alan Cottney	Ratified: Aug 2017 by Chairman's action; Sept 2017 by Medicines Committee	• Section 2.1.5: addition of paragraph about what to do for patients who are prescribed valproate for epilepsy.
7.0	May 2018	Alan Cottney	Ratified by Medicines Committee	• Table of contents added • Introduction updated to include reference to April 2018 MHRA update • New section on Pregnancy Prevention Programme. • Sections on prescribing and dispensing valproate updated with new risk communication materials and restrictions.

				• Requirement for specialist review once a year as per MHRA guidance and added need to complete Risk Acknowledgment Form at review. • Section on contraception advice added • Section added for 'Other Health Professionals' • Consent form & Prescriber checklist removed; replaced with Risk Acknowledgement Form
8.0	May 2019	Indreet Anand	Chairman's Action; May 2019	• Appendix updated to remove the previous Risk Acknowledgement Form and add the new Risk Acknowledgement Form
9.0	June 2019	Indreet Anand/ Annabel Ikwuakolam	Ratified by Medicines Committee June 2019	• Sections on prescribing valproate updated; - amendment of page 8 'Complete the risk acknowledgement form' to include steps 1 to 3 - addition of 3.6 'Patients where there is permanently no possible risk of pregnancy e.g. post-menopausal or post-hysterectomy' - addition of section 3.7 'Complex Patients – For whom the Pregnancy Prevention Programme cannot be fully met' • Section 3.1 amended to include reporting valproate exposure in pregnancy to UKTIS (UK Teratology Information Service).
10.0	May 2021	Indreet Anand Toby Baldwin	Ratified by Medicines Committee	• Inaccuracies from version 9 rectified included missing 'Resources' section which is also referred to within section 'Complex Patient' and missing version control summary for last 2 versions being added. • Section 3.0 amended to included electronic RIO valproate risk acknowledgement form • Appendix A added to include instructions on how to access and complete electronic RIO risk acknowledgment form and send to the GP

Table of contents

1.0 Background

- Valproate is a medication used in the treatment of epilepsy and of bipolar disorder. It is available in three formulations in the UK: Sodium Valproate, Valproic acid and Semisodium Valproate. Brands used in the UK include Epilim, Depakote, Convulex, Episenta and other generic brands.

- *In utero* exposure to valproate is associated with serious adverse effects for the developing child, including:

    - Congenital malformations. Affecting approximately 10% of cases, these include; neural tube defects (spina bifida, anencephaly), facial dysmorphia and cardiac malformations.

    - Developmental disorders. Affecting approximately 30-40% of cases, these can include an increased risk of autistic spectrum disorder (approximately three-fold increase in risk), childhood autism (approximately five-fold increase in risk) and delays in early development. There is evidence that children exposed to valproate *in utero* will go on to have a lower IQ than children exposed to other antiepileptic drugs.

- As a result of this risk, the MHRA published a Drug Safety Update (Valproate and risk of abnormal pregnancy outcomes: new communication materials) in February 2016, stating that:

    - Valproate should not be prescribed for female children, female adolescents, women of childbearing potential or pregnant women unless other treatments are ineffective or not tolerated.

    - Female patients and their carers should be counselled about the risk of taking valproate during pregnancy.

    - For females planning to become pregnant, all efforts should be made to switch to an appropriate alternative treatment prior to conception.

    - Valproate treatment must be started and supervised by a doctor experienced in managing epilepsy or bipolar disorder.

- A new MHRA Drug Safety Update published in April 2018 implemented these further restrictions:

    - Valproate medicines must not be used in women and girls of childbearing potential unless the conditions of a Pregnancy Prevention Programme are met.

    - Specialists must book in review appointments at least annually with women and girls under the Pregnancy Prevention Programme and re-evaluate treatment as necessary; explain clearly the conditions as outlined in the supporting materials; and complete and sign the Risk Acknowledgement Form - copies of the form must be given to the patient or patient/caregiver/responsible person and sent to their GP.

    - Valproate is now completely contraindicated for the treatment of bipolar disorder in women who are pregnant.

- The Drug Safety Update also stipulated new communication materials which the MHRA have asked healthcare professionals to use when valproate is prescribed for females with childbearing potential. These communication materials have been incorporated into the current document.

2.0 Pregnancy Prevention Programme (also referred to as 'prevent')

- All women of childbearing potential and girls being treated with valproate medicines must be supported on a Pregnancy Prevention Programme (PPP).

- The conditions of the PPP must be met even for female patients who are not sexually active unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy.

- The PPP is a system of ensuring all female patients taking valproate medicines:

    - Have been told about, and understand the risks of use in pregnancy and have signed a Risk Acknowledgement Form.

    - Are on highly effective contraception if necessary.

    - See their specialist at least once a year.

- The PPP requires that the following materials be used when valproate is prescribed for a girl (of any age) or women of childbearing potential:

    - **Patient guide:** to be provided to girls (of any age) and women of childbearing potential (or their carers) who are started on or are continuing to use valproate medicines

    - **Guide for Healthcare Professionals**: for guidance to 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 carer) 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.

    - **Patient Card:** to be given by pharmacists to all female patients who are dispensed valproate medicines to inform them of the risks.

    - **Stickers with warning symbols:** for pharmacists to add to the packaging of valproate medicines (see Section 4.0 below for more about warnings added to packs).

3.0 Prescribing valproate

- Prescribers, and specialists making recommendations for treatment, must always carefully balance the benefits of valproate treatment against the risks. Valproate should only be used when other treatment options have been ineffective or have not been tolerated, as judged by an experienced specialist.

- The following actions must be completed by anyone who prescribes valproate, or who makes a recommendation for valproate to be prescribed, for a particular patient:

1. Read the Guide for Healthcare Professionals
    - The guide can also be found online at www.medicines.org.uk by searching for "valproate" then clicking "Risk Materials" next to any of the medicines that appear

2. Assess capacity
    - Assess the patient's capacity to consent to treatment with valproate and document the outcome of this assessment in the patient's notes
    - If patients are found to lack the capacity to consent to treatment, follow the guidance in Section 3.4 of this document.

3. Provide Patient Guide:
    - Provide the patient or their carer with the valproate patient guide
    - The guide can also be found online at www.medicines.org.uk by searching for "valproate" then clicking "Risk Materials" next to any of the medicines that appear
    - If the patient refuses to be provided with information about valproate, follow the guidance in Section 3.5 below

4. Perform serum pregnancy test
    - Perform serum pregnancy test at least 14 days after last possible date on which patient had, or could have had, unprotected sex.
    - For further details see Section 3.2 below.
    - **Note**, valproate is absolutely contraindicated for women with bipolar disorder who are pregnant; it must not be prescribed for this group of patients.

5. Complete the Risk Acknowledgement (RA) Form (2 options: electronic RIO or paper)

    - The form consists of Step 1 to 3:
    - **Step 1:** Decide if the patient needs to be on 'prevent' (the valproate pregnancy prevention programme
    - **Step 2:** 'prevent' applies to this patient i.e. she is of childbearing potential and at risk of pregnancy
    - **Step 3**: Your patient needs to complete this section to confirm they understand the risks of valproate in pregnancy

Option 1) RIO Electronic Risk Acknowledgement Form (Appendix A)

- The risk acknowledgement form can now be completed electronically within RIO and a GP editable letter generated, which **must** be sent to the GP via the 'Drop Zone' function.
- Full instructions on how to complete the electronic form and send to the GP can be found in Appendix A
- A copy should also be given to the patient.

Option 2) Paper Risk Acknowledgement Form (Appendix B)

- The paper risk acknowledgement form can now be found in Appendix B and also via https://www.gov.uk/guidance/valproate-use-by-women-and-girls.
- One copy of the form is to be given to the patient, one copy to be filed in their notes (on RiO under 'Clinical Documentation' with code**: DD/MM/YYYY VALP**), and one copy **must** be sent to their GP.

6. Provide contraception advice:
    - See Section 3.3 below

7. Prescribe folic acid:
    - All women of childbearing potential and girls who are prescribed sodium valproate should also be prescribed folic acid 5mg daily

3.1 Follow-up and specialist review

- Valproate must be reviewed by the patient's specialist at least once a year.

- At each review the specialist should discuss the risks of valproate in pregnancy and complete and sign the Risk Acknowledgement Form with the patient or their carer.

- At each review, prescribers must ensure that the benefits of valproate continue to outweigh the risks.

- For inpatients, the Risk Acknowledgement Form must be completed when valproate is first prescribed and for any newly admitted patients who take the medication. The risks should be reemphasised to the patient when they first go on leave, and when they are discharged.

- Suspected side effects to valproate should be reported via the Yellow Card reporting scheme.

- Exposure to valproate in pregnancy should be reported to UKTIS (UK Teratology Information Service) accessed via their website.

3.2 Pregnancy testing*

* Pregnancy testing information obtained from: Bastian LA and Brown HL. *Clinical manifestations and diagnosis of early pregnancy.* From "UpToDate®" clinical resource (Wolters Kluwer), Topic 440, Version 32.0. Topic last updated: 4th January 2016.

- As with all teratogenic medicines, pregnancy should be excluded before initiation on valproate medicines by a negative plasma pregnancy test, confirmed by a healthcare professional.

- The aim of pregnancy testing is to provide as much certainty as possible that the service user is not pregnant, *before* prescribing valproate.

- Pregnancy testing relies on detection of human chorionic gonadotropin (hCG), which is released after a fertilised egg has implanted into the uterus wall.

- Implantation normally occurs 6 to 12 days after ovulation. As hCG will not be released until after implantation, there is a delay between the time of fertilisation of an egg and the time at which a pregnancy is detectable.

- In the early stages after implantation, an hCG serum assay more sensitively detects pregnancy than an hCG urine dip test.

- Therefore, if there is any possibility that the patient has recently been sexually active, valproate should not be prescribed until:

    - 14 days have elapsed since the last possible day on which the patient could have had unprotected sex (for example, this could be 14 days from the point of admission, or 14 days from the last day on which the patient was given unescorted leave from the ward),

      AND

    - A negative hCG serum assay has been obtained after this 14 day period has elapsed.

- For patients who have been admitted and who are already prescribed valproate for mood stabilisation in the community, if there is any possibility that the patient has recently had unprotected sex, valproate should be stopped. If clinically appropriate, the drug can be restarted provided that a negative serum hCG test has been obtained a minimum of 14 days after the last possible day on which the patient could have had unprotected sex.

- For patients who have been admitted and who are already prescribed valproate in the community for the treatment of epilepsy, if there is any possibility that the patient has recently had unprotected sex, the patient's neurology team must be consulted before stopping the valproate. This consultation should be considered extremely urgent and should occur at the earliest possible opportunity after the patient is admitted. The consultation should involve a thorough discussion about the risks posed by either continuing the valproate or stopping it.

3.3 Contraception advice

- Women and girls who are prescribed valproate must use 'highly effective' contraception if they are able to become pregnant (see guidance from Faculty of Sexual and Reproductive Health [FSRH]).

- Methods of contraception considered 'highly effective' in this context include:
    - The long-acting reversible contraceptives (LARC):
        - Copper intrauterine device (Cu-IUD),
        - levonorgestrel intrauterine system (LNG-IUS), and
        - progestogen-only implant (IMP),
    - male and female sterilisation,

- These methods of contraception all have a failure rate of less than 1% with typical use (see guidance from FSRH for more about user-independent methods and failure rates).

- If a user-independent form is not used, two complementary forms of contraception including a barrier method should be used and regular pregnancy testing considered.

- Individual circumstances should be, in each case, evaluated when choosing the contraception method, involving the patient in the discussion to guarantee her engagement and compliance with the chosen measures.

3.4 Patients who lack capacity

- For patients who are assessed to lack capacity to consent to treatment;

    - Valproate should only be initiated on a Psychiatric Intensive Care Unit (PICU).

- Valproate therapy should be stopped before the patient is transferred out of the PICU or before the patient is given leave from the ward.

- If, after thorough consideration of the risks, it is concluded that the patient should continue to receive valproate after being transferred out of the PICU, a clear risk-minimisation plan should be put in place. This may involve putting the patient on an increased observation level and restricting their leave from the ward until the valproate prescription has been stopped. This plan must be formulated in consultation with medical and nursing staff from the receiving ward. The plan should be clearly documented in the patient's notes.

- Complete as much of the Risk Acknowledgement Form as possible at the current time, and add this to the patient's notes.

3.5 Patients who refuse information

- Occasionally patients may not wish to receive information when valproate is prescribed, or they may not currently be receptive to such information.

- In these circumstances, serious consideration should be given to delaying valproate treatment until the patient is willing and able to accept information about the risks posed by the drug.

- However, if the initiation of valproate is considered to be absolutely necessary, then the prescriber must complete the following actions:

  - Complete as much of the Risk Acknowledgement Form as possible at the current time, and add this to the patient's notes.

  - Ensure that another attempt to provide the information to the patient is made at the earliest possible opportunity.

  - Make an entry in the patient's medical notes stating why it was not possible to complete the full checklist, and why it was considered necessary to prescribe the medication despite this.

  - Put a clear risk-minimisation plan in place. This may involve putting the patient on an increased observation level and restricting their leave from the ward until the valproate prescription has been stopped, or until the patient has received the necessary risk information about the drug. The plan must be clearly documented in the patient's notes.

3.6 Patients where there is permanently no possible risk of pregnancy e.g. post-menopausal or post-hysterectomy

- 'Step 1' of the risk acknowledgment form must still be completed and in such cases the risk does not need to be discussed in the next annual review and the requirements of 'prevent' (valproate pregnancy prevention programme) do not apply i.e. steps 2 and 3 of the risk acknowledgement form do not need to be completed.
- It is the responsibility of the clinical team/consultant to definitively confirm a diagnosis of 'menopause' and document this clearly within the patient's RIO notes and also on Step 1 of the risk acknowledgement form.
- It should not be assumed that the patient has reached menopause based solely on age, due to individual variation.

- It is important to bear in mind women can experience menopausal symptoms with irregular periods during the perimenopausal stage, which can last several years. There is still a risk of pregnancy during the premenopausal stage.
- Please refer to full NICE guideline available for download: NICE guidelines Menopause: diagnosis and management, NICE guideline [NG23] Published date: November 2015

3.7 Complex Patients – For whom the Pregnancy Prevention Programme cannot be fully met

- NOTE: Prescribing without a PPP in place is **contraindicated** and represents an unlicensed use of the drug; the MHRA regulation clearly states valproate must no longer be used in any women or girl able to have children unless she has a pregnancy prevention programme place.

- Psychiatrists must review patients who are currently prescribed valproate-containing medicines at least once a year. This review must include detailed consideration of the alternatives to valproate preparations, and their replacement whenever possible.

- In exceptional circumstances, where it is deemed clinically necessary to prescribe Valproate for a patient who cannot meet the requirements of the PPP, then the responsible **Consultant** must discuss the case of the individual patient with the **Clinical Director** for approval before prescribing. They should also consult with the pharmacist for a professional opinion.

- It may also be appropriate to consider additional resources such as best interest meetings, peer reviews, consultation with multidisciplinary team to facilitate decision making. Each patient should be fully involved in the choices she makes about her health and fertility.

- All discussions, including those with the patient must be fully documented on RIO and the annual risk acknowledgement form must be completed and uploaded correctly onto RIO. The consultant must have **compelling reasons** to indicate there is no risk of pregnancy and must document these on the annual risk acknowledgement form.

- Patients should be reviewed regularly, but at least annually with completion of the risk acknowledgment form.

- The consultant must also consider the possibility that the GP may refuse to continue prescribing valproate in the absence of a PPP and arrangements may need to be made to ensure the provision of continued clinical care and prescribing is maintained by ELFT.

- Prescribe folic acid 5mg daily to minimise any risks should the women become pregnant.

- This section of the policy provides guidance but is not fully exhaustive. For further, guidance in reference to prescribing valproate in females of childbearing potential for whom the PPP cannot be met, clinicians should access and read relevant professional resources including those found in the Resources section of this document (this is not a fully exhaustive list of resources. Prescriber should refer to other relevant resources available).

4.0 Dispensing valproate

- Pharmacists involved in the dispensing of valproate must read the Guide for Healthcare Professionals. The guide can also be found online at www.medicines.org.uk by searching for "valproate" then clicking "Risk Materials" next to any of the medicines that appear.

- When valproate is dispensed for a woman of childbearing potential or girl, it is the responsibility of the pharmacist to ensure she is provided with a valproate patient card, unless she confirms that she already has one.

- The pharmacist must encourage the patient to read the card and enter her name and current date in the spaces provided.

- Pharmacy staff should dispense in whole packs whenever possible. This will ensure that patients always see the warning symbol which has been added to the packaging for valproate.

- If a pack of valproate is split into smaller containers, or if the carton does not have a symbol on it, warning stickers should be added to the box

- Pharmacists must ensure that they discuss the risks in pregnancy with female patients each time valproate medicines are dispensed and ensure they have the Patient Guide and have seen their GP or specialist to discuss their treatment and the need for contraception.

- If a woman or girl of childbearing potential reports that she is not taking effective contraception, pharmacists should advise her to contact her GP for an urgent follow-up.

5.0 Other healthcare professionals

- Any other healthcare professional involved in providing care for a female patient who is prescribed valproate must ensure that they read the Guide for Healthcare Professionals. The guide can also be found online at www.medicines.org.uk by searching for "valproate" then clicking "Risk Materials" next to any of the medicines that appear.

- If a woman who is taking valproate discusses a wish to become pregnant, or states that they are pregnant, they should be asked to contact their GP or specialist as a matter of urgency.

- If a woman or girl of childbearing potential reports that she is not taking effective contraception, they should be advised to contact their GP for an urgent follow-up.

6.0 Further information

- Further information can be accessed online via the MHRA's Drug safety update; *"Valproate medicines (Epilim▼, Depakote▼): contraindicated in women and girls of childbearing potential unless conditions of Pregnancy Prevention Programme are met"*
  https://www.gov.uk/guidance/valproate-use-by-women-and-girls

- The Drug Safety Update also includes links to printable versions of the communication materials mentioned in this document:

    - Valproate information booklet for healthcare professionals
    - Valproate information booklet for patients
    - Valproate patient card

- The materials can also be found online at www.medicines.org.uk by searching for “valproate” then clicking “Risk Materials” next to any of the medicines that appear.

- Hard copies of these materials can be ordered by contacting the Sanofi Medical Information Department on 0845 372 7101, or via e-mail UK-Medicalinformation@sanofi.com

- More detailed information about valproate can be obtained by consulting the most recent Summary of Product Characteristics (SPC), available online through the eMC website (www.medicines.org.uk)

7.0 Resources

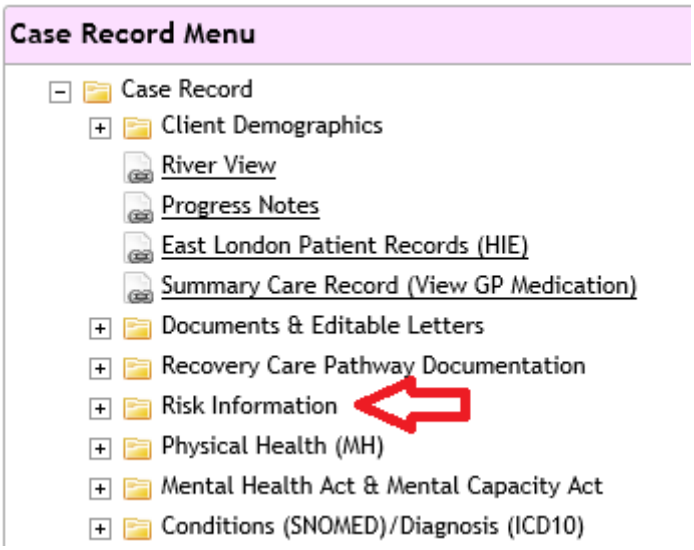
Baldwain, D and Wieck A. Withdrawal of, and alternatives to, valproate-containing medicines in girls and women of childbearing potential who have a psychiatric illness. Position Statement, December 2018. PS04/18 RCPsych 2018. Royal College of Psychiatrists.
https://www.rcpsych.ac.uk/docs/default-source/improving-care/better-mh-policy/position-statements/ps04_18.pdf?sfvrsn=799e58b4_2

Shakespeare, J and Sisodiya, S. Guidance Document on Valproate Use in Women and Girls of Childbearing Years. On behalf of the Royal College of General Practitioners and Association of British Neurologists and Royal College of Physicians, Version 1, 29th March 2019.
https://www.rcog.org.uk/globalassets/documents/guidelines/valproate-guidance-march-2019.pdf

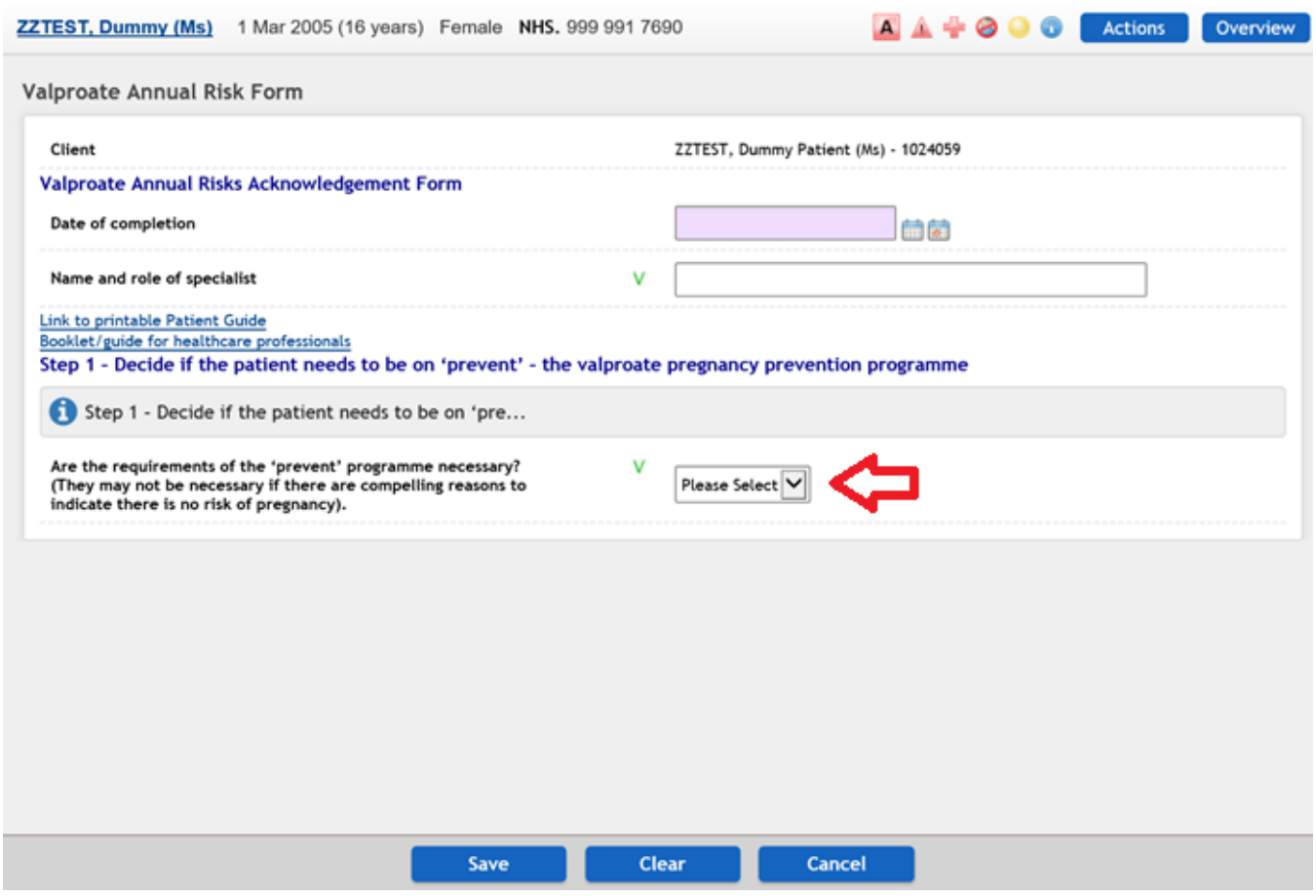
Relevant material below and further information can be accessed via the MHRA through this link: https://www.gov.uk/guidance/valproate-use-by-women-and-girls
- Patient card
- Patient booklet
- Booklet for healthcare professionals
- Annual Risk Acknowledgement Form

Appendix A: Guidance for Using the electronic Valproate Risk Assessment Form in RiO and sending to the GP

The Valproate Risk Assessment form can be found in the Risk Information folder in the case record menu.



The form is straightforward to complete and the informational text on the form guides you through it. When initially opened, a limited number of fields are displayed:



After filling in the date and your name and role, you need to decide whether the requirements of the prevent programme are necessary, as indicated by the arrow in the screenshot above. Clicking on the collapsible "Step 1" information box will expand it to give further guidance. If "Yes" is selected then Steps 2 and 3 are displayed as shown below. If "No" is selected then fields asking you to indicate why the programme is not necessary are displayed.

"Yes" is selected – Steps 2 and 3 are displayed

Step 2 - 'prevent' applies to this patient - she is of childbearing age and at risk of pregnancy

Step 2 - 'prevent' applies to this patient- she is...

I confirm that this patient needs valproate because (tick which applies):

Her condition does not respond adequately to other treatments	V	☐
She does not tolerate other treatments	V	☐
She is undergoing a treatment change from valproate	V	☐

I confirm I have discussed the following with the patient:

Valproate must not be used during pregnancy (except in rare situations in epilepsy for patients who are resistant or intolerant of other treatments)	V	☐
Children exposed to valproate during pregnancy have an approximately 10% chance of birth defects and a 30% to 40% chance of a wide range of early developmental problems that can lead to learning disabilities	V	☐
The conditions of the pregnancy prevention programme must be fulfilled	V	☐
The need for regular (at least annual) review of the need to continue valproate treatment by a specialist	V	☐

Effective contraception is essential while taking ...

The need for effective contraception, without interruption, throughout treatment with valproate	V	☐
The need to arrange an appointment with her specialist as soon as she is planning pregnancy to ensure timely discussion, and a timely switch to an alternative treatment before stopping contraception and conception occurring.	V	☐
The need to contact her GP immediately for an urgent review of her treatment in case of suspected or inadvertent pregnancy.	V	☐
The need for a negative (ideally serum) pregnancy test result at start and if needed thereafter.	V	☐
I confirm I have given the patient or responsible person a copy of the Patient Guide.	V	☐

In case of pregnancy, I confirm that:

We have discussed options for switching treatment	V	☐
She is fully aware of the risks of pregnancy, and has had the opportunity for counselling about the risks.	V	☐
I have given the patient or responsible person a copy of the Patient Guide.	V	☐

Step 3 - Your patient, or their responsible person, needs to complete this section with you to confirm they understand the risks of valproate in pregnancy.

I confirm I have completed this section with the patient, or their responsible person.	V	☐
Name of responsible person (if applicable)	V	

If you use valproate while you are pregnant, your future child has significant risk of serious harm.

Completing this form confirms that you (or your responsible person) understand the risks of using valproate during pregnancy, and what method of contraception you will use to prevent becoming pregnant during treatment.

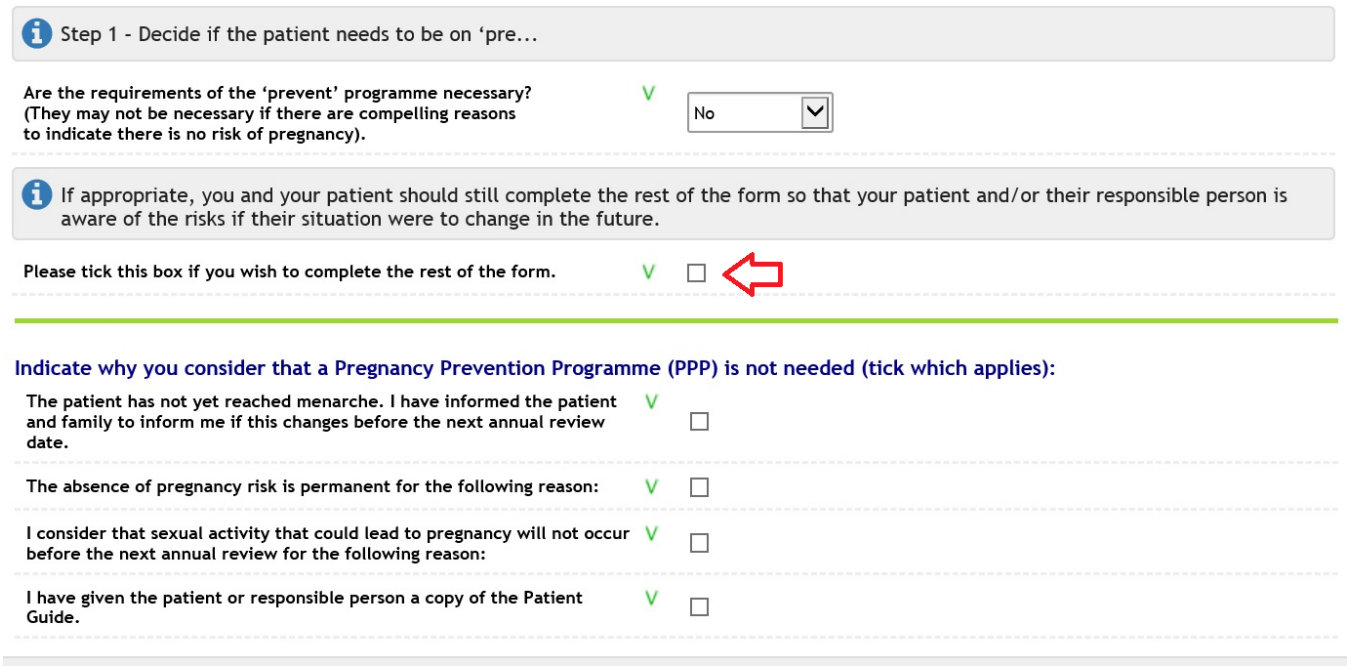
I have discussed the following with my specialist and I understand:

Why I need valproate rather than any other medicine	V	☐
That I should visit a specialist regularly (at least once a year) to review whether valproate remains the best option for me	V	☐
1 in 10 children of mothers who take valproate during pregnancy will have physical birth defects and 3 to 4 out of 10 children will have early developmental problems that can lead to significant learning disabilities	V	☐
That I have had a pregnancy test (if advised by my doctor/specialist)	V	☐
Why I must use effective contraception, without stopping or interruption, at all times while taking valproate	V	☐
The options for effective long-term contraception (or a consultation has been planned with a professional who can give me advice)	V	☐
The need to consult my specialist or GP as soon as I start thinking about becoming pregnant. This is to make sure I have time to switch to another treatment before I come off contraception.	V	☐
That I should request an urgent GP appointment if I think I am pregnant	V	☐
I have been given a copy of the Valproate Patient Guide and know where to find more information	V	☐

In case of pregnancy, I confirm that

Options for switching treatment have been considered	V	☐
I am fully aware of the risks and have had the opportunity to have counselling about the risks	V	☐

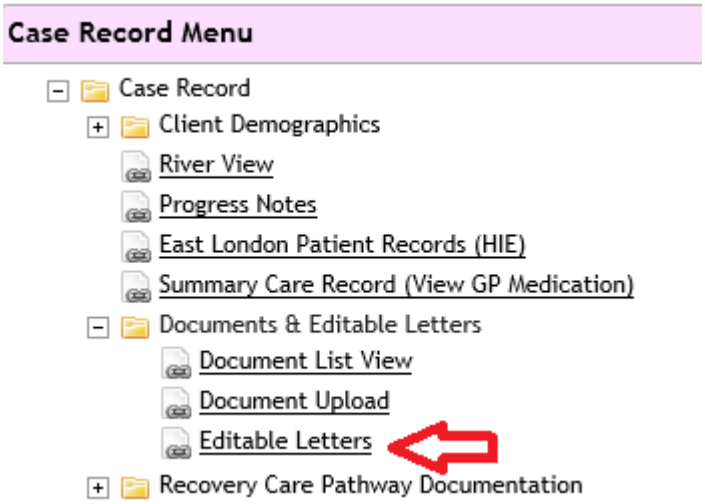
"No" is selected – reasons why programme is not needed are displayed



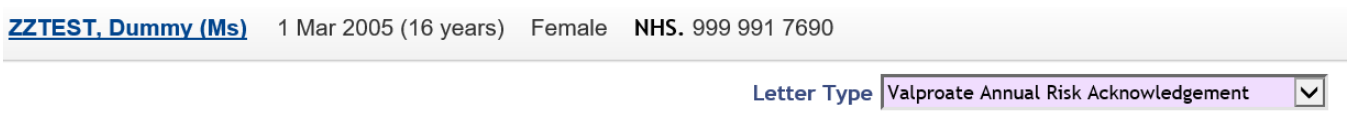
In this case you can still elect to complete the rest of steps 2 and 3 if appropriate. Ticking the box indicated in the screenshot above will display steps 2 and 3 in addition.

Sending the letter to the GP and uploading the finished document

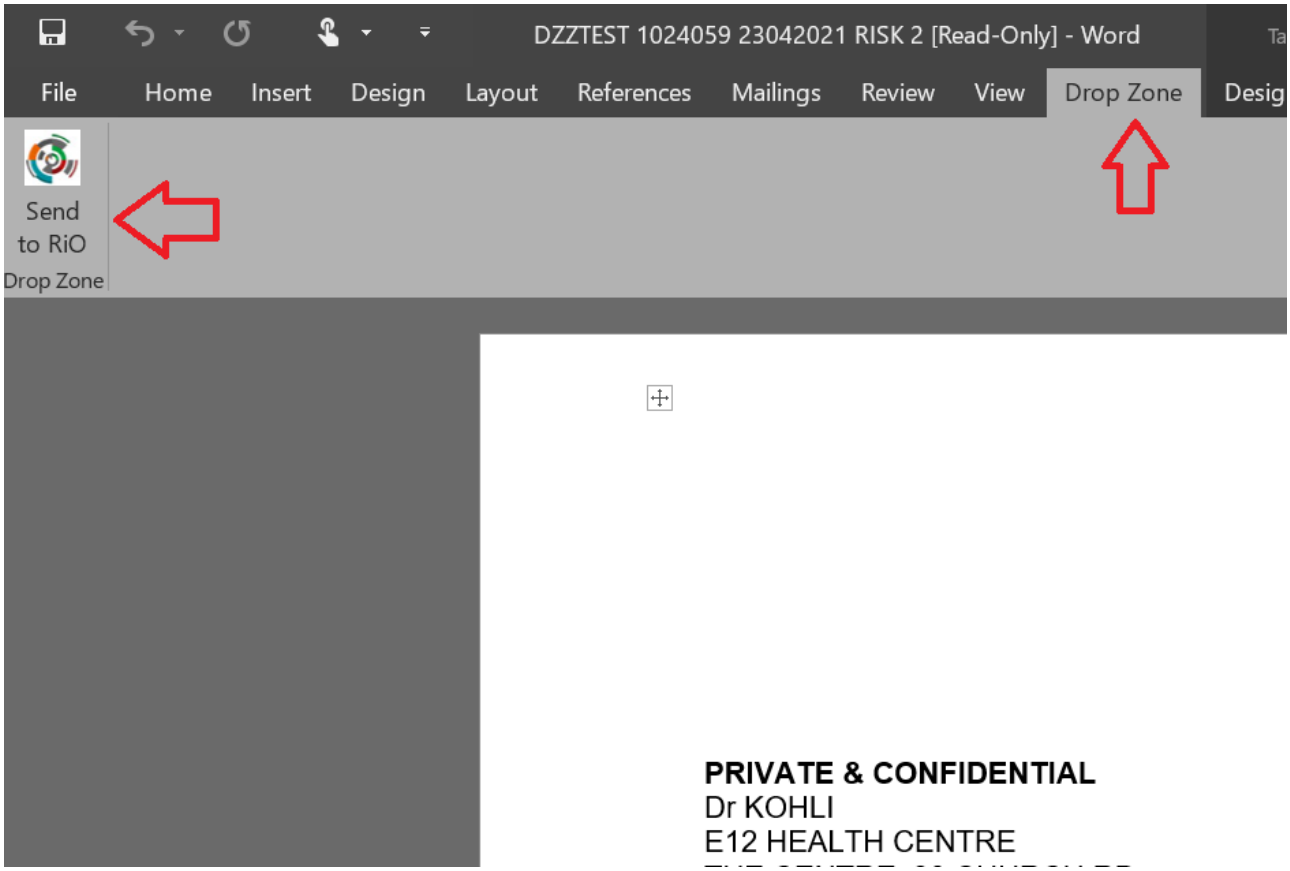
Once the form has been completed, you should send it to the GP. To do this go to editable letters in the case record menu:



On the editable letters screen select the "Valproate Annual Risk Acknowledgement" option in the picklist and the click on create at the bottom of the screen.

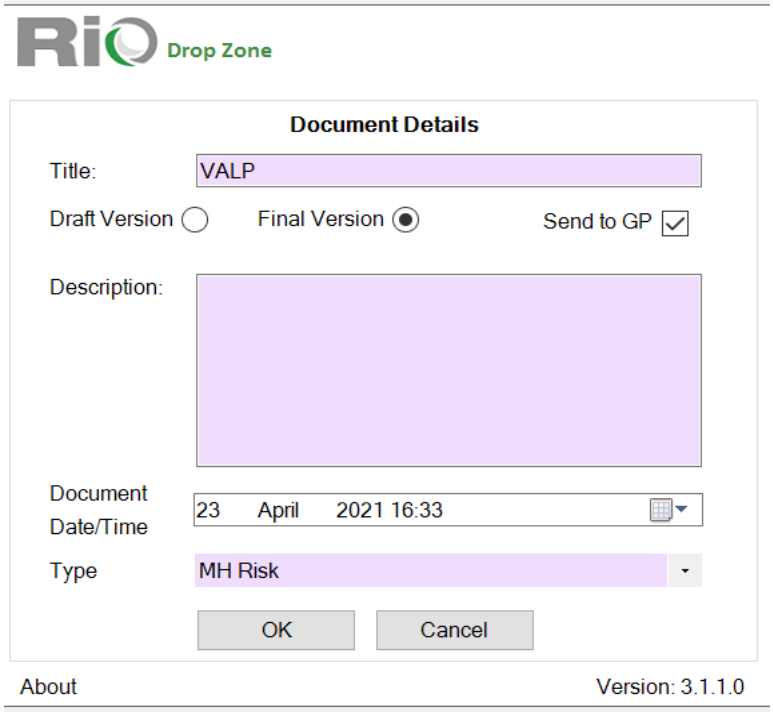


Microsoft Word is opened with a copy of the letter to the GP which pulls the information through from the form you have created. Select the "Drop Zone" tab in the menu bar and then click on "Send to RiO":



Complete the pop-up box that appears as follows:

1. Use “VALP” for title
2. Tick the “Send to GP” box
3. Select “MH Risk” in the “Type” picklist
4. Click “OK”



This will send the letter electronically to the GP and upload the letter to RiO with code “VALP”. This is important is the reporting that runs to check that patients on Valproate have had a risk assessment completed will look for this document.

East London
NHS Foundation Trust

Appendix B

Valproate in female patients:

Annual Risk Acknowledgement PAPER Form

Available via: https://www.gov.uk/guidance/valproate-use-by-women-and-girls.

After completing please upload onto patient's RIO record using the code 'VALP'