**Valproate Safety Dashboard**

**Version: February 2021**

**Dashboard Specification**

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# Introduction

Valproate, also known as sodium valproate, valproic acid and valproate semi-sodium, is a treatment for epilepsy and bipolar disorder which has been available in the UK since 1974. In common with some other anti-epileptic medicines, it was known to be teratogenic i.e., it could cause physical or functional defects in the human embryo or fetus when taken during pregnancy. Evidence about the scale of harm when taken during pregnancy has increased substantially in recent years. The Medicines & Healthcare products Regulatory Agency (MHRA) now states that:

 ‘***If valproate is taken during pregnancy, up to 4 in 10 babies are at risk of developmental disorders, and approximately 1 in 10 are at risk of birth defects’.* [[1]](#footnote-1)**

Responding to concerns that some women were not aware of the risks when used in pregnancy, the MHRA now advise that valproate must not be used in any woman or girl able to have children unless there is a pregnancy prevention programme (PPP) in place.

There has been a steady reduction in prescribing of valproate female patients aged 14-45 since 2016, from approximately 24,000 patients to 13,000 in 2020. [[2]](#footnote-2) However, there are still reports that a small number of become pregnant while on valproate and some may be unaware of the risks of harm to the unborn child. The report of the Independent Medicines and Medical Devices Safety Review, published in July 2020, included actions concerning valproate safety [[3]](#footnote-3) . NHSE&I have established a national Valproate Safety Implementation Group to ensure valproate is only used in people who can get pregnant when there are absolutely no alternative treatments.

Valproate should only be initiated in people able to become pregnant by a specialist prescriber (e.g. a consultant neurologist or psychiatrist) and treatment must be reviewed at least annually by the specialist. However, most prescribing of valproate is in primary care; the GP continues treatment as advised by the specialist. Thus, prescribing data from primary care provides insight on valproate use.

NHSBSA already publishes a spreadsheet with quarterly figures for the number of female patients aged 0-45 that have received prescriptions for sodium valproate. [[4]](#footnote-4)The Valproate Safety Dashboard builds on this work to make monitoring valproate use straight forward for patients, the public and health professionals. Importantly, it enables usage comparisons between localities and includes markers for patients newly initiated on valproate and patients who resume treatment following a period where valproate is not prescribed.

# Purpose and population

Use of valproate at any stage of pregnancy is known to be harmful to the unborn child. The purpose of the valproate dashboard is to support a reduction in use of valproate and help prevent unplanned pregnancies in women taking valproate. The dashboard includes only female patients aged under 55 years. (It is not known whether use of valproate by the male parent can affect the unborn child. This issue requires further research but is outside the scope of the current initiative.)

# Age bands

There are two age bands for the indicators: 0-12 years and 13-54 years. Some females aged 12 or under could potentially become pregnant, but girls of this age are not legally able to consent to sexual intercourse. The 0-12 age band is included to inform possible continued use of valproate in later years. The 13-54 age band is those where pregnancy is considered possible. Clearly some females in this age band are permanently unable to get pregnant (e.g. have had a hysterectomy) but such patients cannot be identified from the prescribing data used to populate this dashboard. Contraception is required until age 55 or until menopause is confirmed [[5]](#footnote-5) Menopause date is difficult to determine; age under 55 is in line with standard contraception guidance (spontaneous conception after this age is exceptionally rare even in women still experiencing menstrual bleeding).

# Dashboard availability and redaction of small numbers

The indicators are available both on Catalyst (open access) and ePACT2 (NHS controlled access). Both include National, Regional and Clinical Commissioning Group data. GP practice data is available only on ePACT2. On Catalyst, to ensure patient confidentiality, small patient numbers (i.e., between 1 and 4 patients at CCG level) are automatically redacted.

# List of indicators

|  |  |
| --- | --- |
| VPA1 | Female patients prescribed valproate per 1,000 population |
| VPA2 | Female patients prescribed valproate as a proportion of all patients prescribed valproate |
| VPA3 | Female patients prescribed valproate |
| VPA4 | Female patients starting valproate |
| VPA5 | Female patients resuming valproate |

# Prescribing data used in these indicators

Users of the indicators should be aware of the following parameters:

The data -

* Covers all items prescribed in practices and other cost centres linked to CCGs (this includes acute and repeat items).
* Does not include hospital prescribing.
* Does not include items prescribed privately.
* Does not include medicines supplied by NHS community services.
* Is restricted to prescription items where the NHS number could be identified for the patient.

Each indicator is derived using prescribing data and reported by month, with totals aggregated to three-month rolling periods. Historic data is available to allow CCGs and Practices to chart their progress in addressing a particular indicator area.

All the indicators are based on data which is collected at Practice level and aggregated to CCG, Region and National (England) level.

# Patient counts

Some indicators are based on a count of unique patients. This has been determined from prescriptions where the NHSBSA has been able to obtain details regarding patient NHS number and age at practice location. Where the same patient appears in the data for more than one practice location they will be counted as one patient for each of the practice locations they appear in.

NB: While NHS numbers are used to formulate these indicators, no personal identifiable data will be released through these indicators.

Patient counts are included for those patients that are recorded with the gender of female, and with an age between 0 and 12, or 13 and 54, in the three-month period being examined. Patients with a recorded gender other than female (i.e., where the patient is recorded as male, or where no gender is recorded), or where the recorded patient age is 55 or older, or is not present, are excluded.

Patient gender and age details are sourced from the Patient Demographic Service and held against individual prescription forms in the NHSBSA data warehouse.

# How to use these indicators

We envisage that the Indicators will be used by CCGs in collaboration with local GP practices and specialists with the relevant and appropriate education, training and support in place.

# Data Source

This data product is provided by NHS Business Services Authority. The information contained herein is based on data from the NHSBSA‟s data warehouse system which contains all NHS prescription data, with the exception of prescriptions which are dispensed in prisons, hospitals and private prescriptions.

Analysis is based on drugs that were reimbursed by the NHSBSA. It excludes items not dispensed and disallowed. If a prescription was issued, but not presented for dispensing or was not submitted to NHS Prescription Services by the dispenser, then it is not included in the data provided.

# Data owner & contact details

This data product is managed by NHS Business Services Authority Information Services, email nhsbsa.help@nhs.net

# Frequency of updates

The data for this dashboard is refreshed on a monthly basis.

# Data quality assurance

NHS Prescription Services have their own internal quality process to assure the data they provide matches what was originally submitted as part of the prescription processing activity. Some processes are complex and manual therefore there may be random inaccuracies in capturing prescription information which are then reflected in the data but checks are in place to reduce the chance of issues occurring. The processes operate to a number of key performance indicators, one of which is the percentage Prescription Information Accuracy, the target being 99.3% and as of December 2018 prescribing, the accuracy level achieved over the latest 12 month rolling period was 99.68%.

The indicators take advantage of the developments linking the NHS number to prescription items. Currently, nearly 95% of all paper prescription items can be linked to an NHS number with an accuracy of over 99%. Age and date of birth can be linked to 73% of paper prescription items with an accuracy of 97%. As the utilisation of EPS increases, the coverage and accuracy of this data will increase.

# Indicator Specifications

## VPA1 Female patients prescribed valproate per 1,000 population

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| **Section 1: Introduction / Overview** |
| 1.1 | **Title** | Female patients prescribed valproate per 1,000 population |
| 1.2 | **Definition** | This indicator shows the number of female patients in the age bands 0-12 and 13-54 receiving a prescription for valproate, per 1,000 female patients. |
| 1.3 | **Reporting Level** | Three-monthly, based on practice level data and aggregated to CCG, NHS Region and national levels. |
| 1.4 | **Numerator** | Number of female patients in the age bands 0-12 and 13-54 in the three-month period, who have been prescribed one or more items of a valproate product. |

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| 1.5 | **Denominator** | Number of female patients in the age bands 0-12 and 13-54, who are registered with GP practices in the CCG, in the same three-month period. |

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| 1.6 | **Methodology** | Numerator divided by denominator, expressed per 1,000 patients. |
| **Section 2: Rationale** |
| 2.1 | **Purpose and Limitations** | This indicator can be used to enable valproate usage comparison between localities. However, this assumes consistent disease prevalence across different geographies which may not be justified. VPA1 should be used with VPA2 and the actual patient numbers (VPA3-VPA5) to get an overall picture of valproate use. |

## VPA2 Female patients prescribed valproate as a proportion of all patients prescribed valproate

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| **Section 1: Introduction / Overview** |
| 1.1 | **Title** | Female patients prescribed valproate as a proportion of all patients prescribed valproate |
| 1.2 | **Definition** | This indicator shows the number of female patients in the age bands 0-12 and 13-54 receiving a prescription for valproate, as a proportion of all patients (male and female) prescribed valproate. |
| 1.3 | **Reporting Level** | Three-monthly, based on practice level data and aggregated to CCG, NHS Region and national levels. |
| 1.4 | **Numerator** | Number of female patients (in each age band) in the quarter prescribed valproate. |
| 1.5 | **Denominator** | All patients in the quarter that have been prescribed valproate. |
| 1.7 | **Methodology** | Numerator divided by denominator, expressed as a percentage |
| **Section 2: Rationale** |
| 2.1 | **Purpose and Limitations** | This indicator can be used to enable valproate usage comparison between localities. Using all patients prescribed valproate as the denominator may account to some extent for differences in disease prevalence between geographies. However, if valproate use is high overall in a particular geography, high use in female patients may not be identified. VPA2 should be used with VPA1 and the actual patient numbers (VPA3-VPA5) to get an overall picture of valproate use. |

## VPA3 Female patients prescribed valproate

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| **Section 1: Introduction / Overview** |
| 1.1 | **Title** | Female patients prescribed valproate |
| 1.2 | **Definition** | This indicator shows the number of female patients in the age bands 0-12 and 13-54 that have been prescribed a valproate medicine. |
| 1.3 | **Reporting Level** | Three-monthly, based on practice level data and aggregated to CCG, NHS Region and national levels. |
| 1.4 | **Numerator** | Number of female patients in each age band, who have been prescribed one or more prescription items of a valproate medicine in the selected quarter. |
| 1.5 | **Denominator** | None. |
| 1.6 | **Methodology** | Data is presented as numerator only.  |
| **Section 2: Rationale** |
| 2.1 | **Purpose and Limitations** | This indicator reports the actual number of female patients prescribed valproate. This indicator is not suitable for direct comparison with other localities because it is not adjusted for population size or disease prevalence. Actual numbers are used at national and local levels to monitor overall valproate use and support effective governance. |

## VPA4 Female patients starting valproate

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| **Section 1: Introduction / Overview** |
| 1.1 | **Title** | Female patients starting valproate |
| 1.2 | **Definition** | This indicator shows the number of female patients in the age bands 0-12 and 13-54 that have been newly prescribed valproate. For the purposes of this indicator, ‘new patient’ is taken to mean a patient receiving an item of a valproate medicine in a given three-month period, who has had no valproate prescribing in the **previous 24 months.** |
| 1.3 | **Reporting Level** | Three-monthly, based on practice level data and aggregated to CCG, NHS Region and national levels. |
| 1.4 | **Numerator** | Number of female patients in the current quarter prescribed valproate who have not had valproate prescribed in the previous 24 months. |
| 1.5 | **Denominator** | None. |
| 1.6 | **Methodology** | This indicator shows the number of female patients who have been prescribed valproate in a chosen three-month period, and have had no prescriptions for valproate in the preceding 24 months.Data is presented as numerator only. |
| **Section 2: Rationale**  |
| 2.1 | **Purpose and Limitations** | This indicator can be used to report the number of new valproate patients. Current knowledge of the risks posed by valproate means that there will be very few occasions where the efficacy-safety balance is favourable for people who can get pregnant. The number of new initiations should be rare, and this will be monitored at national and local level. This indicator is not suitable for direct comparison with other localities because numbers are small and are not adjusted for population size or disease prevalence. **NB** The experimental [Medicines in Pregnancy Registry](https://digital.nhs.uk/data-and-information/publications/statistical/mi-medicines-in-pregnancy-registry/valproate-use-in-females-aged-0-to-54-in-england-april-2018-to-september-2020) Valproate data from NHS Digital [[6]](#footnote-6) defines new patients as those who have a prescription for valproate in the reporting month, but have not had valproate prescribed in the previous **12 months.** The shorter time frame reflects the more limited historical data available in the Registry. Time frames will be jointly reviewed by NHSBSA and NHS Digital as data sets are updated.  |

## VPA5 Female patients resuming valproate

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| **Section 1: Introduction / Overview** |
| 1.1 | **Title** | Female patients resuming valproate |
| 1.2 | **Definition** | This indicator shows the number of female patients who restart valproate after a period where it has not been prescribed. |
| 1.3 | **Reporting Level** | Three-monthly, based on practice level data and aggregated to CCG, NHS Region and national levels. |
| 1.4 | **Numerator** | Number of female patients in the current quarter prescribed valproate, who have not been prescribed valproate in the previous 6 months, but who have been prescribed valproate in the 24 months before that.  |
| 1.5 | **Denominator** | None. |
| 1.6 | **Methodology** | In this indicator we first examine all female patients in the 0-12 and 13-54 bands for evidence of prescribing in the three-month period; this cohort is then analysed to remove any patients that have had valproate prescribing in the 6 months prior to that quarter.Finally, from the resultant cohort we identify any patients that had prescribing in the 24 months before the start of that 6-month gap and return them to the numerator.Data is presented as numerator only. |
| **Section 2: Rationale** |
| 2.1 | **Purpose** | This indicator can be used to report the number of valproate patients who have a period without valproate use but then recommence treatment. This is an exploratory indicator which may provide insight on how frequently patients who stop valproate/switch to an alternative treatment subsequently need to resume valproate use. |

# Process for development and review of indicators

The indicators have been developed from initial work on valproate prescribing by NHSBSA, NHS Digital and MHRA. Development was supported by the NHSE&I Valproate Safety Implementation Group in consultation with data experts from NHS Digital, NHSBSA, GIRFT and the MHRA and with other NHS policy and pharmacy leads.

Andrew Evans (Chief Pharmaceutical Officer for Wales) also kindly shared information on measurement of valproate prescribing prevalence, incorporated in these indicators.

For more information or to comment on the dashboard please contact nhsbsa.help@nhs.net.

In parallel to this work, the MHRA with NHS digital produce a Valproate Registry which links NHSBSA prescribing data with GP clinical records, hospital records and maternity services data. The intention is to build the Valproate Registry in 3 phases, eventually adding detailed information from clinical systems and from patients.

# Appendix 1: Medications included in the indicators

Medicines under the following chemical substances have been included in the indicators:

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| **BNF Chemical Substance Code** | **BNF Chemical Substance Name** |
| 0408010W0 | Sodium Valproate |
| 0402030Q0 | Valproic acid |
| 040801020 | Valproic acid |

A full list of presentations is contained in the accompanying drug list, which can be found on the Valproate Safety Dashboard web page.

1. MHRA, *Valproate use by women and girls*, <https://www.gov.uk/guidance/valproate-use-by-women-and-girls> [↑](#footnote-ref-1)
2. NHS BSA, *Sodium Valproate,* <https://www.nhsbsa.nhs.uk/prescription-data/prescribing-data/sodium-valproate> [↑](#footnote-ref-2)
3. IMMDS, *The Independent Medicines and Medical Devices Safety Review*, <https://www.immdsreview.org.uk/Report.html> [↑](#footnote-ref-3)
4. Ibid. 2 [↑](#footnote-ref-4)
5. FSRH, *Contraceptive Choices for Young People*, <https://www.fsrh.org/documents/fsrh-guidance-contraception-for-women-aged-over-40-years-2017/> [↑](#footnote-ref-5)
6. <https://digital.nhs.uk/data-and-information/publications/statistical/mi-medicines-in-pregnancy-registry/valproate-use-in-females-aged-0-to-54-in-england-april-2018-to-september-2020> [↑](#footnote-ref-6)