

North of England Commissioning Support

Medicines Optimisation

Valproate Care Bundle

Version issue date:	29/5/19
Date of MO Q&G approval:	
Date of review:	
Circulation:	Internal/External

Author Name	Email Address
Nicola McNicol	nicola.mcnicol@cumbria.necsu.nhs.uk



1. Introduction

1.1. What is a care bundle?

A care bundle is a set of interventions that, when used together, significantly improve patient outcomes. The measures chosen reflect best practice and are based on NICE quality standards or other national guidance. Care bundles have been used extensively and successfully in Secondary Care, their use in Primary Care is more recent. This care bundle is based on the work of Healthcare Improvement Scotland and the Scottish Patient Safety Programme in Primary Care.

Reliability in health care is a failure-free operation over time. This equates to ensuring patients receive all the evidence-based care they are entitled to receive.

A care bundle is a structured way of improving processes of care to deliver enhanced patient safety and clinical outcomes. In relation to care bundles, this means ensuring that patients receive optimum care at every contact. The process for achieving reliability is to implement this set of measures (a care bundle). The key measure in a care bundle is the score which measures the level of compliance with all measures for all patients.

The care bundle data collection tool is a way of sampling whether optimum care is being delivered by applying the bundle to a sample of patients. This approach is therefore very different from traditional auditing approaches that are designed to identify whether individual measures are being implemented.

1.2. What makes up a care bundle?

- 4-5 measures
- All or nothing compliance
- Measurement done by a non-clinician if possible
- Spread over patient's journey
- Evidence based
- Creates teamwork and communication
- Multiple functions of care essential for desired outcome

1.2.1. How should a care bundle be used in practice?

A care bundle is a quality improvement tool which can be used in general practice to identify both where care is in line with best practice and where improvements are needed. Some are disease specific and some are medication specific. The latter are also known as patient safety bundles as they relate to high risk medication.

NECS Care Bundle Valproate final.docx	Issue Date:	Page 2 of 9
Status: Draft/Approved	Approved date:	Next Review Date:

Bringing about changes in practice is not easy. To be an effective tool the results of the care bundle measurements must be discussed by ALL members of the team involved in the care of the patient. The practice team then need to take ownership of the issues identified and commit to changing the way care is provided, using tools such as the Plan Do Study Act (PDSA) cycle.

Principles of successful measurement:

- The support of all members of the practice team should be obtained
- Data should be collected anonymously
- The results should be discussed by every member of the team
- The results should be used to plan and implement improvement initiatives
- Clinician support may be needed initially by the data collector until they are familiar with the measures.

1.3. Records

The care bundle is not a performance tool and so there is no requirement to report the measures achieved. The practice should keep a reflective log of improvements.

1.4. Resources

This care bundle has the following supporting resources:

- A word document data collection form
- An excel spreadsheet data collection form with a graphing function
- A PowerPoint presentation for use in educational sessions
- A reflective log template

Further information on Care Bundles and Improvement Models can be found at NHS Scotland: <https://learn.nes.nhs.scot/931/patient-safety-zone/patient-safety-tools-and-techniques/care-bundles>

Evidence:

<https://implementationscience.biomedcentral.com/articles/10.1186/s13012-017-0670-0>

The above link may need copying and pasting into web browser if struggling to access via control and click.

Further advice can be obtained from the Medicines Optimisation team, and specific queries about this care bundle can be directed to the author (details are on the front page).

NECS Care Bundle Valproate final.docx	Issue Date:	Page 3 of 9
Status: Draft/Approved	Approved date:	Next Review Date:

2. Valproate – use in girls and women of child bearing potential.

2.1. Search Criteria

Please identify a random sample of up to 20 female patients of child bearing age a month in your practice taking drug Sodium Valproate/ Semisodium valproate (valproic acid). Numbers in practice may actually be much lower.

This may be done by using the search within the practices clinical system. In EMIS this search may be found under: EMIS Library/Emis Clinical Utilities/Drug Monitoring/Anticonvulsants/Valproate/Females of child bearing age (12-49) on Valproate. Alternatively you may wish to use previously circulated search templates.

Use the data collection form to record the answer to each measure and transfer this to the Excel spreadsheet data collection form if wanting to use this. If used the Excel spreadsheet will result in graphs being populated with ongoing scores. This should be repeated over a period of time, and the results discussed by the clinical team at regular intervals. Every three months is recommended. Use of the spreadsheet will enable changes in practice to be monitored and compliance with the care bundle to be measured.

2.2. Measures

01

Measure	All patients have an up to date*, completed and signed Annual Acknowledgment Risk Form filed in the notes. Y/N
Rationale	<p>The guidance approved by the Medicines & Healthcare Products Regulatory Authority (MHRA) states that all patients should have an up to date, signed, Annual Acknowledgment of Risk Form (ARAF) filed in the notes, and this should be checked each time a repeat prescription is issued. This is a requirement of the pregnancy prevention programme which will minimise risks to patients, and to ensure patients have an adequate level of understanding of the risk.</p> <p>Up to date * - For women who are required to be on the Pregnancy Prevention Programme (PPP), this should be a date within the last 12 months. For women who have seen a specialist and have been assessed as not needing annual review, this may be a copy of the 'one off' ARAF confirming the reason she does not require PPP in place.</p>
Source	<p>prevent valproate pregnancy prevention programme - GUIDE FOR HEALTHCARE PROFESSIONALS</p> <p>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/708850/123683_Valproate_HCP_Booklet_DR15.pdf</p>

NECS Care Bundle Valproate final.docx	Issue Date:	Page 4 of 9
Status: Draft/Approved	Approved date:	Next Review Date:

--	--

02

Measure	Patient has been referred to appropriate specialist in last 12 months, or patient has been reviewed by appropriate specialist in the last 12 months and is already on Pregnancy Prevention Programme Y/N/NA
Rationale	Guidance approved by the MHRA is to ensure the patient is referred to the specialist for review annually. (Patient's may have been proactively provided with ARAF by their specialist at a recent clinic visit and therefore already on prevent). The objective of the valproate pregnancy prevention programme is to provide information about the teratogenic risks associated with the use of valproate during pregnancy, and for healthcare professionals and patients to follow the actions listed which are necessary to minimise the risks to patients, and to ensure patients have an adequate level of understanding of the risk.
Source	prevent valproate pregnancy prevention programme - GUIDE FOR HEALTHCARE PROFESSIONALS https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/708850/123683_Valproate_HCP_Booklet_DR15.pdf

03

Measure	Patient has been informed of the known risks and understands she must not get pregnant whilst taking valproate and there is documentation of this in the notes (while waiting for the first ARAF to be received from the specialist) Y/N/NA
Rationale	Guidance is for patients to have a copy of the Patient Guide and a copy of the Annual Risk Acknowledgment Form signed by the specialist. The Annual Risk Acknowledgement Form will contain details that the patient has been given a copy of the patient guide. GP responsibility is to ensure that she does have the Patient Guide and has a copy of the Annual Risk Acknowledgment Form signed by the specialist. In the interim period where patients have had initial referral to the specialist, but the review has not taken place, the patient should be informed of the known risks and understand she must not get pregnant and this should be documented in the notes.
Source	prevent valproate pregnancy prevention programme - GUIDE FOR HEALTHCARE PROFESSIONALS https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/708850/123683_Valproate_HCP_Booklet_DR15.pdf

NECS Care Bundle Valproate final.docx	Issue Date:	Page 5 of 9
Status: Draft/Approved	Approved date:	Next Review Date:

04

Measure	Patient is of child bearing potential and has appropriate contraception in place OR a reason documented in the notes why this is not in place Y/N/NA
Rationale	Guidance states that all women of child bearing potential should use a highly effective continuous method of contraception, understand the need to comply with contraception throughout treatment and may need to undergo pregnancy testing when required – e.g. if there is any reason to suggest lack of compliance or effectiveness of contraception. This will minimise risks to patients.
Source	prevent valproate pregnancy prevention programme - GUIDE FOR HEALTHCARE PROFESSIONALS https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/708850/123683_Valproate_HCP_Booklet_DR15.pdf

05

Measure	There is a recorded date on the practice system of when pregnancy prevention plan is due for review. Y/N/NA
Rationale	Guidance is that, each time a repeat prescription is issued, a check is made that an up to date, signed, Annual Acknowledgment of Risk Form is in place. This should ensure that the ARAF is renewed in a timely manner and the pregnancy prevention plan does not lapse. Best practice would be to have a proactive system in place to ensure the patient is referred to specialist again when the programme is nearing renewal (unless a “one-off” form has been completed). The use of Due Diary Dates or including the information within the directions of the medicine, E.g. ‘One to be taken Twice a Day. PPP review due March 2020’ may be ways of evidencing this. Use N/A response for those not requiring annual review.
Source	prevent valproate pregnancy prevention programme - GUIDE FOR HEALTHCARE PROFESSIONALS https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/708850/123683_Valproate_HCP_Booklet_DR15.pdf

Appendix One: Abbreviations

Abbreviation	Definitions
ARAF	Annual Review Acknowledgement Form
PDSA	Plan, Do, Study, Act
MHRA	Medicines & Healthcare Products Regulatory Authority (MHRA)
PPP	Pregnancy Prevention Programme

Appendix Two: Guidance notes

Measures 1 to 5 will help practices evidence the Prescribing Safety QI module in the 'A five-year framework for GP contract reform to implement The NHS Long Term Plan' document.

Girls and women of childbearing potential currently being prescribed valproate have had an annual specialist medication review and are taking this in compliance with the pregnancy prevention programme as documented by a specialist in the annual risk acknowledgement form. This standard applies equally to unlicensed use for pain, migraine and other conditions.

Girls and women of childbearing potential currently being prescribed valproate have had an annual specialist medication review – measures 1, 2 and 5

And are taking this in compliance with the pregnancy prevention programme as documented by a specialist in the annual risk acknowledgement form – measures 3 and 4

Suggested evidence checks

Measure 1 - There is an in date (within the last 12 months) record of Annual Risk Acknowledgement Form filed in the patients notes (Y) or there is a record of the 'one off' Annual Risk Acknowledgement Form detailing why the patient currently does not require annual review (Y)

Measure 2 – There is a record of referral to appropriate specialist in the last 12 months) (Y) or an ARAF that details the patient is already on prevent (Y) or there is a record of the 'one off' Annual Risk Acknowledgement Form detailing why the patient does not require annual review (N/A response)

Measure 3 - Documentation in the patient notes that evidences the patient has been provided with the patient guide and/or risk information. E.g. signed ARAF, or In the interim period where patients have had initial referral to the specialist, but the review has not taken place a record in practice notes that the guide has been provided (Y). Use N/A response for those not requiring annual review.

Measure 4 - Documentation in the notes that evidences prescription of appropriate contraception (Y) or a record that the patient obtains appropriate contraception from another provider (Y) or documentation of the patient's contraceptive/menopausal status/reasons why not using highly effective contraceptive method (Y). Use N/A response for those patients who are not or are no longer of child bearing potential.

Measure 5 – Documentation of a review date. This record might be evidenced as a due diary date on the practice clinical system or be included within the directions of

NECS Care Bundle Valproate final.docx	Issue Date:	Page 8 of 9
Status: Draft/Approved	Approved date:	Next Review Date:

the medicine. E.g. 'One to be taken Twice a Day. PPP review due March 2020' Use N/A response for those not requiring annual review.

NECS Care Bundle Valproate final.docx	Issue Date:	Page 9 of 9
Status: Draft/Approved	Approved date:	Next Review Date: