The following information is a summary to help guide practices to achieve the new prescribing safety module in QOF, contractors should refer to the original document for further information


Quality Improvement is a new domain in the GP contract to be introduced from 2019/20, the aim of which is to provide support for GPs and their staff to recognise areas of care which require improvement and take steps to address this through the development and implementation of a quality improvement plan and sharing of learning across their network. One of the two topic areas identified for 2019/20 is prescribing safety (end of life care being the other module). These topics will change on an annual basis.

**Indicator and Points**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Points</th>
<th>Achievement thresholds</th>
</tr>
</thead>
<tbody>
<tr>
<td>QI001</td>
<td>27</td>
<td>NA</td>
</tr>
<tr>
<td>QI002</td>
<td>10</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Aim**

The overarching aim of the prescribing safety module is to lead to improvements in the following aspects of prescribing safety:

- **NSAIDs** - Reduce the rate of potentially hazardous prescribing, with a focus upon the safer use of non-steroidal anti-inflammatory drugs (NSAIDs) in patients at significant risk of complications such as gastro-intestinal bleeding.

- **Lithium** - Better monitoring of potentially toxic medications and the creation of safe systems to support drug monitoring through a focus upon lithium prescribing (or another agreed medication if no patients on the registered list are currently being prescribed lithium).

- **Sodium Valproate** - Better engagement of patients with their medication through a focus upon sodium valproate and pregnancy prevention.

- **Improve collaboration** between practices, Primary Care Networks (PCNs) and community pharmacists to share learning and improve systems to reduce harm and improve safety.
What do practices need to do?

<table>
<thead>
<tr>
<th>Activity</th>
<th>Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Identify areas for improvement</td>
<td>QI001</td>
</tr>
<tr>
<td>2  Identify quality improvement activities and set improvement goals</td>
<td>QI001</td>
</tr>
<tr>
<td>3  Implement the plan</td>
<td>QI001</td>
</tr>
<tr>
<td>4  Participate in network peer review meetings</td>
<td>QI002</td>
</tr>
<tr>
<td>5  Reporting and verification</td>
<td>QI001 and QI002</td>
</tr>
</tbody>
</table>

1. **Identify areas for improvement**

Practices should evaluate the current quality of prescribing safety in each of the prescribing areas listed below, and identify areas for improvement. This would include:

- Deriving some standards from good quality guidelines eg NICE, MHRA, local guidelines,
- Carrying out a baseline assessment of current prescribing against the chosen standards

*See Appendix A for further information about the 3 individual prescribing areas listed below*

**NSAIDs**

Patients at significant risk of gastrointestinal adverse effects who have been prescribed a nonselective nonsteroidal anti-inflammatory drug (NSAID) without co-prescription of a proton-pump inhibitor (PPI) in the preceding 6 months.

**Lithium***

Patients receiving lithium and being monitored in primary care who have not had a recorded check of their lithium concentrations, eGFR, U&Es, serum calcium and thyroid function in the previous 6 months.

**Sodium valproate***

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.

*Where practices do not have any patients being prescribed lithium they may select an alternative medication to focus on based on their prescribing data and professional judgement. It is recommended that the medication chosen reflects similar issues to lithium prescribing e.g. a requirement for systematic toxicity monitoring. Suggested alternatives include the appropriate monitoring of amiodarone, phenobarbital or methotrexate

**Even if a practice does not have any girls of any age or women of childbearing potential who are currently prescribed valproate, they should ensure their practice has a robust system in place to identify and refer for annual specialist review any new at-risk patients being prescribed valproate and should ensure continuous measurement of this measure.
2. **Identify quality improvement activities and set improvement goals**

Following the initial baseline assessment, practices should:

(a) **Develop a quality improvement plan**

The plan should describe the actions to be taken to address the prescribing safety improvements including:
- Review of patients identified as potentially at risk through the audit
- Review of practice systems to address organisational factors which contribute to medication related harm
- Ongoing measurement to demonstrate the impact of any changes

(b) **Develop objectives to support the plan**

Practices should set their own targets for improvement based upon their baseline assessment results. Objectives should be SMART and challenging but realistic. They should be validated by network peers as part of the initial network review meeting (see point 4 below).

*See Appendix B for examples of SMART objectives*

3. **Implementing the plan**

Practices should implement the improvement plan developed to support their objectives. It is recommended that these plans and associated improvement activities should involve the whole practice team and practices are encouraged to engage with colleagues in community pharmacy where practicable. Practices should undertake continuous improvement cycles to achieve the outcomes they have set themselves. Example cases are available:


4. **Network Peer review meetings**

The key objective of the network peer review meetings is the establishment of a system to enable shared learning across PCNs. The aim of this is to share best practice in prescribing safety. Contractors should:

- have their PCN as their peer review group..
- participate in a minimum of two network peer review discussions unless there are unforeseen circumstances
- have face to face meetings unless this is not possible in which case networks are able to explore other mechanisms to facilitate real time peer learning and sharing including virtual meetings.
- consider the suggested discussion points for these meetings *(See Appendix C for suggested discussion points)*
- nominate the network clinical lead (or deputy) to facilitate the meetings and maintain a record of attendance.
- organise the first meeting early in the QI activity and the second towards the end *(See Appendix D for a proposed schedule of work)*

5. **Reporting and verification**

Contractors are required to complete and provide a copy of the QI monitoring template in relation to this module *See Appendix E(i-iii)* (NB there are separate templates for each of the 3 prescribing areas) It is recommended that the template is completed throughout the year *See Appendix D for a proposed schedule of work*. Contractors will be required to confirm that they have attended a minimum of two peer review meetings as described above, unless there are exceptional and unforeseen circumstances. In these circumstances contractors are expected to make efforts to ensure alternative participation in peer review. *See Appendix F for an example of a completed template. The resources are available as separate documents on the [QOF Quality Improvement](http://example.com) section of the CCG website* 

*Appendix D – proposed schedule of work*  
*Appendix E(i-III) – QI monitoring templates*  
*Appendix F – an example of a completed template*

The completed QI monitoring templates should be submitted for approval to the Medicines Optimisation Team *(occg.medicines@nhs.net)* by 31<sup>st</sup> March 2020
Appendix A

**NSAIDs – patients at risk of gastrointestinal effects**

There is some useful information on the following websites regarding the safe prescribing of NSAIDs including contraindications, risk factors for NSAID-induced gastrointestinal adverse effects and the management of the risk factors

**Clinical Knowledge Summaries**
https://cks.nice.org.uk/nsaids-prescribing-issues#!scenario

**NICE CG177 Osteoarthritis: Care and management**
https://www.nice.org.uk/guidance/cg177/chapter/1-Recommendations#pharmacological-management

**Special Product Characteristics (SPCs) for individual NSAIDs**
https://www.medicines.org.uk/emc/

**Examples of audit standards**

Below are some examples of audit standards which could be adopted by practices

- No patients with a current clinical contraindication are currently being prescribed an NSAID medication.
- 100% of patients with an NSAID medication, regularly receiving a repeat prescription, have had a documented clinical safety risk review in the last 12 months.
- 100% of patients identified as high risk and requiring ongoing treatment are prescribed a selective NSAID if appropriate plus a proton pump inhibitor.
- 100% of patients identified as moderate risk and requiring ongoing treatment have been prescribed an appropriate NSAID with proton pump inhibitor unless contraindicated

**Searches to identify patients**

It is not essential to use PINCER to support the prescribing safety element of QOF but there are searches in the PINCER library for the patient groups below

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>GI_P3A</td>
<td>Prescription of an oral NSAID, without co-prescription of an ulcer healing drug, to a patient aged ≥65 years</td>
</tr>
<tr>
<td>GI_P3B</td>
<td>Prescription of an oral NSAID, without co-prescription of an ulcer healing drug, to a patient with a history of peptic ulceration</td>
</tr>
<tr>
<td>GI_P3D</td>
<td>Prescription of warfarin or DOAC in combination with an oral NSAID</td>
</tr>
</tbody>
</table>
Lithium Monitoring

The Prescribing Safety module in QOF requires contractors to ensure that patients receiving lithium have had a recorded check of their serum lithium concentrations, eGFR, U&Es, serum Ca and TSH in previous 6 months.

**NICE Clinical Guideline [CG185]** Bipolar disorder: assessment and management Sep 2014 and the Oxfordshire Lithium Shared Care Protocol specify:

1. Measure the person’s plasma lithium level every 3 months for the first year.
2. After the first year, measure plasma lithium levels every 6 months, or every 3 months for people in any of the following groups:
   - older people
   - people taking drugs that interact with lithium
   - people who are at risk of impaired renal or thyroid function, raised calcium levels or other complications
   - people who have poor symptom control
   - people with poor adherence
   - people whose last plasma lithium level was 0.8 mmol per litre or higher.
3. Test for urea and electrolytes including calcium, estimated glomerular filtration rate (eGFR) and thyroid function every 6 months, and more often if there is evidence of impaired renal or thyroid function, raised calcium levels or an increase in mood symptoms that might be related to impaired thyroid function.

**Searches to identify patients**

The Medicines Optimisation team can provide an Emis search and autoreport to support practices with identifying patients on lithium.

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Sodium Valproate – Pregnancy prevention programme

Valproate use in pregnancy is associated with an increased risk of children with congenital abnormalities and developmental delay. Valproate is contraindicated in women of childbearing potential unless the conditions of the valproate pregnancy prevention programme are fulfilled (the requirement for a Pregnancy Prevention Programme is applicable to all premenopausal female patients unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy). Whilst the rates of prescribing of valproate continue to decline slowly there are wide geographical variations in prescribing. Clear actions have been set for general practices to identify and recall existing patients, provide them with a copy of the Patient Guide, to check they have had a specialist review in the last year and to have systems in place to identify and appropriately manage new patients who are prescribed valproate and are of child bearing potential.

The pregnancy prevention programme requires GPs to:

- provide patients with a copy of the **Patient Guide**
- Ensure continuous use of highly effective contraception* in all women of childbearing potential (consider the need for pregnancy testing if not a highly effective method).
- Check that all patients have an up to date, signed, **Annual Risk Acknowledgment** form each time a repeat prescription is issued.
- Ensure the patient is referred back to the specialist for an annual review.
- Refer back to the specialist urgently (within days) in case of unplanned pregnancy or where a patient wants to plan a pregnancy.
- For children or for patients without the capacity to make an informed decision, provide the information and advice on highly effective methods of contraception and on the use of valproate during pregnancy to their parents/ caregiver/ responsible person and make sure they clearly understand the content.
The SPC for valproate states ‘at least one effective method of contraception (preferably a user independent form such as an intra-uterine device or implant) or two complementary forms of contraception including a barrier method should be used. Individual circumstances should be evaluated in each case when choosing the contraception method, involving the patient in the discussion to guarantee her engagement and compliance with chosen measures. Even if she has amenorrhea she must follow all the advice on effective contraception.’

The practice should regularly use the audit function on their clinical system to identify at risk patients and ensure timely recall for clinical review in line with the MHRA alert. Such continuous measurement can be used to demonstrate compliance with the MHRA alert. This quality improvement programme offers general practice a further opportunity to ensure these actions have been completed and that ongoing systems to protect patients from harm have been put in place. Even if a practice does not have any girls of any age or women of childbearing potential who are currently prescribed valproate, they should ensure their practice has a robust system in place to identify and refer for annual specialist review any new at-risk patients being prescribed valproate and should ensure continuous measurement of this measure.

References
https://www.gov.uk/guidance/valproate-use-by-women-and-girls
Appendix B

Examples of SMART Objectives

**NSAIDs**

(i) Baseline practice prescribing analysis identifies: patients on regular NSAID prescriptions with a recorded contraindication.

SMART outcome: Repeat analysis after 3 months (and repeated at 3monthly interval thereafter) shows NO PATIENTS with a recorded contraindication have been prescribed NSAIDS.

(ii) Baseline practice prescribing analysis: shows only 5% of patients obtaining a regular (repeat) NSAID have had a clinical safety risk assessment clearly documented within the last 12months.

SMART outcome: Increase from 5% to X% over the next 6 months (practice to decide) and X-Y% over the 6-12 months (practice to decide) of people prescribed NSAIDs regularly have a documented clinical safety risk assessment (as part of their medication review) as per NICE advice, within the preceding 12months.

**Lithium**

(i) Baseline practice prescribing analysis: shows 50% of patients prescribed lithium have had a recorded serum lithium level checked within the last 6 months.

SMART outcome: at a repeat analysis 6 months there is an increase from 50% to X% (practice to decide) of patients prescribed lithium who have a recorded serum lithium level within the last 6 months.

(ii) Baseline practice prescribing analysis: shows 40% of patients prescribed lithium have had their eGFR checked within the last 6 months.

SMART outcome: at a repeat analysis 6 months there is an increase from 40% to X% (practice to decide) of patients prescribed lithium who have had their eGFR checked within the last 6 months.

**Sodium Valproate**

Baseline practice prescribing analysis shows no girls or women of childbearing potential are currently prescribed valproate without a highly effective pregnancy prevention plan in place as per MHRA guidelines. However no practice system is in place to routinely identify new potential at risk patients.

SMART outcome: Within one month the practice can demonstrate an appropriate repeated monthly search of the clinical system to identify all girls or women of childbearing potential who have been recommended to start valproate medication have had a clinical review to ensure compliance with the pregnancy prevention programme as recommended by the MHRA.
**Appendix C**

### Suggested peer review meeting discussion points

**The 1st peer review meeting:**

Should take place early in the QI process and focus upon:

- Sharing of the outputs of diagnostic work to understand the issues associated with prescribing safety
- Validation of practice improvement targets

**Discussion points could include:**

1. What relevant evidence-based guidance / quality standards can the group use?
2. What data has each practice used to inform its review of current performance?
3. Has the right focus been chosen by each practice based on their current performance?
4. Has each practice set a clear aim with a challenging but realistic local target, and agreed an appropriate measurement to monitor impact?
5. What ideas for changes is each practice planning to try in an improvement cycle?
6. How are practices ensuring the whole practice team (including other clinical colleagues and patients and carers) are engaged in the proposed QI activity?

**The 2nd peer review meeting:**

Should take place towards the end of the QI process and focus upon:

- Celebrating successes and sharing of key changes made in practice.
- How these changes can be embedded into practice.

**Discussion points could include:**

1. What results have each practice seen in their QI activity testing?
2. What changes have been adopted in each practice?
3. How will these changes be sustained in the future?
4. What new skills have staff developed and how can they be used next?
5. What further QI activity prescribing safety is planned in each practice?
6. What further actions may need to take place (e.g. at network or CCG level) to support the changes in practices