Community Pharmacy
NSAID Gastro-Intestinal
Safety Audit

Working with Primary Care
Commissioning, Strategy and
Innovation Directorate

The first stop
for professional
medicines advice
Community Pharmacy NSAID Gastro-Intestinal Safety Audit

Introduction

Adverse effects of non-steroidal anti-inflammatory drugs (NSAIDs) including cyclo-oxygenase-2 (COX2) selective inhibitors are a frequent cause of hospital admissions which are potentially preventable. The adverse effects include gastro-intestinal (GI) bleeds, pro-thrombotic events (e.g. heart attack, stroke) and reduced renal blood flow leading to acute kidney injury. This audit links directly to the WHO Global Patient Safety Challenge ‘Medication Without Harm’. The goal of the WHO Challenge on Medication Safety is to reduce the level of severe, avoidable harm related to medications by 50% over 5 years.

National Institute for Health and Care Excellence guidance requires patients prescribed oral NSAIDs for osteoarthritis or rheumatoid arthritis to be co-prescribed gastro-protection (e.g. a proton pump inhibitor). All older patients (aged 65 and over) are at increased risk of NSAID induced GI adverse effects. Additional risk factors include prolonged treatment and concomitant use of other medicines which increase the likelihood of GI events. GI adverse events have also been reported where patients have self-medicating with a second NSAID in addition to the prescribed agent or have not taken a gastro-protective despite this being co-prescribed.

Whist guidance on co-prescribing gastro-protection is clear – pharmacy professionals are reminded of the potential risks of inappropriate prescribing of proton pump inhibitors, including Clostridium difficile infection and increased fracture risk. General rules for prescribing gastro-protection are still advised, such as using the lowest effective dosage and regular review.

The national medicine safety indicators, first published in May 2018, include four linked to GI safety. This audit aligns to Indicator 1: Patients at increased risk of a GI bleed. The indicator shows prescribing data for patients 65 years old or over prescribed an NSAID and NOT concurrently prescribed a gastro-protective medicine. Current data show that about 40% of older patients do not have gastro-protection co-prescribed. A similar safety marker is also part of the PINCER programme used in GP practices to identify ‘at risk’ patients.

Why has this audit been included in the Quality Payments Scheme (England)?

To prevent patient harm by ensuring all older patients prescribed NSAIDs are co-prescribed a gastro-protective agent. Data from the medicine safety indicators (Jan-March 2018) showed 175,000 older patients in England were at increased risk of harm because no gastro-protection was prescribed. From this ‘at risk’ group, 156 were admitted to hospital with a gastric bleed.

There will be further ‘at risk’ cohorts of patients including those who do not take prescribed gastro-protection as intended or who also self-medicate with an NSAID bought from a non-pharmacy outlet (i.e. they take two NSAIDs together, one prescribed and one bought). Pharmacists can help prevent these harms via conversations with patients about their medicines to support understanding and decision making.

Full information about the quality payments scheme for pharmacy contractors 2018-19 is available at https://www.england.nhs.uk/commissioning/primary-care/pharmacy/framework/ppp/. Collecting audit data from pharmacies across England will help document both locally and nationally the contribution community pharmacy makes to this important patient safety issue.

Aims

- To identify older patients (65 years or over) at increased risk of a GI bleeding from oral NSAIDs
- To refer older patients with no prescribed gastro-protection to prescribers for review
- To support patient understanding and decision making about their NSAID/COX2 medicines
Audit time frame

Data must be collected for 2 weeks with a minimum sample size of 10 patients. In cases where there is difficulty in obtaining the minimum sample size, the audit should be extended to 4 weeks after which contractors will be able to submit the data with the number of patients they have if less than 10.

Audit population

INCLUDE - All patients aged 65 years or over who present a prescription for any oral NSAID or COX2 inhibitor.

(NSAIDs/COX2 inhibitors are in BNF Chapter 10, Pain and inflammation in musculoskeletal disorders; this does not include patients prescribed aspirin. A list of oral NSAIDs/COX2 inhibitors is given in Appendix 1.)

Audit standards

Standard 1A Gastro-protection
All patients aged 65 years or over prescribed an oral NSAID or COX2 inhibitor are co-prescribed gastro-protection.
AUDIT standard 100%

Standard 1B Gastro-protection
All patients aged 65 years or over prescribed an oral NSAID or COX2 inhibitor but not co-prescribed gastro-protection are referred to the prescriber for review unless such a referral has been made in the previous 6 months. An example referral letter is given in Appendix 2.
AUDIT standard 100%

Standard 2 Conversation/ medicines advice
Verbal advice/conversation is offered to all audit patients to support understanding/decision making about their NSAID/COX2 medicine.
AUDIT standard 100%

For the purpose of this audit, we have set the audit standards at 100%, but it is recognised that in practice this may not be achievable because, for example, a patient is unwilling to take a gastro-protective agent.

How to complete the audit

You will need to implement a local system to identify patients in the audit population. The audit can be undertaken at any time from November 2018 - 15th February 2019. (To prevent duplication, please ensure that you keep your own record of which patients you have included in the audit.)

A paper data collection form is provided on p4-5. Please familiarise yourself with the questions before beginning the audit. The data can be collected on paper forms for later online entry or entered directly into the online data entry system. If using paper data collection forms, you will need a copy for each patient included in the audit.

All pharmacies can enter their data for each patient via the Business Services Authority (BSA) SnapSurvey. You will need your pharmacy's NHS Organisation Data Service (ODS) Code (the 'F code') to start the data entry. Other pharmacy computer system suppliers may also offer a data entry system which will feed data directly to the NHS BSA. More information on these routes for data collection is available on the PSNC website. Contractors must complete the audit and submit their data by 15th February 2019.
Community Pharmacy NSAID GI safety audit 2018-19
DATA COLLECTION FORM (complete 1 per patient) Circle choices where necessary.
Make sure you keep a local record of each patient entered in the audit to prevent duplication
The form has 2 pages: This is Page 1 of 2.

Patient number [   ] (Use sequential numbers for each patient ie 1-10+, not patient identifiable)

[   ] .1 Date:

[   ] .1a Patient Age:

[   ] .2 Gender: Male Female Not confirmed

[   ] .3 Name of oral NSAID or COX2 inhibitor prescribed:

<table>
<thead>
<tr>
<th>Name of oral NSAID or COX2 inhibitor</th>
<th>Aceclofenac</th>
<th>Acemetacin</th>
<th>Celecoxib</th>
<th>Dexketoprofen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diclofenac Potassium</td>
<td>Diclofenac Sodium</td>
<td>Etodalac</td>
<td>Etoricoxib</td>
<td></td>
</tr>
<tr>
<td>Flurbiprofen</td>
<td>Ibuprofen</td>
<td>Indometacin</td>
<td>Ketoprofen</td>
<td></td>
</tr>
<tr>
<td>Mefenamic Acid</td>
<td>Meloxicam</td>
<td>Nabumetone</td>
<td>Naproxen</td>
<td></td>
</tr>
<tr>
<td>Piroxicam</td>
<td>Sulindac</td>
<td>Tenoxicam</td>
<td>Tiaprofenic Acid</td>
<td></td>
</tr>
<tr>
<td>Other (please state):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[   ] .4 Total Daily Dose prescribed: mg

[   ] .5 NSAID or COX2 inhibitor prescribed for more than 2 months? Yes No Unknown

[   ] .6 NSAID or COX2 inhibitor taken regularly ie taking at least 3 days each week? Yes No Unknown

[   ] .7 Is the patient taking any other medicines (listed below) that might increase the risk of GI bleeding? Circle ALL that apply:

<table>
<thead>
<tr>
<th>Name of Other Medicine</th>
<th>Anticoagulant</th>
<th>Antiplatelet (including aspirin)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selective serotonin re-uptake inhibitor</td>
<td>Unknown</td>
<td>Other (please state):</td>
</tr>
</tbody>
</table>
Community Pharmacy NSAID GI safety audit 2018-19
DATA COLLECTION FORM: This is Page 2 of 2

[ ] 8. Is the patient prescribed a proton pump inhibitor at a licensed daily dose for NSAID prophylaxis?

<table>
<thead>
<tr>
<th></th>
<th>Yes - Esomeprazole 20mg or more</th>
<th>Yes - Lansoprazole 15mg or more</th>
<th>Yes - Omeprazole 20mg or more</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes - Pantoprazole 20mg or more</td>
<td>No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

[ ] 9 Is any other gastro-protection prescribed?

<table>
<thead>
<tr>
<th></th>
<th>Yes - Proton pump inhibitor not listed above (in Question [ ] 8)</th>
<th>Yes - H2 receptor antagonist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes - Misoprostol</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>

[ ] 10 Was there any conversation with the patient to support understanding/decision making about their NSAID/COX2 medicine?

<table>
<thead>
<tr>
<th></th>
<th>Yes - Conversation with the patient in the pharmacy</th>
<th>Yes - Conversation with the patient by telephone/remote</th>
<th>Data not recorded (e.g. forgot, prescription not collected during audit period)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No - Patient's representative attended pharmacy, patient not contacted</td>
<td>No - Medicine delivered by pharmacy, patient not contacted</td>
<td>No - Other</td>
<td></td>
</tr>
</tbody>
</table>

[ ] 11 Was the patient referred to the prescriber for a review of gastro-protection?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No - Gastro-protection already prescribed</th>
<th>No - Referred for gastro-protection within the last 6 months</th>
<th>No - Other reason</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Please state:</td>
</tr>
</tbody>
</table>

[ ] 12 Please add any other comments in the box below

END
Audit results and local actions

<table>
<thead>
<tr>
<th>Dates of audit:</th>
<th>to</th>
</tr>
</thead>
</table>

| A | Total number of patients in audit |
| B | Number of patients prescribed proton pump inhibitor at licensed dose (Yes to Q8) |
| C | Number of patients prescribed other gastro-protection (Yes to Q9) |
| D | Number of patients NOT prescribed any gastro-protection (No to both Q8 and Q9) |
| E | Number of patients referred to prescriber about gastro-protection (Yes to Q11) |
| F | Number of patients already referred to prescriber about gastro-protection in last 6 months (No – Referred within the last 6 Months to Q11) |
| G | Number of patients where NSAID was discussed (Yes to Q10) |

Were the audit standards met?

Standard 1A Gastro-protection
All audit patients are co-prescribed gastro-protection – Standard 100%

\[(A-D)/A \times 100 =\]

Standard 1B Gastro-protection
All audit patients not co-prescribed gastro-protection are referred to the prescriber for review unless such a referral has been made in the previous 6 months – Standard 100%

\[(E+F)/D \times 100 =\]

Standard 2 Conversation/medicines advice
Verbal advice/conversation is offered to all audit patients about their NSAID/COX2 medicine – Standard 100%

\[G/A \times 100 =\]

Your local audit actions

Possible areas to be addressed: Is there a problem ensuring NSAID safety because patients are not present in the pharmacy? Are local prescribers following NICE guidance on gastro-protection? How can these audit checks become ‘normal’ practice?

Record your audit actions here:

1
2
3
Any queries or problems?

Technical issues about accessing/using the BSA online data entry audit tool: nhsbsaresearch@nhs.net

Questions about the audit: samrina.bhatti1@nhs.net 020 8869 2140
carina.livingstone@nhs.net 01903 708432

Questions about the Quality Payments Scheme: ENGLAND.CommunityPharmacy@nhs.net info@psnc.org.uk

Thank you for doing this audit
Appendix 1

NSAIDs and COX 2 inhibitors (BNF Chapter 10, Section 4 Pain and inflammation in musculoskeletal disorders. Aspirin is not included.)

Some brand names have been included for ease of identification but there may be other brands available.

Aceclofenac (*Preservex*)
Acemetacin
Celecoxib (*Celebrex*)
Dexibuprofen
Dexketoprofen (*Keral*)
Diclofenac Potassium (*Voltarol Rapid*)
Diclofenac Sodium (*Voltarol, Diclomax, Motifene, Arthrotec*)
Etodolac (*Etopan, Lodine*)
Etoricoxib (*Arcoxia*)
Fenoprofen
Flurbiprofen
Ibuprofen
Indometacin
Ketoprofen (*Oruvail*)
Mefenamic Acid (*Ponstan*)
Meloxicam
Nabumetone (*Relifex*)
Naproxen (*Naprosyn, Vimovo*)
Piroxicam (*Feldene*)
Sulindac
Tenoxicam (*Mobiflex*)
Tiaprofenic Acid (*Surgam*)
Appendix 2

Example referral letter

This can be sent to the prescriber by post, safe haven fax or NHSmail. An alternative secure referral method can be used with local agreement. This is also available as a standalone form on the [PSNC website].

Pharmacy Address:

Prescriber Name:
Surgery Address:

Date

Dear

NSAID safety - gastro-protection

Patient Name:

Date of Birth: NHS Number:

Patient Address:

Our pharmacy records show this patient is prescribed an NSAID or COX2 inhibitor. The patient is aged 65 years or older and appears to have no gastro-protection prescribed. I would be grateful if you could review the NSAID treatment and consider whether a gastro-protective agent is necessary.

Best wishes

Yours sincerely