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North of England Commissioning Support

Care Bundle

Adult patients prescribed Non-Steroidal Anti-inflammatory Drugs (NSAIDs) on repeat prescription

North of England Commissioning Support
Medicines Optimisation on behalf of Cumbria CCG

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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 may also be known as patient safety bundles if they relate to high risk medication.

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 reflective log template

Further information on Care Bundles and Improvement Models can be found at www.healthcareimprovementscotland.org/pspc.aspx

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).

2. Adult patients prescribed Non-Steroidal Anti-inflammatory Drugs (NSAIDs) on repeat prescription

2.1. Search Criteria

Please identify a random sample of up to 20 adult patients a month in your practice prescribed an NSAID* on repeat prescription. Use the data collection form to record the answer to each measure and transfer this to the spreadsheet. This should be repeated over a period of time, and the results discussed by the clinical team at regular intervals. Use of the spreadsheet will enable changes in practice to be monitored and compliance with the care bundle to be measured.

***NSAID** – See list in Appendix 1. The use of the Read codes is entirely optional but may make searching for these drugs easier.

2.2. Measures

01

Measure	**Was simple analgesia e.g. paracetamol and/or topical non-steroidal anti-inflammatory drugs (NSAIDs) prescribed before initiation of an oral NSAID on <u>repeat</u> prescription?**
Rationale	There are long-standing and well recognised gastro-intestinal and renal safety concerns with all NSAIDs. In the last ten years there has also been an increase in concern about the cardiovascular safety of some NSAIDs. The single most common indication for NSAID on repeat prescription is the treatment of musculoskeletal pain in osteoarthritis. This population is also more likely to be at a higher risk of NSAID-mediated adverse events. The National Institute for Care and Excellence (NICE) Clinical Guidelines (CG) which cover treatment with NSAIDs are: • CG177 Osteoarthritis care and management in adults • CG79 Rheumatoid arthritis • CG88 Low back pain CG177 recommend paracetamol and/or topical NSAIDs should be considered ahead of oral NSAIDs, cyclo-oxygenase 2 (COX-2) inhibitors or opioids. As NSAIDs in single doses have analgesic activity comparable to paracetamol, and in regular full dosage, have both a lasting analgesic and anti-inflammatory effect they are often prescribed early on in treatment for both acute pain and chronic inflammatory conditions. NICE recommends that non-pharmacological methods, regular paracetamol and topical NSAIDs should be tried first and documented. N.B. NICE intends to undertake a full review of evidence on the pharmacological management of osteoarthritis. In the meantime the above recommendations remain current. However, the review of the previous guidelines identified reduced effectiveness of paracetamol in the management of osteoarthritis compared with

	what was previously thought. This information should be taken into account in routine prescribing practice.
Source	NICE clinical guideline 177. Osteoarthritis: care and management in adults. February 2014 http://www.nice.org.uk/guidance/CG177 Cutts C, La Caze A. Nonsteroidal anti-inflammatory drugs and potential risks in a convenience sample of general practitioners. Aust Fam Phys 2002; 31: 590-2

02

Measure	**Is ibuprofen or naproxen currently prescribed on repeat prescription?**
Rationale	Ibuprofen and naproxen are associated with the lowest gastro-intestinal (GI) and cardiovascular (CV) risks respectively (although neither are without risk) Systematic reviews have found no important difference in efficacy between different NSAIDs for the symptoms of musculoskeletal disorders. Two Cochrane systematic reviews found that celecoxib and rofecoxib (since withdrawn) were no more effective in arthritic conditions than non-selective NSAIDs. Therefore, as there is no difference in efficacy, apart from individual experience, the choice of NSAID should be decided primarily on the safety profile. Recent cohort data have confirmed previous safety warnings that diclofenac has a higher risk of thrombotic events (including myocardial infarction and stroke) than naproxen or low-dose ibuprofen (1200mg/day or less). Even a few days of treatment may increase risk, in individuals with and without cardiovascular disease. High doses of ibuprofen (more than 2400mg/day) may also have an increased risk but its safety (or lack of it) requires further study. Two meta-analyses have both established that, compared to placebo, diclofenac causes around three additional major vascular events per 1000 patients per year, with one such event causing death. Ibuprofen (1200mg/day or less) or naproxen (1g/day or less) are recommended first-line agents, combined with gastro-protection if at high risk for gastro-intestinal symptoms. NSAIDs should be prescribed for the shortest time and lowest dose necessary to control symptoms.
Source	Garner SE, Fidan D, Frankish RR, Judd M, Shea B, Towheed T, Tugwell P, Well GA. Celecoxib for rheumatoid arthritis. Cochrane Database of Systematic Reviews 2002, Issue 4. Art. No.: CD003831. DOI: 10.1002/14651858.CD003831. Garner SE, Fidan D, Frankish RR, Maxwell L. Rofecoxib for osteoarthritis. Cochrane Database of Systematic Reviews 2005, Issue 1. Art. No.: CD005115. DOI: 10.1002/14651858.CD005115. NICE Eyes on Evidence. Non-steroidal anti-inflammatory drugs: new information and warnings about cardiovascular risk. September 2013. https://www.evidence.nhs.uk/document?ci=http://arms.evidence.nhs.uk/resources/Hub/1028786 NICEKTT13. Non-steroidal anti-inflammatory drugs. January 2015 (last modified February 2016) www.nice.org.uk/advice/ktt13 MHRA Guidance. Cox-2 selective inhibitors and non-steroidal anti-inflammatory drugs (NSAIDs): Cardiovacular Safety. January 2015.

	https://www.gov.uk/government/publications/cox-2-selective-inhibitors-and-non-steroidal-anti-inflammatory-drugs-nsaids-cardiovascular-safety/cox-2-selective-inhibitors-and-non-steroidal-anti-inflammatory-drugs-nsaids-cardiovascular-safety

03

Measure	**Has a proton pump inhibitor (PPI) been co-prescribed in a patient at high risk of gastro-intestinal (GI) complications?**
Rationale	The benefits from gastro-protection depend on an individual's baseline risk of GI complications. People are at high risk of serious NSAID-induced GI adverse events if they have one or more of the following risk factors • Age 65 years or older. • History of peptic ulcer disease • Concomitant use of medicines that are known to increase the risk of upper GI adverse events (see **question 4** below). • Serious co-morbidity such as cardiovascular disease, hepatic/renal impairment, diabetes, or hypertension. • Requirement for prolonged NSAID use, including people with osteoarthritis or rheumatoid arthritis (any age) and chronic low back pain (age 45 or older) • Use of the maximum recommended dose of an NSAID NICE guidance recommends that a PPI should be co-prescribed with a NSAID (including COX-2 inhibitors) for anyone with osteoarthritis, rheumatoid arthritis and anyone 45 years of age or older with chronic low back pain. The guidelines also recommend that a PPI should be considered for anyone receiving a NSAID who is at high risk of GI side effects including those over 65 years and/or using them long-term. The use of NSAIDs is associated with around a fourfold increase in the incidence of severe upper GI ulcer complications compared with the rate in non-users. The MHRA has reviewed the relative GI risks of NSAIDs on several occasions. It concluded that, of the traditional NSAIDs, low dose ibuprofen offers the lowest risk. There is a widely held view (backed up by post-marketing surveillance data) which suggests that naproxen has a higher GI risk than diclofenac. The evidence supporting this assertion, however, is not strong and there are no comparative RCTs. COX-2 inhibitors are associated with lower GI risk than traditional NSAIDs but their safety advantage is diminished when they are co-administered with aspirin. The combination of any NSAID with low-dose aspirin can increase the risk of GI side effects and should only be used if absolutely necessary. There is no good evidence that adding a PPI to a COX-2 inhibitor offers any significant advantage over adding a PPI to a traditional NSAID in preventing GI complications. In addition there is no good evidence to suggest that one PPI is superior to another. Omeprazole capsules 20mg and lansoprazole 15mg and 30mg capsules are the least expensive options with licences for gastro-protection.
Source	Anon. Reducing NSAID-induced gastrointestinal complications. Drug and Therapeutics Bulletin. 2011; 49(2): 18-21. NICE clinical guideline 177. Osteoarthritis: care and management in adults. February 2014

	http://www.nice.org.uk/guidance/CG177 NICEKTT13. Non-steroidal anti-inflammatory drugs. January 2015 (last modified February 2016) www.nice.org.uk/advice/ktt13 NICE Clinical Knowledge Summaries. NSAIDs – prescribing issues. Last revised July 2015. http://cks.nice.org.uk/nsaids-prescribing-issues

04

Measure	**Are no drugs that increase the risks of adverse effects being used with the NSAID?**
Rationale	This includes drugs that increase the risk of upper GI adverse effects – antiplatelets (aspirin, clopidogrel), anticoagulants, corticosteroids and selective serotonin re-uptake inhibitors (SSRIs) and drugs that increase the risk of adverse renal effects – ACE inhibitors, Angiotensin-II Receptor antagonists and diuretics. See appendix 1 for a more comprehensive list Co-prescribing NSAIDs with ACE inhibitors and Angiotensin-II Receptor antagonists may pose particular risks to renal function; this combination should be especially carefully considered and if continued, regularly monitored. SSRIs and NSAIDs/COX-2s when taken at the same time can greatly increase the risk of an upper gastro-intestinal event (risk increased up to six-fold when age is taken into account). An observational study in 2007 looked at the risk of bleeding for individuals taking warfarin, clopidogrel, aspirin, NSAIDs and COX-2 inhibitors and various combinations. There was a similar increased risk of GI bleeding with both standard NSAIDs and COX-2 inhibitors. In combination with clopidogrel or warfarin the risk was greater than that observed with each drug alone and there was no significant difference between standard NSAIDs and COX-2 inhibitors.
Source	Delaney JA, *et al*. Drug-drug interactions between antithrombotic medications and the risk of gastrointestinal bleeding. *CMAJ* 2007; **177:** 347-351. Joint Formulary Committee. British National Formulary. London: BMJ Group and Pharmaceutical Press. July 2016 update. www.medicinescomplete.com/mc/bnf/current/ MHRA (2009b) Non-steroidal anti-inflammatory drugs: reminder on renal failure and impairment. *Drug Safety Update* **2**(10), 4. https://www.gov.uk/drug-safety-update/non-steroidal-anti-inflammatory-drugs-nsaids-reminder-on-renal-failure-and-impairment

05

Measure	**Has there been a full discussion with the patient on the risks/benefits of NSAID therapy recorded in the notes?**
Rationale	Full discussion on benefit versus risk of medication including increased risk of GI, cardiovascular and renal adverse events All patients on a repeat prescription for an oral NSAID should be reviewed as regards continued need, dose and appropriateness of NSAID choice in relation to risk factors and cost – effectiveness. The risks should be discussed with the patient and the review documented.

Source	NHS Wales. High Risk Medicines 8: NSAIDs pp. 38-40 in Improving Medicines Management. April 2012. www.1000livesplus.wales.nhs.uk NICE Academic detailing aid. Non-steroidal anti-inflammatory drugs. February 2013. https://www.nice.org.uk/about/what-we-do/into-practice/education-learning-and-professional-development/academic-detailing-aids

Appendix One: Abbreviations

Abbreviation	Definitions
NICE	National Institute for Health and Care Excellence
SPC	Summary of Product Characteristics
NICE CG	NICE Clinical Guideline
NICE QS	NICE Quality Statement
MHRA	Medicines and Healthcare products Regulatory Agency
NSAID	Non Steroidal Anti-Inflammatory Drug
PPI	Proton pump inhibitor
GI	Gastrointestinal

Appendix Two: NSAIDs

NSAID and COX-2 inhibitor prescribing		
Standard/traditional NSAIDs **(Drug Read code starts with "j2")**	**"intermediate" NSAIDs** **(Drug Read code starts with "j2")**	**Selective COX-2 inhibitors** **(Drug Read code starts with "jA")**
Aceclofenac (starts with j2m)	**Etodolac (j24)**	**Celecoxib (jA2)**
Acemetacin (starts with j2j)	**Meloxicam (j2n)**	**Etoricoxib (jA5)**
Dexibuprofen (starts with j2t)		
Dexketoprofen (j2q)		
Diclofenac* (j22)		
Fenoprofen (j26)		
Flurbiprofen (j27)		
Ibuprofen (j28)		
Indometacin (j29)		
Ketoprofen (j2a)		
Mefenamic acid (j2b)		
Nabumetone (j2k)		
Naproxen (j2c)		
Piroxicam		
Sulindac (j2f)		
Tenoxicam (j2l)		
Tiaprofenic acid (j2g)		

Appendix 3: Read Codes

Indications: Continuous or regular pain associated with inflammation
Rheumatoid arthritis and other inflammatory polyarthropathies **(N04..)**
Osteoarthritis and allied disorders **(N05..)**
Gout **(C34..)**
Ankylosing spondylitis **(N100.)**
Other:
Back pain and soft tissue disorders **(N145. 16C..)**
Migraine **(F26..)**
Dental and orofacial pain **(JO5y.)**

Contraindications
Peptic ulceration or GI bleed:
History of peptic ulcer Peptic ulcer symptoms Peptic ulcer of oesophagus **(1956.**
Personal history of peptic ulcer Peptic ulcer, site unspecified Acute peptic ulcer
Chronic peptic ulcer **(J131.)**
Unspecified peptic ulcer **(J13y.)**
Peptic ulcer – not otherwise specified **(J13z.)**
NSAID induced gastric ulcer NSAID induced duodenal ulcer **(J713. J726.)**
Acute Renal failure:
Acute renal failure **(K04..)**
Heart failure:
Heart failure **(G58..)**
Congestive heart failure **(G580.)**
Left ventricular failure **(G581.)**
Acute heart failure **(G582.)**
Heart failure – not otherwise specified **(G58z.)**
NSAID/aspirin hypersensitivity
Personal history of aspirin allergy **(ZV148)**
Risk Factors
Age over 65 years

IHD:
IHD **(G3…)**
Acute MI **(G30..)**
Other acute and subacute IHD **(G31..)**
Old MI **(G32..)**
Angina pectoris **(G33..)**
Other chronic IHD **(G34..)**
Subsequent MI **(G35..)**
Cardiac syndrome **(G37..)**
Other specified IHD **(G3y..)**
IHD NOS **(G3z..)**
Cerebrovascular disease:
Cerebrovascular disease **(G6…)**
Intracerebral haemorrhage **(G61..)**
Other and unspecified intracranial haemorrhage **(G62..)**
Precerebral arterial occlusion **(G63..)**
Cerebral arterial occlusion **(G64..)**
Transient cerebral ischaemia **(G65..)**
Stroke and cerebrovascular accident unspecified **(G66..)**
Other cerebrovascular disease **(G67..)**
Other specified cerebrovascular disease **(G6y..)**
Cerebrovascular disease NOS **(G6z..)**
Peripheral vascular disease (G73..)
Chronic kidney disease:
Chronic renal failure **(K05..)**
Chronic renal impairment **(1Z1..)**
End stage kidney disease **(K0D..)**
Chronic kidney disease monitoring **(66i..)**
Renal failure unspecified **(K06..)**
Diabetes:
H/O: diabetes mellitus **(1434.)**
Type 1 diabetes mellitus **(C10E.)**
Type 2 diabetes mellitus **(C10F.)**
Hypertension:
H/O: hypertension **(1434.)**
Hypertensive disease **(G2…)**
Hypertensive heart disease **(G21..)**
Drugs increasing risk of bleeding when co-prescribed with NSAIDS:
Antiplatelets:
Low dose aspirin:
aspirin 75mg dispersible tablets **(bu23.)**
aspirin 75mg tablets **(bu25.)**
aspirin 75mg e/c tablets **(bu2B.)**
Clopidogrel **(bu5..)**
clopidogrel prophylaxis **(8B6P.)**
Anticoagulants:

warfarin sodium **(bs1..**
warfarin therapy started **(66Q6.)**
phenindione
dabigatran etexilate, rivaroxaban, edoxaban, apixaban
SSRIs:
Citalopram **(da9..)**
Escitalopram **(dac..)**
Fluoxetine **(da4..)**
Fluvoxamine **(da3..)**
Paroxetine **(da6..)**
Sertraline **(da5..)**
(venlafaxine**) (da7..)**
Glucocorticoids
Betamethasone
Cortisone
Deflazocort
Dexamethasone
Hyrdocortisone
Methylprednisolone
Prednisolone
Prednisone
Triamcinolone
Drugs increasing nephrotoxicity when co-prescribed with NSAIDS:
Renin-angiotensin system drugs:
ACE inhibitor prophylaxis **(8B6B.)**
Angiotensin II receptor antagonist prophylaxis **(8B6E.)**
Diuretics:
loop diuretics **(b3…)**
thiazide diuretics **(b2…)**
potassium sparing diuretics **(b4…)**
Other drugs
Tacrolimus **(h83..)**
Ciclosporin **(h82)**
Lithium **(d6…)**
Methotrexate
other NSAIDS: (see list above)

Risk/benefit assessment in the last 12 months
NSAID risk assessment completed **(9OhB.)**

PPI co-prescribed:

esomeprazole **(a6h..)**
Lansoprazole **(a6c..)**
Omeprazole **(a6b..)**
Pantoprazole **(a6e..)**
rabeprazole sodium **(a6f..)**

Renal function test in the last 12 months:
Renal function tests **(451..)**
Serum creatinine **(44J3.)**
Creatinine clearance **(451A.) (4517.)**
Glomerular Filtration Rate **(451E.)**