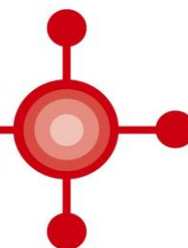


All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan



Clinical Effectiveness Prescribing Programme (CEPP)

All Wales Audit:

Towards Appropriate Non-Steroidal Anti-Inflammatory Drug (NSAID) Prescribing 2010-2012

Quality Improvement Toolkit

This audit was endorsed by the All Wales Medicines Strategy Group (AWMSG) at their meeting on the 3rd March 2010 and forms part of the Clinical Effectiveness Prescribing Programme (CEPP), formerly known as the Prescribing Incentive Scheme.

Please send the Data Summary Sheet 1 (and sheet 2 if applicable) and the Practice Review Sheet to your local Head of Pharmacy and Medicines Management (HoPMM) on or before the 31st October 2010.

Your HoPMM will compile the local information and forward to The Welsh Medicines Partnership (wmp@wales.nhs.uk) who will provide a national perspective (which is required by the Welsh Assembly Government).

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Clinical Effectiveness Prescribing Programme (CEPP)

All Wales Audit:

Towards Appropriate Non-Steroidal Anti-Inflammatory Drug (NSAID) Prescribing 2010-2012

Quality Improvement Toolkit

Background:

Quality improvement toolkits have been developed to assist general practices in collating and auditing information. These are produced with reference to evidence based practice and Welsh priorities. They should be seen as good practice and are intended to improve data quality and aid development within the practice.

Improvements in practice will be optimised by multidisciplinary involvement in the audit and team discussion of the results. It is recommended that action plans following audit are reviewed within six months and re-audit undertaken if possible in 6-12 months.

Purpose and Summary of Document:

The following audit has been developed by the All Wales Prescribing Advisory Group (AWPAG) in collaboration with the Primary Care Quality and Information Service (PCQIS), which is part of Public Health Wales. This document is for use by primary care general practitioners to highlight safety issues associated with NSAID prescribing, particularly in patients with a higher risk of side effects. It will be available via the All Wales Medicines Strategy Group (AWMSG) and Public Health Wales websites.

The audit will be available from April 2010, so that it can be used as the CEPP national audit for the following two years (2010–2012).

Also included is a practice review section designed to encourage a whole practice response to the audit findings and an evaluation of the quality and usefulness of the audit itself.

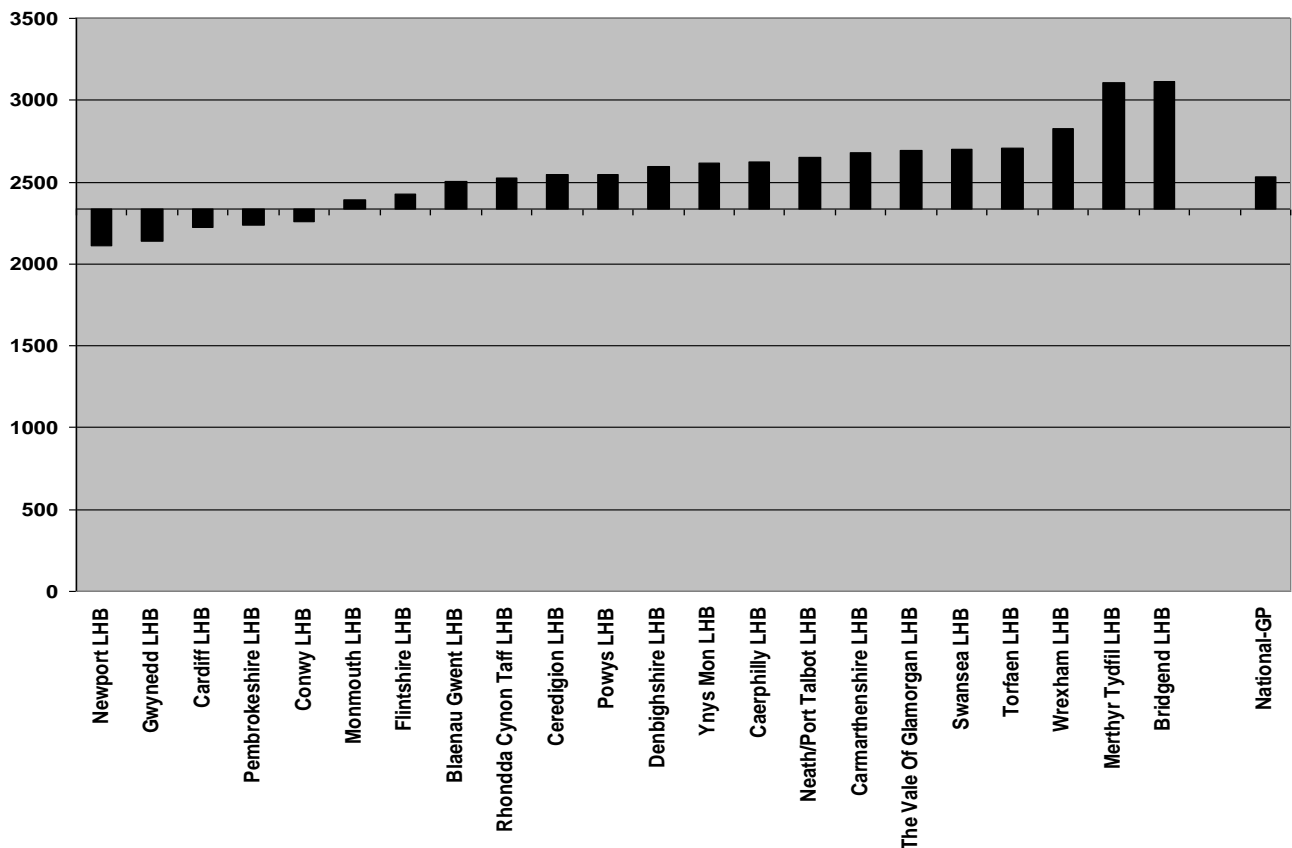
Introduction

Non-steroidal anti-inflammatory drugs (NSAIDs) are licensed and prescribed for a range of indications. They include traditional NSAIDs (including aspirin), meloxicam, etodolac and selective cyclo-oxygenase (COX)-2 inhibitors (“coxibs”). The majority of NSAID use is for musculoskeletal pain, particularly osteoarthritis, and prescribing for older people is common. However, other treatment options such as paracetamol, topical NSAIDs and non-drug treatments such as exercise may be just as effective in some conditions such as osteoarthritis¹.

There are no important differences in efficacy between NSAIDs in the management of musculoskeletal disorders. All are associated with gastrointestinal (GI) toxicity and some are also associated with an increased risk of thromboembolic events. The Medicines and Healthcare Products Regulatory Authority (MHRA) has issued advice that applies to all traditional NSAIDs and selective COX-2 inhibitors^{2,3}. The National Prescribing Centre (NPC) also provides information on cardiovascular and GI safety in NSAIDs⁴.

Prescribing

NSAIDs DDD Per 1000 PUs - September 2009 Qtr (Target = 2333 or Below)



The September 2009 average All Wales figure for the NSAID National Prescribing Indicator was 2,530 DDD* per 1,000 PUs ranging from 2,109 to 3,111 across the 22 previous Local Health Board (LHB) localities. The target figure for 2009/10 is 2,333 DDD per 1000 PUs^{5,6}.

*The Defined Daily Dose (DDD) is a measure of prescribing volume maintained by the World Health Organisation (WHO) and represents the assumed average maintenance dose per day for a drug used for its main indication in adults. It allows prescribing activity to be compared fairly and accurately across localities.

The All Wales comparator for oral NSAID prescribing was 79 items per 1,000 PU for the quarter up to March 2009, ranging from 67 to 94 across the 22 previous LHB localities⁷.

Prescribers are reminded that^{2,3,4}:

- GI and cardiovascular risks of NSAIDs may be minimised by selecting the lowest dose of NSAID for the shortest duration of treatment.
- The risks of GI toxicity are higher in the elderly.
- Aspirin and another NSAID should only be used together when absolutely necessary - the combination substantially increases GI risk. Patients taking long-term aspirin should be reminded to avoid NSAIDs, including those bought without prescription.
- Ibuprofen is associated with the lowest GI risk of the traditional NSAIDs, however serious and fatal GI reactions have also been reported in association with its use.
- Clinical trial data suggest that selective COX-2 inhibitors have GI safety advantages over standard NSAIDs. Serious and fatal GI reactions have, however, been associated with these drugs. The incidence of potentially serious GI problems with all NSAIDs is reduced by the use of PPIs^{1,8}
- Prescribing should be based on the safety profiles of individual NSAIDs, COX-2 inhibitors and on individual patient risk profiles (e.g. GI and cardiovascular).
- Prescribers should not switch between NSAIDs without careful consideration of the overall safety profile of the products, a patient's individual risk factors, and patient preference.
- Renal function can be impaired with NSAIDs and should be monitored in patients on long term NSAID treatment⁹. Patients with pre existing renal impairment are especially at risk, and doses of NSAIDs should be kept as low as possible in such patients.
- Prescribers should check for a history of hypersensitivity to aspirin or any other NSAIDs, including any worsening of asthma, urticaria or rhinitis with aspirin or NSAIDs.
- Many drugs interact with NSAIDs (see Method; risk factors, table E): increased bleeding with selective serotonin reuptake inhibitors (SSRIs) is of note. Other drugs such as angiotensin converting enzyme inhibitors (ACEIs) and diuretics increase the risk of renal impairment. Drugs with a narrow therapeutic range such as lithium and antiepileptics can be affected by NSAIDs.

Risks versus Benefits⁸

COX-2 selective inhibitors are associated with an increased risk of thrombotic events (e.g. myocardial infarction [MI] and stroke) and should not be used in preference to non-selective NSAIDs except when specifically indicated (i.e. for patients at a particularly high risk of developing gastroduodenal ulceration or bleeding) and after assessing their cardiovascular risk.

Non-selective NSAIDs are also associated with a small increased risk of thrombotic events even when used short-term in those with no cardiovascular risk factors. Diclofenac (150mg daily) and ibuprofen (2.4g daily) are associated with an increased risk of thrombotic events. The increased risk for diclofenac is similar to that of licensed doses of etoricoxib. Naproxen (1g daily) is associated with a lower thrombotic risk, and low doses of ibuprofen (1.2g daily or less) have not been associated with an increased risk of MI.

The lowest effective dose of NSAID or COX-2 selective inhibitor should be prescribed for the shortest period to control symptoms and the need for long-term treatment should be reviewed periodically.

All NSAIDs are associated with serious GI toxicity; the risk is higher in the elderly. Evidence on the relative safety of seven non-selective NSAIDs indicates differences in the risks of serious upper GI side-effects. Azapropazone is associated with the highest risk and ibuprofen with the lowest; piroxicam, ketoprofen, indometacin, naproxen and diclofenac are associated with intermediate risks.

Recommendations:

- All patients offered regular NSAID treatment should be co-prescribed a proton pump inhibitor (PPI)^{1,8}.
- NSAIDs associated with a low risk, e.g. ibuprofen, are generally preferred
- Start at the lowest recommended dose
- Do not use more than one oral NSAID at a time
- Remember that all NSAIDs (including selective inhibitors of COX-2) are contra-indicated in patients with active peptic ulceration. The Committee on the Safety of Medicines (CSM) also contra-indicates non-selective NSAIDs in patients with a history of peptic ulceration².
- The combination of a NSAID and low-dose aspirin can increase the risk of GI side-effects; this combination should be used only if absolutely necessary, and the patient should be monitored closely⁸.

Useful Resources

- Bridgend LHB locally developed guideline on the management of pain associated with osteoarthritis in adults¹⁰
- Bridgend LHB information leaflet on NSAIDs¹¹
- Welsh Backs campaign¹², including GP desk aid¹³ and the “Back Book” available through NPHS¹⁴.
- NPC Support Materials – NSAIDs¹⁵
- Drug and Therapeutics Bulletin. Volume 48. Number 3. March 2010¹⁶

Aim of the Audit

- To estimate how many patients have received a NSAID on their repeat prescription record in the last 12 months. A NSAID repeat is used as a marker for long term and/or intended long term NSAID use.
- To encourage practices to review their NSAID prescribing in line with the MHRA recommendations and the agreed audit criteria.
- To ensure all repeat NSAID prescribing is appropriate.
- To ensure those older patients or those with established ischaemic heart disease (IHD), cerebrovascular disease, peripheral vascular disease, renal disease, hypertension, diabetes or peptic ulcer disease, for whom a NSAID is considered essential, have had their risks adequately assessed and minimised.

Audit Criteria

- All patients prescribed a NSAID as a repeat prescription should have a linked indication/diagnosis read coded.
- No patient receiving a NSAID on repeat medication should have any contraindication to such medication.
- All patients prescribed a NSAID as a repeat medication should have a record of a risk/benefit assessment with the patients documented in the medical record in the past 12 months.
- All patients prescribed a NSAID as a repeat medication should have a PPI co-prescribed.
- All patients prescribed a NSAID as a repeat medication should have a record of renal function in the past 12 months.

Method

1. Find the total number of patients prescribed a NSAID as a repeat medication within the past 12 months (A):

Search the practice computer system for all patients with a NSAID (remember to search for *branded* products as well) prescribed as a “repeat” in the past 12 months. Include COX-2 selective drugs in your search. Enter the figures for the total number of patients on the data summary sheet.

Generic names for NSAIDs (please see Appendix B for a full list of READ codes to aid in searching for this information)

NSAID	
Acemetacin	Nabumetone
Aceclofenac	Naproxen (includes Napratec®)
Dexibuprofen	Piroxicam
Dexketoprofen	Sulindac
Diclofenac (includes Arthrotec®)	Tenoxicam
Diflunisal	Tiaprofenic acid
Fenbufen	
Fenoprofen	COX-2 selective NSAIDs:
Flurbiprofen	Celecoxib
Ibuprofen	Etodolac
Indometacin	Etoricoxib
Ketoprofen	Meloxicam
Mefenamic acid	

(tip- remember to exclude low dose aspirin from your list of NSAIDs)

2. Sample (B):

Select a number of patients from the total number of patients prescribed a NSAID (A) to sample which will depend on the number of patients in your list. *Appendix A* indicates a sample size which would give statistically significant results. The proportion of patients to sample may alternatively be decided at local level. Randomly select these patients from this list of patients to the required number.

3. Complete patient data collection:

Use the patients’ medical records to complete the patient data collection form for these patients. Include the indications, contraindications and any risk factors which the patients have.

See Appendix B for a full list of READ codes to aid in searching for the data. Prior to April 2010 there is no read code for risk/benefit assessment and the medical record for the past 12 months would need to be reviewed for any documented discussion with patient. After the read code is available this search could be facilitated.

4. Complete Data Summary sheet 1. Use summary sheet 2 to collate data from the data summary sheet 1.

5. Complete Practice Review sheet (see points below and data from the summary sheets to inform discussion.)

6. Return the Data Summary sheet 1 (and sheet 2 if applicable) and the Practice Review sheet (*localities to insert contact*) ideally before 31st October 2010.

(C) Indications: Continuous or regular pain associated with inflammation ⁷
Rheumatoid arthritis and other inflammatory polyarthropy
Osteoarthritis and allied disorders
Gout
Ankylosing spondylitis
Other:
Back pain and soft tissue disorders
Migraine
Dental and orofacial pain
Short term management of post operative pain

(D) Contraindications
Peptic ulceration or GI bleed:
History of peptic ulcer
Peptic ulcer symptoms
Peptic ulcer of oesophagus
Personal history of peptic ulcer
Peptic ulcer, site unspecified
Acute peptic ulcer
Chronic peptic ulcer
Unspecified peptic ulcer
Peptic ulcer – not otherwise specified
NSAID induced gastric ulcer
NSAID induced duodenal ulcer
Acute Renal failure:
Acute renal failure
Heart failure:
Heart failure
Congestive heart failure
Left ventricular failure
Acute heart failure
Heart failure – not otherwise specified
Heart failure confirmed
NSAID/aspirin hypersensitivity

(E) Risk Factors
Age over 65 years
IHD:
IHD
Acute MI
Other acute and subacute IHD
Old MI
Angina pectoris
Other chronic IHD
Subsequent MI
Cardiac syndrome
Other specified IHD
IHD NOS
Cerebrovascular disease:
Cerebrovascular disease
Intracerebral haemorrhage
Other and unspecified intracranial haemorrhage
Precerebral arterial occlusion
Cerebral arterial occlusion
Transient cerebral ischaemia
Stroke and cerebrovascular accident unspecified
Other cerebrovascular disease
Other specified cerebrovascular disease
Cerebrovascular disease NOS
Peripheral vascular disease
Chronic kidney disease:
Chronic renal failure
Chronic renal impairment
End stage kidney disease
Chronic kidney disease monitoring
Renal failure unspecified
Diabetes:
H/O: diabetes mellitus
Type 1 diabetes mellitus
Type 2 diabetes mellitus
Hypertension:
H/O: hypertension
Hypertensive disease
Hypertensive heart disease
Drugs increasing risk of bleeding when co-prescribed with NSAIDs:
Antiplatelets:
Low dose aspirin:
aspirin 75mg dispersible tablets
aspirin 75mg tablets
aspirin 75mg e/c tablets
clopidogrel
clopidogrel prophylaxis

Anticoagulants:
warfarin sodium
warfarin therapy started
SSRIs:
citalopram
escitalopram
fluoxetine
fluvoxamine
paroxetine
sertraline
venlafaxine
Drugs increasing nephrotoxicity when co-prescribed with NSAIDs:
Renin-angiotensin system drugs:
ACE inhibitor prophylaxis
Angiotensin II receptor antagonist prophylaxis
Diuretics:
loop diuretics
osmotic diuretics
thiazide diuretics
mercurial diuretics
potassium sparing diuretics
tacrolimus
penicillamine
ciclosporin
lithium
phenytoin
other NSAIDs: (see list above – Method (1))

(F) PCQIS has requested a new READ code to describe “NSAID risk /benefits assessed (or discussed)”. New READ codes are released quarterly; updates are available on the “Connecting For Health” website <http://www.connectingforhealth.nhs.uk/systemsandservices/data/readcodes/changestocurrentrelease>. The next READ code release is in April 2010.

(G) PPI co-prescribed:
esomeprazole
lansoprazole
omeprazole
pantoprazole
rabeprazole sodium

(H) Renal function test in last 12 months :
Renal function tests

Results and Reflection

When completing the Practice Review sheet consider:

- Are the results what we expected?
- Can we make any improvements?
- What might be stopping us getting better?

Discuss the results of the audit within the practice. Details from summary page 2 may help identify groups of patients to prioritise for review, or indicate patterns of prescribing to comment on.

Identify areas for improvement - formulate an action plan to optimise prescribing:

- Decide what it is that you want to achieve
- Think about how you will know if you are improving or not
- Generate ideas for the things that you could do differently
- Use some of the reference material to inform debate and discussion
- Record your progress.

Notes on medication review for NSAIDs and good practice points:

Medication reviews of NSAIDs should address the following questions:

- Has alternative treatment been tried, e.g. paracetamol (regular dosing may be required)⁸?
- Is a NSAID still necessary?
- Have the risks as well as the benefits of NSAIDs been assessed and communicated to the patient and has this been recorded?
- Is the NSAID prescribed the one with the lowest cardiovascular risk suitable for this particular patient?
- Is the NSAID prescribed the one with the lowest GI risk suitable for this particular patient?
- Has the patient's renal function been assessed in the last 12 months?
- Should a PPI be co-prescribed to reduce adverse GI effects?
- When should treatment and the prescribed dose next be reviewed?

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3. G Duff. (MHRA). Safety of Selective and non-selective NSAIDs. October 2006. Available at: <http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningandsmessagesformedicines/CON2025040>. Accessed 22 December 2009.
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10. Bridgend Local Health Board. The management of pain associated with osteoarthritis in adults - A locally developed guideline.
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15. National Prescribing Centre (NPCi). National Support Materials - NSAIDs. Available at: http://www.npci.org.uk/nsm/nsm/nsaids/room_nsaids.php. Accessed 09 February 2010.
16. Drug and Therapeutics Bulletin. Volume 48. Number3. March 2010

Data Summary Sheet (1)

Practice _____

Date of Audit _____

	Number	Percentage of practice population
Practice list size		100%
(A) Number of patients in the practice with repeat NSAID prescription recorded in past 12 months		

	Number	Percentage of the audit sample	Suggested Audit standard*
(B) Sample size ie number of patients with a repeat NSAID prescription included in the audit		100%	NA
(C) Number of patients with a clear indication for NSAID prescribing documented and recorded in their record			90
(D) Number of patients with 1 or more NSAID contraindications recorded			0%
(E) Number of patients with 1 or more risk factors for NSAID prescribing recorded			No national audit standard set.
(F) Number of patients with assessment of prescribing risk/benefit documented in notes			90
(G) Number of patients with PPI co-prescribed			75
(H) Number of patients with U&Es documented in past 12 months			75

**these represent realistic standards based on clinicians discussions as objectives for the time of the audit cycle.*

Please send the Data Summary Sheets 1 (and sheet 2 if applicable) and the Practice Review Sheet to your local Head of Pharmacy and Medicines Management who will compile the local information and forward to The Welsh Medicines Partnership for a national perspective.

Data Summary Sheet (2)

Factor	Number of patients with this characteristic
Total sampled	
Acute renal failure contraindication	
Peptic ulcer disease/GI bleed contraindication	
Heart failure contraindication	
Age >65 years of age	
IHD	
CVD	
Peripheral vascular disease	
Chronic Kidney Disease 1-5	
Diabetes	
Hypertension	
Number of patients on interacting drugs	
Number of patients taking Ibuprofen	
Number of patients taking Naproxen	
Number of patients taking Diclofenac	
Number of patients taking other NSAID	
Number of patients taking COX-2 inhibitor	

Please send the Data Summary Sheets 1 (and sheet 2 if applicable) and the Practice Review Sheet to your local Head of Pharmacy and Medicines Management who will compile the local information and forward to The Welsh Medicines Partnership for a national perspective.

Practice Review Sheet

A. What lessons did the practice discover from carrying out this audit?

B. What discussion/activities did the practice undertake as a result of the audit

C. What changes have the practice agreed to implement as a result of this audit?

This audit was completed by:

Name(s) _____

Signature(s) _____

Practice (name and address)

Please send the Data Summary Sheets 1 (and sheet 2 if applicable) and the Practice Review Sheet to your local Head of Pharmacy and Medicines Management who will compile the local information and forward to The Welsh Medicines Partnership for a national perspective.

Appendix A

Sample selection

Total number of patients at risk prescribed NSAID	Sample size: 95% confidence; +/-5%
50	44
100	79
150	108
200	132
500	217
1000	278
2000	322

Appendix B

Recommended READ codes

NSAID	READ code CTV2	READ code CTV3
Acemetacin	j2j..	
Aceclofenac	j2m..	
Dexibuprofen	j2t..	
Dexketoprofen	j2q..	
Diclofenac (includes Arthrotec®)	j22..	
Diflunisal	j23..	
Fenbufen	j25..	
Fenoprofen	j26..	
Flurbiprofen	j27..	
Ibuprofen	j28.. j2p..	
Indometacin	j29..	
Ketoprofen	j2a..	
Mefenamic acid	j2b..	
Nabumetone	j2k..	
Naproxen (includes Napratec®)	j2c..	
Piroxicam	j2c..	
Sulindac	j2f..	
Tenoxicam	j2l..	
Tiaprofenic acid	j2g..	
Celecoxib	jA2..	
Etodolac	j24..	
Etoricoxib	jA5..	
Meloxicam	j2n..	
Indications	READ code (CTV2)	
Rheumatoid arthritis and other inflammatory polyarthropy	N04..	
Osteoarthritis and allied disorders	N05..	
Gout	C34..	
Ankylosing spondylitis	N100.	
Pain in thoracic spine	N141.	
Pain in lumbar spine	N142.	
Sciatica	N143.	
Thoracic and lumbrosacral neuritis	N144.	
Backache unspecified	N145.	
Intervertebral disc disorders	N12..	
Backache symptom	16C..	
Migraine	F26..	
H/O Migraine	1474.	
Dental and orofacial pain:		
Toothache	JO5y. 1912.	

Dental swelling	1914.
Post operative pain	SP2y2
Contraindications	
Peptic ulcer symptoms	1956.
Peptic ulcer of oesophagus	J1020
Peptic ulcer, site unspecified	J13..
Acute peptic ulcer	J130.
Chronic peptic ulcer	J131.
Unspecified peptic ulcer	J13y.
Peptic ulcer – not otherwise specified	J13z.
NSAID induced gastric ulcer	J713.
NSAID induced duodenal ulcer	J726.
Acute renal failure	K04..
Heart failure	G58..
Congestive heart failure	G580.
Left ventricular failure	G581.
Acute heart failure	G582.
Heart failure – not otherwise specified	G58z.
Heart failure confirmed	101..
Personal history of aspirin allergy	ZV148
Risk Factors	
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 X	G37..
Other specified IHD	G3y..
IHD NOS	G3z..
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..
Other peripheral vascular disease	G73..
Chronic renal failure	K05..
Chronic renal impairment	1Z1..
End stage kidney disease	K0D..
Chronic kidney disease monitoring	66i..
Renal failure unspecified	K06..
H/O: diabetes mellitus	1434.
Type 1 diabetes mellitus	C10E.

Type 2 diabetes mellitus	C10F.
H/O: hypertension	14A2.
Hypertensive disease	G2...
Hypertensive heart disease	G21..
Drugs increasing risk of bleeding when co-prescribed with NSAIDs:	
Antiplatelets:	
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.
SSRIs:	
citalopram	da9..
escitalopram	dac..
fluoxetine	da4..
fluvoxamine	da3..
paroxetine	da6..
sertraline	da5..
venlafaxine	da7..
Renin-angiotensin system drugs:	
ACE inhibitor prophylaxis	8B6B.
Angiotensin II receptor antagonist prophylaxis	8B6E.
Diuretics:	
loop diuretics	b3...
osmotic diuretics	b6...
thiazide diuretics	b2...
mercurial diuretics	b7...
potassium sparing diuretics	b4...
tacrolimus	h83..
penicillamine	j52..
ciclosporin	h82
lithium	d6...
phenytoin	dn8..
phenytoin sodium	dn9..
Proton Pump inhibitors co-prescribed	
esomeprazole	a6h..
lansoprazole	a6c..
omeprazole	a6b..
pantoprazole	a6e..
rabeprazole sodium	a6f..
Renal function tests	451..