Community pharmacy Non-Steroidal Anti-Inflammatory Drug safety audit 2014
National data from PharmOutcomes

Key points

* Inadequate prescribing of gastro-protection with NSAIDs is a common prescribing error known to cause avoidable harm

* This community pharmacy audit identified almost 3,000 patients (1 in 4) regularly prescribed NSAIDs without gastro-protection; the majority were notified to prescribers by the pharmacy for a safety review

* This is the first time a safety audit has been made available across England on PharmOutcomes. The methodology provided a successful large-scale means of raising awareness of a key safety issue and driving improvement; it could well be used to address other medicines safety issues on a national basis

Summary

In early 2014 a clinical audit on NSAID safety was made available across England via the PSNC and the NHS Specialist Pharmacy Service to all community pharmacies. 1,278 pharmacies took part providing data on 16,366 patients. Coverage across England was good, with patients from 87% of CCGs. The audit included any patient prescribed an oral NSAID or COX2 inhibitor and was generally conducted over 1-2 weeks. The most frequently prescribed agents were naproxen (59%), ibuprofen (19%) and diclofenac (9%).

The audit focused on gastro-intestinal safety and provision of gastro-protection. 6,475 (40%) patients were not co-prescribed gastro-protection. Older people are at particular risk of gastro-intestinal damage and there were 1,669 (10%) aged over 65 without gastro-protection. Pharmacies referred 2,317 patients to the prescriber, largely for review of on-going NSAID use and gastro-intestinal safety. These referrals should prevent well-recognised avoidable harm from NSAIDs and all the subsequent morbidity and associated healthcare cost.

10,467 (66%) patients were offered medicines advice. Where advice was not offered, this was largely because the medicine was collected by someone other than the patient or it was delivered to the patient's home.

Background

Non-steroidal anti-inflammatory drugs (NSAIDS) are widely used, effective treatments for pain and inflammation. However, they are also known to occasionally cause serious side effects such as gastro-intestinal (GI) bleeding, stroke and heart attacks. The risk of GI adverse effects can be reduced by co-prescribing a protective agent. NICE advises that protection with a proton pump inhibitor (PPI) is prescribed to all patients receiving NSAIDs for management of osteoarthritis or rheumatoid arthritis.

A previous community pharmacy study of NSAID safety reported that provision of gastro-protection to patients regularly prescribed NSAIDs was variable[1]. Of particular concern were significant numbers of patients with a very high risk of GI problems not taking a proton pump inhibitor. An important national study of prescribing errors in general practice has also reported that not co-prescribing gastro-protection was a relatively common error of 'moderate' severity, which required corrective action[2].

Some NSAIDs are available to buy from a range of general retail outlets. Thus, another safety concern for patients prescribed NSAIDs is that they may self-medicate with a second NSAID, unaware of the risk this entails.

Audit details

Community pharmacists are required to do at least 2 clinical audits each year. Medicines safety is a vital part of the medicines optimisation agenda, so an NSAID safety audit was made available to all community pharmacists in England via the Pharmaceutical Services Negotiating Committee (PSNC). Data could be reported on the PharmOutcomes web-based system, which will generate both local reports and anonymised total data sets.

Audit sample: All patients who present prescriptions for any oral NSAID or cyclo-oxygenase-2 selective (COX2) inhibitor; suggested time frame at least 1 week and includes a minimum of 10 patients

Standard 1 Gastro-protection: All patients regularly prescribed an oral NSAID or COX2 inhibitor for more than 2 months are co-prescribed gastro-protection

Standard 2 Verbal advice: All patients presenting prescriptions for an oral NSAID or COX2 inhibitor are offered verbal advice about their medicines

Results

*1,278 community pharmacies *16,366 patients
* Number of patients per pharmacy: Range 1-77 (mode 10, mean 12.8)
* Patient age 1-99 years (mean 56.8)

<u>Geography</u>

Good coverage across England, 183/211 (87%) CCGs represented.

Number of patients by region:

North of England 9,503	London 368
Midlands and East of England 1,603	South of England 4,230
(Unknown 662)	

The audit was mandated by 3 NHS England Area Teams, 2 in the North of England (Durham Darlington & Tees; Cumbria, Northumberland, Tyne & Wear) and 1 in the South (Surrey and Sussex). These 3 areas contributed 10,165/15,704 (64.7%) patients.

Choice of NSAID

21 different NSAIDs were prescribed. 8 were prescribed rarely, less than 15 patients. 7 had moderate usage, 30-250 patients. The top 6 high use agents are listed below
Naproxen 9,713 (59.3%)
Ibuprofen 3,062 (18.7%)
Diclofenac Sodium 1,489 (9.1%)
Meloxicam 498 (3.0%)
Celecoxib 399 (2.4%)
Etoricoxib 334 (2.0%)

Regular and chronic use

Regular usage i.e NSAID taken at least 3 days each week 12,341 (84.6%)
NSAID prescribed for more than 2 months 11,585 (73.7%)

Regular usage AND prescribed for more than 2 months 10,323 (71.9%)

Gastro-protection

PPI prescribed at licensed dose for gastro-protection 9,170 (56.0%)
Other gastro-protection prescribed 721 (4.4%)
No gastro-protection 6,475 (39.6%)

Regular usage more than 2 months and prescribed PPI at licensed dose 6,944 (67.3%)
Regular usage more than 2 months and prescribed other gastro-protection 541 (5.2%)
Regular usage more than 2 months and no gastro-protection 2,838 (27.5%)

Age profiles of patients with no gastro-protection are shown in figures 1 and 2.

[˜Totals less than those given above where data not reported.]

Figure 1 Regular NSAID usage more than 2 months with no gastro-protection (n=2,801˜)

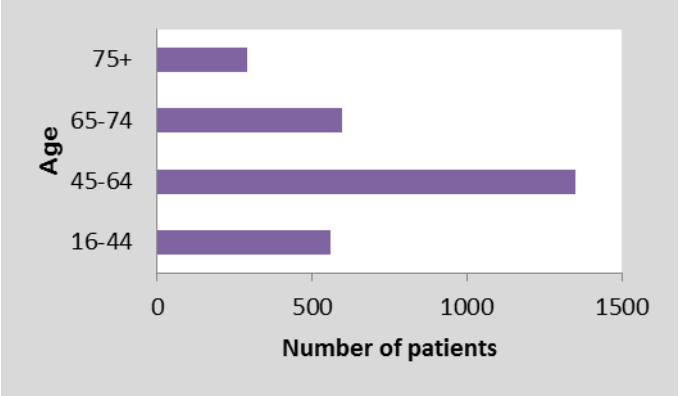
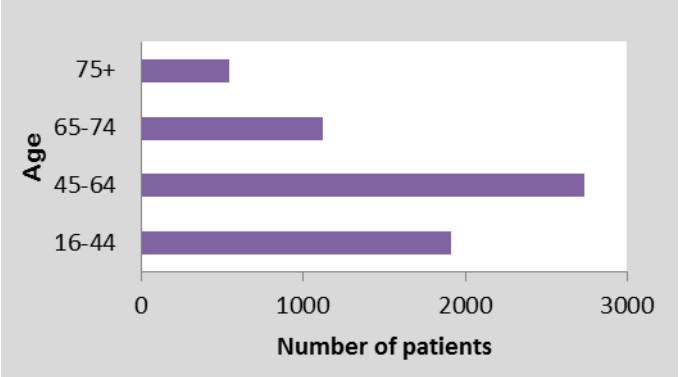


Figure 2 All NSAID patients with no gastro-protection (n=6,316~)



Referrals

In total 2,317 patients were referred to the prescriber, of which 2,138 had no gastro-protection. The referral details were not recorded, but 748 had additional free text notes about the referral and nearly all confirmed that this was about GI safety.

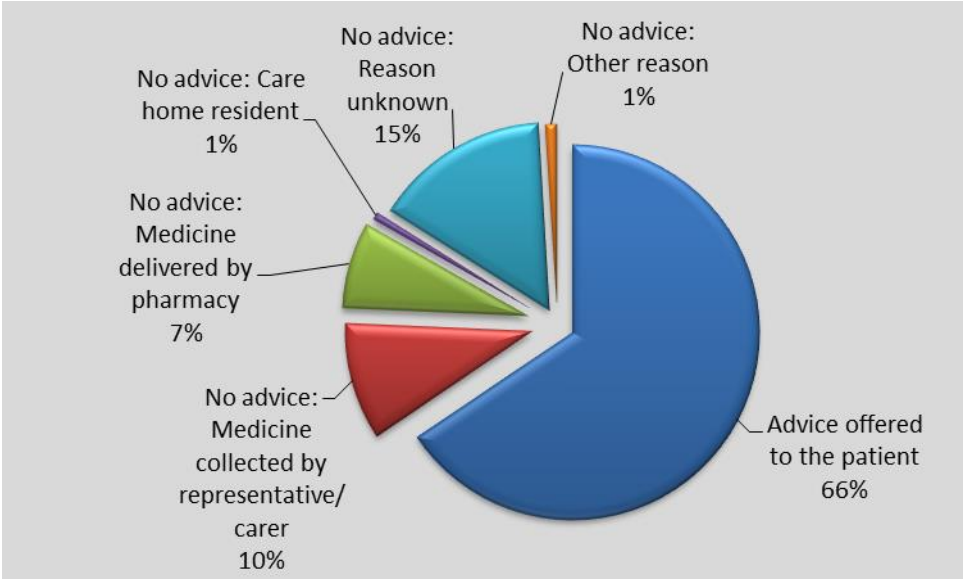
There were 521 referrals (58.6%, 521/889) for those in a notable high risk group (regular NSAID usage more than 2 months and aged over 65).

179 referrals were made for patients who did have gastro-protection. Comments indicated that these referrals were mostly about use of products not licensed for gastro-protection (eg omeprazole 10mg or rabeprazole). Occasional issues included poor compliance with gastro-protection, GI symptoms, NSAID dosage queries and other monitoring eg kidney function.

Patient advice

Advice was offered to 10,467 (65.6%) patients. Patients not offered advice generally did not attend the pharmacy to collect their medicine, see Figure 3 Patient advice.
(Data not recorded 409)

Figure 3 Patient advice



Performance against audit standards

Standard 1 Gastro-protection: All patients regularly prescribed an oral NSAID or COX2 inhibitor for more than 2 months are co-prescribed gastro-protection. Result 72.5%

In practice a 100% performance on this standard may not be attainable as the sample includes some young people where the GI risk is low and there may be patients who choose not to take additional medication. However, 72.5% is still an unacceptably low value and action is needed to address this.

Standard 2 Verbal advice: All patients presenting prescriptions for an oral NSAID or COX2 inhibitor are offered verbal advice about their medicines. Result 65.6%

This result is not unexpected because a significant number of prescriptions are collected by someone other than the patient. The purpose of this standard was to identify patients not offered verbal advice, but who may well be in need of pharmacy support.

Discussion

This is the first national community pharmacy clinical audit with electronic data entry via PharmOutcomes. Using this method it has been possible to collate data on NSAID usage in a large patient cohort and determine whether national safety guidance is being followed when these drugs are prescribed. There have been repeated warnings about cardio-vascular adverse events occurring more frequently with diclofenac than ibuprofen or naproxen and almost 80% of patients were prescribed the latter two agents. In 2008 diclofenac accounted for 50 per cent of NSAID items prescribed, but in recent years there has been a major reduction in use.

NICE advises that all patients prescribed NSAIDs for osteoarthritis or rheumatoid arthritis should be co-prescribed a proton pump inhibitor for gastro-protection. The annual chance of an NSAID related gastro-intestinal bleed for patients aged 75+ has been calculated as 1 in 110[3] and the estimated cost of an NSAID induced gastro-intestinal admission as £6,825[4]. 545 patients aged 75+ with no gastro-intestinal prophylaxis were identified here, so 5 are likely to end up in hospital if no action is taken. For younger people the risk of NSAID induced GI damage is less, but gastro-protection is still advised, particularly for regular long-term users. It is interesting that despite the current focus on cardio-vascular safety of NSAIDs, for 1000 patients at moderate risk, one would expect about 3 major vascular events per year compared to 4 to 16 gastro-intestinal complications[5].

Over 2,000 patients without gastro-protection were referred to prescribers for review and while the outcomes of the referral are not known, other studies indicate that positive action will result for at least 60%[1,6]. These referrals should prevent well-recognised avoidable harm from NSAIDs and all the subsequent morbidity and associated healthcare cost. The advantages of using a community pharmacy clinical audit to identify patients at risk of adverse events are that there are no additional resource requirements, pharmacists may also identify adherence and self-medication issues, and the pharmacists can provide a final safety net, should other strategies fail. 66% of patients were offered advice when they collected their medicines from the pharmacy. Those not attending the pharmacy and not offered advice include care home and housebound patients; pharmacies may need to develop additional strategies to reach such vulnerable groups.

References

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